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Disclosure of Substance Use Disorder Records Enters the 21st Century: SAMHSA Proposes Changes to Part 2, But Do They Go Far Enough?

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Background

As many health care practitioners, health information management professionals, and health lawyers know, balancing patients' privacy interests with the need to access accurate, up-to-date medical information can be challenging. Over the decade and a half since the passage of HIPAA,¹ though, most have learned to maneuver within the mandates of the Privacy Rule² while navigating its intersection with more restrictive state laws. Health care providers have implemented policies and procedures that safeguard patients' health information—in compliance with federal and state requirements—while ensuring appropriate and timely access to medical records for permissible purposes, such as for treatment, payment, peer review, quality, public health, and law enforcement. Substance abuse records, however, are subject to more restrictive federal requirements related to disclosure and have remained particularly vexing to assess and incorporate into today's modern health care environment. This is especially true as health care providers have sought to improve and enhance the interoperability of electronic health records, not only in response to the Affordable Care Act's meaningful use and health information exchange ("HIE") mandates, but also in response to the development of alternative payor models, innovative and collaborative care programs, and provider consolidation.

The federal rule that protects substance abuse records is known formally as the Confidentiality of Alcohol and Drug Abuse Patient Records regulations and is commonly referred to as "Part 2."³ In recognition of the stigma imposed upon patients who are referred to or receive substance abuse treatment, Part 2 provides more stringent federal protections for substance abuse records, as compared to other health privacy laws, such as the Privacy Rule. Part 2 protects the confidentiality of records pertaining to the identity, diagnosis, prognosis, or treatment of any patient maintained in connection with a "federally assisted" program or activity (as defined by the rule)⁴ relating to substance abuse education, prevention, training, treatment, rehabilitation, or research. Written out of "great concern" that the misuse of substance abuse records could lead to a host of negative consequences such as loss of employment, housing, custody, and discrimination in the delivery of health care and public services,⁵ the regulations generally allow disclosure of such records only with the

¹ Health Insurance Portability and Accountability Act of 1996 and its implementing regulations at 45 C.F.R. parts 160 and 164.

² See 45 C.F.R. parts 160 and 164, subparts A and E.

³ 42 C.F.R. part 2, as authorized by 42 U.S.C. § 290dd-2.

⁴ See 42 C.F.R. § 2.12(b).

⁵ See Confidentiality of Substance Use Disorder Patient Records; Proposed Rule, 81 Fed. Reg. 6988, 6989 (Feb. 9, 2016).

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individual's express written consent, with an exception only for emergencies—but not for payment or treatment.⁶

With regulations promulgated as a final rule in 1975,⁷ and amended in 1987⁸ and 1995,⁹ Part 2 predates the Privacy Rule and electronic health records. Significantly, Part 2 also predates the movement among health care providers, payors, and the federal government to develop new models of integrated health care as a means of improving patient care and reducing costs, such as through continuing care organizations (“CCOs”) and accountable care organizations (“ACOs”), as well as the technological capabilities to meaningfully and timely exchange health information in a way that facilitates such integration.

On February 9, 2016, the Substance Abuse and Mental Health Services Administration (“SAMHSA”), which implements and enforces Part 2, published a proposed rule that seeks to modernize the Part 2 regulations “to increase opportunities for individuals with substance abuse disorders to participate in new and emerging health and health care models and health information technology (IT),”¹⁰ while retaining important privacy protections.

According to SAMHSA,

[t]his modernization is necessary because behavioral health, including substance abuse disorder treatment, is essential to overall health; the costs of untreated substance use disorders, both personal and societal, are substantial; and there continues to be a need for confidentiality protections that encourage patients to seek treatment without fear of compromising their privacy.¹¹

SAMHSA's proposed rule is the result, at least in part, of general comments and feedback about Part 2, solicited through a public Listening Session, held June 11, 2014, and written comments received through June 25, 2014. In addition to inviting general comments, SAMHSA solicited feedback about six key provisions—applicability, consent requirements, re-disclosure, medical emergency, Qualified Service Organizations (“QSOs”), and research. Approximately 1,800 individuals participated in the Listening Session, at which 112 oral comments were made and 635 written comments were submitted during the comment period.¹²

In commentary to the proposed rule, SAMHSA reiterates the statute's purpose, which is to protect the confidentiality of substance abuse patient records to assure that an individual receiving substance abuse treatment in a Part 2 program is no more vulnerable to adverse

⁶ See 42 C.F.R. § 2.51.

⁷ 40 Fed. Reg. 27,802 (July 1, 1975).

⁸ 52 Fed. Reg. 21,798 (June 9, 1987).

⁹ 60 Fed. Reg. 22,296 (May 5, 1995).

¹⁰ 81 Fed. Reg. at 6990.

¹¹ *Id.* at 6993.

¹² The Listening Session comments are available at <http://samhsa.gov/about-us/who-we-are/laws-regulations/public-comments-confidentiality-regulations>. See *id.* Comments ranged from those who expressed concern that continued segregation of substance abuse records within increasingly integrated health systems with unified electronic health record systems was not only unwarranted in the age of HIPAA but also dangerous to patient health and safety, to those who argued that their ability to treat patients struggling with addiction was heavily dependent on the enhanced security provided by Part 2, which, in their opinion, should not be compromised in the slightest.

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consequences than is an individual who does not seek treatment.¹³ Carefully setting expectations, SAMHSA states that, while it recognizes the importance of facilitating information exchange within new and emerging health care models to promote coordination of care and enhanced patient safety, it nonetheless must operate within the parameters of the authorizing legislation and its statutory intent, thus “respecting the legitimate privacy concerns of patients seeking treatment for a substance use disorder.”¹⁴

Proposed Changes to the Consent Requirements

Arguably, the most significant changes proposed to Part 2 to address concerns related to sharing of health information for care coordination, treatment, and payment occur in the context of the consent requirements. As an initial matter, it may be helpful to articulate what SAMHSA does not do in its proposed rule: it does not create a general exception to the patient consent requirement for release of Part 2 records for treatment or payment purposes. SAMHSA does, however, propose to move away from its current one-size-fits-all approach to consent form requirements that would vary, to a certain degree, depending on the relationship between the recipient of the information and patient.

Under the current rule, a consent form must *specifically* identify the name or title of the individual or organization to which a Part 2 Program may disclose records.¹⁵ This specificity requirement assures that patients identify, at the point of consent, “exactly who they are authorizing to receive their information.”¹⁶ For disclosures to treating providers and third-party payors who require information for reimbursement purposes, in addition to naming a specific individual, SAMHSA is proposing to retain the option of naming an entity as the recipient of the information,¹⁷ e.g., “Hospital Name,” or “Medicare.”

The ability to name an entity for treatment and payment, however, does not address criticism that the current specificity requirement imposes unwieldy consent management burdens on HIEs, CCOs, and ACOs, since new treating provider participants may join these organizations on a rolling basis. As a result, many of these organizations do not include substance use disorder treatment information in their systems, handicapping care coordination efforts and raising patient safety concerns.

In response, and in recognition that effective substance use disorder treatment depends on collaboration among mental health, substance use disorder, general health, and other service providers, SAMHSA proposes to allow a general designation for disclosure to treating providers by an entity that does not have a treating provider relationship with the patient, “such as an entity that facilitates the exchange of health information or a research institution.”¹⁸ Thus, where a patient authorizes disclosure to an HIE, CCO, or research institution, for example, the patient may also designate a disclosure to an individual or entity “participant” of such organization, or generally to a “class of participants,” provided such participant or class of participants has a treating provider relationship with the patient.¹⁹ As

¹³ *Id.*

¹⁴ *Id.*

¹⁵ 42 C.F.R. § 2.31.

¹⁶ See 81 Fed. Reg. at 7000.

¹⁷ *Id.* at 7019 (to be codified at 42 C.F.R. § 2.31(a)(4)(i)–(iii)).

¹⁸ *Id.* at 7000.

¹⁹ *Id.* at 7019 (to be codified at 42 C.F.R. § 2.31(a)(4)(iv)).

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an example, the consent form could designate the HIE and “my treating providers.”²⁰ The initial recipient of the patient identifying information must be sufficiently identified, so merely listing a function, such as “HIE,” is not permissible. Moreover, to assure that patient identifying information is disclosed only to those individuals and entities on the health care team with a need to know, the general designation is limited to individuals and entities with a treating provider relationship.²¹

In creating a distinction between individuals and entities that have a treating provider relationship and those that do not, the revised consent requirements compel the need to define “treating provider relationship.” SAMHSA’s proposed definition of “treating provider relationship” does not require an actual in-person encounter. Rather, a “treating provider relationship” is “clearly established”²² when an individual seeks diagnosis, evaluation, and/or treatment for any condition from an individual or entity, and such individual or entity agrees to undertake to diagnose, evaluate, and/or treat the patient for any condition or to consult with the patient.²³ Such relationship can be established by a health care provider or another member of a health care team, provided the relationship meets the above definition, and the term “agree” does not imply a formal, written agreement; rather, an agreement may be evidenced by, for example, making an appointment or a telephone consultation.²⁴ An entity will have a treating provider relationship if the entity employs or privileges one or more individuals who have a treating provider relationship with the patient.²⁵

Designating an entity as a QSO does not provide an avenue to avoid consent requirements for care coordination activities. In fact, SAMHSA clarifies that, although it is proposing to revise the definition of QSO to include population health management in the list of examples of services a QSO may provide, the QSO Agreement (“QSOA”) is limited to the office or unit responsible for population health management, but not the entire organization or its participants.²⁶ Thus, within entities such as ACOs, patient-centered medical homes, or managed care organizations, disclosure to participants such as case managers, physicians, addiction counselors, hospitals, and clinics (other than the originating Part 2 Program) would be prohibited without a Part 2-compliant consent.²⁷ Similarly, SAMHSA proposes to revise the definition of “medical services” to clarify that it is limited to “medical staffing services,” emphasizing that QSOAs should not be used to avoid obtaining patient consent when otherwise required for treatment purposes.²⁸

²⁰ Commentary to the proposed rule reiterates that, in the case of a research institution, a “participant” could be a clinical researcher with a treating provider relationship with the patient. Conversely, a general researcher without a treating provider relationship with the patient would have to be named on the consent form. *Id.* at 7000.

²¹ But note, a patient may designate the name of an individual participant, such as Jane Doe, MD, or John Doe, without requiring a treating provider relationship. *See id.* at 7000; *see also id.* at 7019 (to be codified at 42 C.F.R. § 2.31(a)(4)(iv)(A)). *See id.* at 7001 for a chart that provides an overview of permissible options when completing the “To Whom” designation section of the proposed consent form.

²² *Id.* at 6994.

²³ *Id.* at 7014 (to be codified at 42 C.F.R. § 2.11).

²⁴ *Id.* at 6994, 7000.

²⁵ *Id.* at 7000, 7002.

²⁶ *Id.* at 6996.

²⁷ SAMHSA clarifies in commentary to the proposed rule that population health management “refers to increasing desired health outcomes and conditions through monitoring and identifying individual patients within a group . . . [and] supply[ing] proactive, preventive, and chronic care . . . both during and between encounters with the health care system. This is particularly important for patients with substance use disorders, many of whom have comorbid conditions.” *Id.*

²⁸ *Id.*

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In light of this new option for a general designation, SAMHSA makes clear that the intermediary entity must have a mechanism in place to determine whether a treating provider relationship exists with the entity receiving patient records pursuant to a general designation.²⁹ SAMHSA defers to the entities to implement this requirement, encouraging “innovative solutions.”³⁰ The proposed rule also creates a new patient right, called the List of Disclosures provision, to receive from the intermediary entity a list of entities to which the patient’s information has been disclosed. The List of Disclosures must include the name of the entity to which each disclosure was made, the date of disclosure, and a brief description of the information disclosed. An entity will not satisfy the disclosure requirement with a list of entities that *potentially* could receive the patient’s identifying information.³¹ According to SAMHSA, assuring that patients can be informed, upon request, of who received their information pursuant to a general designation will “facilitate patients’ participation in advances in the health care delivery system.”³² Recognizing that systems may need to be implemented to comply with the List of Disclosures requirement, SAMHSA proposes to delay implementation for two years from the effective date of the final rule.³³

Arguably, the language of the proposed rule is broader than its intended purpose, particularly because the term “participant” is not defined, though the general designation disclosure clearly is limited to entities that have a treating provider relationship with the patient.³⁴ In its proposed rule, SAMHSA also proposes an alternative approach that would reflect the same policy goal but simplify language in the consent form. This approach would not change language in the “To Whom” section of the consent form, but would add a definition of “organization,” which would include treating providers, third-party payors, and intermediary entities that are not treating providers but provide patient identifying information to participants that are treating providers. While this approach may further elucidate the meaning of “participant,” there is still some room for interpretation as to what those terms mean. SAMHSA is requesting public comments on the advantages and disadvantages of each approach, as well as whether the definition of “organization” should be broader. SAMHSA specifically requests proposals for alternate or additional required elements of the consent form “that facilitate the sharing of information within the health care context while assuring that the patient is fully informed of the individuals and organizations that potentially could receive” the patient’s information.³⁵

Other changes related to the consent requirement include greater specificity regarding the amount and kind of substance use disorder-related information that can be disclosed³⁶ and a specific identification of the Part 2 Program allowed to make the disclosure.³⁷ This latter requirement is actually more restrictive since the current rule, amended in 1987, permits a

²⁹ Also in light of the general designation for treating provider relationships, SAMHSA proposes to eliminate the current option of designating an individual only by his/her title, e.g., “Chief of General Medicine, Hospital Name.” *Id.* at 7000.

³⁰ *Id.* at 7001.

³¹ *Id.* at 7016 (to be codified at 42 C.F.R. § 2.13(d)(2)). The proposed rule includes additional detail regarding the timeframe in which a response is due, the method of transmission, and detail regarding what must be included within the response.

³² *Id.* at 6998.

³³ *Id.* at 7010.

³⁴ The term “treating provider relationship” is a newly defined term in the proposed rule. *Id.* at 7014 (to be codified at 42 C.F.R. § 2.11).

³⁵ 81 Fed. Reg. at 7002.

³⁶ *Id.*

³⁷ *Id.* at 7002, 7019 (to be codified at 42 C.F.R. §2.31(a)(1)–(3)).

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patient to consent to disclosure from a category of facilities or from a single specified program. SAMHSA states that this revision “would avoid any unintended consequences of including general designations in both the ‘From Whom’ and ‘To Whom’ sections.”³⁸

Changes to Definitions

SAMHSA proposes to consolidate definitions into a single section of Part 2 (Section 2.11). Changes to definitions are primarily editorial and non-substantive for clarity and consistency, including changes to defined terms used inconsistently throughout the existing regulations. Additionally, SAMHSA proposes the addition of new defined terms helpful to a more complete understanding of the applicability of Part 2, such as “Part 2 Program,” and updated to match currently acceptable terms, such as “substance use disorder” and “withdrawal management.”³⁹ Of particular interest:

- The new term “substance use disorder” replaces “alcohol abuse and drug abuse,” in recognition of classification manuals, current diagnostic lexicon, and commonly used terminology. The term “substance use disorder” includes disorders associated with altered mental status that have the potential to lead to risky and/or socially prohibited behaviors, including alcohol, cannabis, hallucinogens, inhalants, opioids, sedatives, hypnotics, anxiolytics, and stimulants, excluding tobacco and caffeine.⁴⁰ Accordingly, the title of 42 C.F.R. Part 2 will be revised to “Confidentiality of Substance Use Disorder Patient Records.”⁴¹
- “Program” is revised to make clear that an individual or entity holding itself out as providing, and that does provide, substance use disorder diagnosis, treatment, or referral, does not apply to a general medical facility or general medical practice that, on occasion, provides substance use disorder treatment services, but only incident to the provision of general health care. This revision recognizes that more substance use disorder treatment services are occurring in general health care and integrated care settings, including general medical *practices* (i.e., not just general medical facilities), but limits the applicability of Part 2 to specialized programs. Excluding health care providers who work in general medical practices but only provide substance abuse disorder treatment services incident to the provision of health care is consistent with SAMHSA’s original approach, which was to assure confidentiality protections and access to specialized programs “while not unnecessarily imposing requirements on general medical facilities or practices in an overly broad manner.”⁴² Moreover, exclusion of these health care providers should not act as a deterrent to individuals seeking assistance for substance abuse disorders.⁴³

Research

SAMHSA proposes to expand the entities that can disclose and receive patient identifying information for research purposes.

³⁸ *Id.* at 7002.

³⁹ *Id.* at 6994.

⁴⁰ *Id.*

⁴¹ Note, however, that the term “substance abuse” will continue to be used when referring to the authorizing statute or when referencing publications that use that term, as will the terms “drug abuse” and “alcohol abuse.” See *id.*

⁴² *Id.* at 6995.

⁴³ *Id.* at 6997.

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Currently, Part 2 permits only the Part 2 program director to release patient identifying information for research purposes and only if the program director makes certain determinations. These include that the recipient of the information is qualified to conduct the research, has a research protocol that provides for the security of the information that is at least as restrictive as the requirements of Part 2 and states that the information will not be re-disclosed except back to the Part 2 program from which it originated, and has provided a satisfactory written statement that a group of at least three independent individuals has reviewed the protocol and determined patient rights and welfare will be adequately protected and that the potential benefits of the research outweigh the risks of disclosing the information.⁴⁴

As proposed, Part 2 would permit an individual who is the director, managing director, or chief executive officer (or his/her designee) of a Part 2 program or of a lawful holder of Part 2 data (such as third-party payors, HIEs, ACO, and CCOs)⁴⁵ to release patient identifying information for research purposes upon determination that the recipient is:

- (1) A HIPAA covered entity or business associate that has obtained an authorization or waiver of authorization in accordance with the Privacy Rule;
- (2) Subject to and in compliance with the Common Rule (45 C.F.R. part 46) requirements for informed consent or waiver of informed consent; or
- (3) In compliance with the requirements of both HIPAA and the Common Rule if subject to both.

The recipient of the information will be fully bound by Part 2, must resist judicial efforts to compel disclosure except as permitted by Part 2, must maintain and destroy the information in accordance with Part 2 requirements, and must retain records in accordance with applicable law. Reports may only include Part 2 information in de-identified aggregate form to restrict the potential for disclosure of patient identifiers. Further, similar to the current rule, the information may only be re-disclosed back to the Part 2 program that provided it, except that the proposed rule provides for the disclosure of Part 2 patient identifying information to federal data repositories to create linkages to federal data sets if approved by an Institutional Review Board registered with the Office for Human Research Protections.⁴⁶

SAMHSA notes that there are currently proposed revisions to the Common Rule. While SAMHSA indicates it does not expect that rulemaking process to affect these Part 2 provisions, SAMHSA notes it will revisit Part 2 as needed through an appropriate mechanism.⁴⁷

SAMHSA is soliciting comments on the proposed revisions to the research regulation, including whether the data linkage provision should be expanded beyond federal data repositories and what safeguards should be in place to protect the information in such cases.⁴⁸

⁴⁴ 42 C.F.R. § 2.52.

⁴⁵ *Id.* at 7004.

⁴⁶ *Id.* at 7020–21 (to be codified at 42 C.F.R. § 2.52).

⁴⁷ *Id.* at 7003.

⁴⁸ *Id.* at 7004–05.

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Applicability to Electronic Medical Records

As expected, SAMHSA proposes to modernize the regulations such that Part 2 is specifically applicable to both paper and electronic processes, including electronic medical records, which did not exist 30 years ago when the rule was last substantively revised. The security provisions as amended would address standards for both paper and electronic records, particularly regarding storage and disposal (including disposition of records by discontinued programs). In commentary, SAMHSA directs Part 2 programs to security resources published by the Office for Civil Rights (OCR) and the National Institute of Standards and Technology (NIST).⁴⁹ SAMHSA also proposes to permit notice to patients of federal confidentiality requirements by paper or electronic means.⁵⁰

Additional Proposed Changes

- SAMHSA proposes to remove the concept in section 2.13 of the current rule that the regulations do not restrict a disclosure that an identified individual is not and never has been a patient of a Part 2 Program. Such confirmation could result in an inadvertent disclosure regarding one or more individuals, for example, when a reporter asks about three individuals and the Part 2 Program confirms that only one individual is not and has never been a patient but remains silent with regard to the other two patients. Because such confirmation could, by inference, compromise patient privacy, the proposed rule warns that “caution should be used so as not to make an inadvertent disclosure.”⁵¹
- Part 2 Programs still would be permitted to make disclosures without consent in medical emergencies, though the regulatory standard would be revised to allow disclosures 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,” thus allowing providers more discretion to determine when an emergency exists.⁵²
- SAMHSA proposes to strike from the regulation the sample confidentiality notice to patients, as well as the sample patient consent form, but indicates it will consider issuing a revised notice and consent form at a later date.
- The proposed rule requires that the consent form include a statement affirming the patient’s understanding of the terms of their consent and, for disclosures pursuant to a general designation, the List of Disclosures provision. Additionally, SAMHSA proposes to allow electronic signatures for patient consent forms where not prohibited by law.⁵³
- Reports of violations by methadone clinics no longer will be reported to the Food and Drug Administration; rather, such violations would be reported to the U.S. Attorney’s

⁴⁹ *Id.* at 6999.

⁵⁰ *Id.*

⁵¹ *Id.* at 6998.

⁵² *Id.* at 7003. The current regulations state that information may be disclosed without consent for the purpose of treating a condition that poses an immediate threat to the health of any individual and that requires immediate intervention. *Id.*

⁵³ *Id.* at 6999–7000, 7002–03.

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Office for the district in which the violation occurred, as well as the SAMHSA office responsible for opioid treatment program oversight.⁵⁴

- SAMHSA proposes to revise the audit and evaluation regulation to, among other things, apply it to electronic as well as paper records and permit the Part 2 program, rather than just the program director, to determine who is qualified to conduct an audit or evaluation of the Part 2 program. Further, SAMHSA proposes to expressly permit disclosure of patient identifying information for an audit or evaluation necessary to meet the requirements of a CMS-regulated ACO or similar organization if certain requirements are met.⁵⁵

Prohibition on Re-Disclosures

SAMHSA also attempted to alleviate provider confusion regarding how much of a patient's record is protected by Part 2 and therefore subject to the regulatory prohibition on re-disclosures. The prohibition requires that a disclosing entity, when properly transferring information that is subject to Part 2, must provide accompanying notice that the information is protected by Part 2 and that further re-disclosures are not permitted without authorization.

SAMHSA clarified that only information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for a substance use disorder, including through a narrative description or use of standard medical codes, is subject to the rule. While information regarding, e.g., a patient's high blood pressure, would likely be considered unrelated, illnesses that are brought about by drug or alcohol abuse, e.g., cirrhosis of the liver, could indirectly reveal a substance abuse disorder. Patient data specifying a particular prescription used to treat addiction, or listing a site of service at a drug treatment clinic, would also likely be considered related to treatment for a substance use disorder. SAMHSA also clarified that the information may not be used to criminally investigate or prosecute any patient with a substance use disorder, except as otherwise permitted by Part 2.⁵⁶

Summary

The revisions proposed by SAMHSA reflect the first substantial overhaul to Part 2 in several decades, and clearly reflect SAMHSA's intent to remove current regulatory obstacles to the inclusion of substance use disorder records in HIEs, care coordination models, and the latest research initiatives. Notwithstanding its intent, SAMHSA acknowledges that it must strike a balance between facilitating such activities and complying with the statute.⁵⁷ During the Listening Session, some stakeholders, including some behavioral health providers, expressed the opinion that the statute's fundamental premise, which is that substance abuse treatment stigmatizes patients, is outdated, and further, that the heightened, pre-HIPAA protections are unnecessary and can be injurious to patients' best interests.⁵⁸ Sweeping changes of the nature desired by some may be difficult for SAMHSA to accomplish within the framework of the underlying statute.

⁵⁴ *Id.* at 6993.

⁵⁵ *Id.* at 7005, 7021 (to be codified at 42 C.F.R. § 2.53).

⁵⁶ *See id.* at 7003.

⁵⁷ *See id.* at 6993.

⁵⁸ *See supra* note 12.

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SAMHSA's proposed rule, with a comment period that extends through April 11, 2016, provides interested parties an important opportunity to further educate SAMHSA and the health care community regarding not only the challenges faced by this patient population, but also the benefits to devising workable solutions that will further quality patient care and health care innovation while reducing unnecessary costs.

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