

Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR Part 2)

Summary and Implications of the January, 2017 Final Rule, Supplemental Notice of Proposed Rulemaking, Trump Administration Executive Action, and the Congressional Review Act

I. Introduction

On January 18, 2017, SAMHSA published an updated Final Part 2 rule in the Federal Register, 30 years after the last meaningful update. SAMHSA's Final Rule constitutes an effort to modernize the Part 2 requirements and facilitate the health information exchange required for participation in new payment models, while addressing the privacy concerns of patients seeking treatment for substance use disorders. Due to additional potential changes not adequately addressed in the proposed rule, SAMHSA concurrently published a Supplemental Notice of Proposed Rulemaking (SNPR) in the Federal Register.

The Final Rule and the SNPR make significant improvements to the Part 2 regulatory regime but a number of significant barriers remain to the full integration of substance use disorder treatment into the health care system. In particular, the Final Rule and SNPR retain barriers to the exchange of information related to substance use disorder treatment for the purposes of care coordination and case management. The SNPR presents an opportunity for additional comment and policy change on this issue.

In addition, the inauguration of President Trump and release of executive memoranda on January 20, 2017 portend significant changes to the regulatory process of the Federal Government and will almost certainly impact the timing of the implementation of the Part 2 Final Rule, if not the content. Similarly, the Congressional Review Act presents another mechanism by which Congress and President Trump could substantially alter the regulatory

landscape for Part 2. However, due to the relative size of the economic impact of the Part 2 rule in comparison to other Federal Regulations as well as the political and procedural implications of using the Congressional Review Act, the Part 2 rules are unlikely to be the subject of any Congressional action.

II. History of 42 CFR Part 2 Regulations

Title 42, Section 290dd-2 of the United States Code provides sweeping confidentiality protections for substance abuse treatment records and authorizes the regulations at 42 CFR Part 2. Regulations were first promulgated in 1975 (40 FR 27802) and the previous meaningful update was in 1987 (52 FR 21796).

A broad range of individuals and entities commented on the NPRM, including associations, health care providers, health insurers, state and local governments, patients, and people in recovery. Public comments were responded to in the Final Rule.

The final rule is currently scheduled to become effective February 17, 2017 but, as discussed below, due to administrative actions by the Trump Administration, this schedule is very likely to change.

III. Summary of Key Requirements Under the Final Rule

a. Applicability:

The Part 2 Regulations will continue to apply to a program that is federally assisted and holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment, including an identified unit or medical personnel or other staff within a general medical facility. SAMHSA had proposed to add “general medical practices” to the definition of a Part 2 Program, but did not finalize this proposal. The Final Rule amends the Part 2 Regulations to apply to records in the possession of “other lawful holders of patient identifying

information” (e.g., individuals or entities who receive such records pursuant to a Part 2-compliant patient consent).

b. Consent Requirements:

The Final Rule amends the Part 2 Regulations to allow patients to include a general designation for individuals and/or entities with a treating provider relationship (e.g., “my treating providers”) in the “To Whom” section of the consent form, to allow for their records to be disclosed to such providers. This is a significant revision to the existing regulations which require each provider be specifically named in the consent form. However, the amount and kind of substance use disorder treatment information that may be disclosed must be specified on the consent form. This could be specified broadly, e.g., “all my substance use disorder information” or more granularly, e.g., medications, substance use history, employment information, living situation, and/or social supports.

c. Consent Requirements

The Final Rule amends the Part 2 regulations to require that patients who have agreed to a general disclosure designation in the “To Whom” section of their consent form must have the option to receive a list of entities to which their information has been disclosed, if requested. For entities that would disclose Part 2 information pursuant to a general designation on a patient’s consent form (e.g., accountable care organizations, health information exchanges), the Final Rule amends the Part 2 Regulations to require that they may not do so until they have the ability to comply with the “List of Disclosures” provision.

d. Prohibition on Re-Disclosure:

The Final Rule amends the Part 2 Regulations to revise language to the existing re-disclosure notification to clarify that the prohibition on re-disclosure of a patient’s information

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.

In particular, the Part 2 Regulations include notice language that must be included with each disclosure made with the patient's written consent. Specifically, each disclosure must be accompanied with the following written statement (with revised language in bold type):

This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR Part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information **to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65.**

e. Qualified Service Organization:

The Final Rule amends the Part 2 Regulations to expand the definition of a qualified service organization, which can receive information from a Part 2 provider without express patient consent, to include entities that provide population health management services to a Part 2 program, but not care coordination services.

f. Research:

The Final Rule amends the Part 2 Regulations to allow any lawful holder of patient identifying information to disclose Part 2 data to qualified personnel for purposes of conducting scientific research so long as the researcher meets certain regulatory requirements related to other existing protections for human research (e.g., the researcher is subject to patient authorization and/or privacy protections under the HIPAA Privacy Rule or the Common Rule). The Final Rule also revised the Part 2 regulations to permit researchers holding Part 2 data to obtain data linkages to other data sets from data repositories holding Part 2 data if certain safeguards are in place.

g. Audits and Evaluations

The Final Rule amends the Part 2 Regulations to permit a Centers for Medicare & Medicaid Services (CMS)-regulated accountable care organization or Qualified Entity (e.g., an entity allowed to receive standardized extracts of Medicare data) to receive Part 2 data for purposes of conducting a required audit or evaluation without patient consent, under certain conditions, including having a signed participation agreement with CMS.

IV. Summary of Supplemental Notice of Proposed Rulemaking

Some of the comments submitted regarding the Part 2 Proposed Rule encouraged SAMHSA to make changes that were not contemplated within the Proposed Rule. On a number of meaningful provisions, SAMHSA determined that subsequent changes to address comments would have violated the notice and comment requirements of the Administrative Procedures Act (APA). As such, concurrent with the Final Rule, SAMHSA released a SNPR to provide an opportunity for the public to comment on the new provisions. A summary of the SNPR is included herein as Attachment A. The comment period on the SNPR is currently scheduled to close February 17, 2017, but as discussed below, this is likely to change.

V. Ongoing Challenges and Next Steps

Both the Final Rule and the SNPR retain a number of policy positions could continue to create barriers to the delivery of coordinated care to individuals receiving treatment for substance use disorders. In particular, the Final Rule and SNPR retain very narrow exceptions to the broad consent requirement and stringent re-disclosure limitations that impose substantially more rigorous requirements on Part 2 records than medical records covered by HIPAA. The flexibility in the use of broad “to whom” fields in consent forms, and proposed changes to allow for disclosure and re-disclosure for population health management and “health care operations” will meaningfully increase the access of health plans, providers, and related entities to critical information on prevalence and utilization trends among their client populations. The Final Rule and SNPR should also make it easier for health plans to contract with community-based Part 2 providers.

VI. The Trump Administration’s Regulatory Freeze

As described above, the Final Rule is currently scheduled to take effect on February 17, 2017 and that is also the date when the comment period on the SNPR is scheduled to close. However, that schedule is likely to change, potentially substantially. On January 20, 2017, shortly after President Trump’s inauguration, Assistant to the President and Chief of Staff Reince Priebus issued a memorandum entitled “Regulatory Freeze Pending Review,” known as the “Freeze Memo.” Depending on the approach taken by the new political leadership at SAMHSA, the Freeze Memo may delay the effective date of the Part 2 final rule, result in substantial revisions, including additional comment periods, or even result in the complete rescission of the rule.

Among other provisions, the Freeze Memo provides that, for all regulations that have been published in the Federal Register as of January 20, 2017 but that have not taken effect as of that date, the effective date will be postponed for at least 60 days. That delay is said to be for the purpose of reviewing questions of fact, law, and policy raised by all regulations with effective dates falling within this window. The final 42 CFR Part 2 rule falls within the scope of this provision of the Freeze Memo. While the Freeze Memo does provide for certain exceptions, none would apply to the Part 2 final rule. The effective date delay may extend beyond 60 days as the Freeze Memo encourages the agencies “[w]here appropriate and as permitted by applicable law, [to] consider proposing for notice and comment a rule to delay the effective date for regulations beyond that 60-day period.” However, if agencies determine that the regulation does not raise any “substantial questions of law or policy,” such that further notice and comment is not required, the memo allows for regulations to take effect after 60 days without additional changes.

In addition, on January 24, 2017, Mark Sandy, the Acting Director of the Office of Management and Budget, provided additional guidance to agency and department heads. Sandy instructed each agency to undertake several actions in furtherance of the Freeze Memo. First, Sandy directed the heads and acting heads of all executive departments and agencies to postpone the effective date of regulations for at least 60 days as allowed by law and to consider postponing the effective date further where appropriate. Sandy specifically recommended that heads and acting heads of departments and agencies consider “taking comment on the regulation itself, including about questions of fact, law, and policy that the agency should recognize as it considers whether the regulation raises any substantial questions.”

As such, the effective date of the 42 CFR Part 2 Final Rule will almost certainly be delayed by 60 days at a minimum and likely more. It is unclear whether the comment period on the SNPR will likewise be extended or whether it will be included within a broader new open comment period on the entire regulation.

VII. Congressional Review Act

In addition to the provisions of the Freeze Memo, the Final Rule is subject to the provisions of the Congressional Review Act (5 U.S.C. §§801-808). The Congressional Review Act (CRA) is a provision granting Congress with the authority to overturn a rule issued by a federal agency. Under the CRA, agencies are required to submit a report to Congress and the Comptroller General that includes a copy of the rule; a concise general statement relating to the rule, including whether it is a major rule; and the proposed effective date of the rule. Once this report has been submitted to Congress, Members of Congress have specific time periods in which to submit and take action on a joint resolution of disapproval. If both houses pass the resolution, it is sent to the President for signature or veto. Importantly, when a joint resolution of disapproval is passed by discharge petition with the support of 30 Senators, it cannot be filibustered in the Senate. Although a supermajority is generally required as a practical matter because most joint resolutions would be vetoed by the sitting President, in circumstances at the beginning of a new President's term where the new President supports the use of the CRA, it is possible for the CRA to be used by a simple majority in the House and Senate.

The CRA cannot be used to make tailored adjustments to a proposed rule, it can only be used to invalidate a rule in its entirety. In addition, once the CRA is invoked to invalidate a regulation, the agency may not reissue the rule in "substantially the same form" or issue a "new rule that is substantially the same" as the disapproved rule, "unless the reissued or new rule is

specifically authorized by a law enacted after the date of the joint resolution disapproving the original rule.”

As such, although the CRA could be used to overturn the 42 CFR Part 2 final rule, Congress is very unlikely to do so and it would be potentially more harmful than using the authority under the Freeze Memo to make changes to the Final Rule. 42 CFR Part 2 is not a Major Rule (\$100 million or more in economic impact any one year), which not only shortens the window in which Congress can act, but also makes it less important of a target for their action.

VIII. Conclusion

The 42 CFR Part 2 Final Rule and SNPR issued on January 18, 2017 reflect a tremendous amount of work on the part of SAMHSA and the stakeholders in the substance use disorder community. Any delays and changes to the Part 2 rule as a result of the change in administration should not undermine or halt the implementation of this crucial step forward for the substance use disorder system. However, the SNPR and Freeze Memo present an opportunity for the further incremental improvement in the Part 2 regulatory structure to ensure that individuals with substance use disorder needs access all the evidence based and coordinated care they need.

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ATTACHMENT A

Summary of SAMHSA Supplemental Proposed Rule *Additional Clarifications to the Part 2 Regulations*

On Friday, January 13, 2017, the Substance Abuse and Mental Health Services Administration (“SAMHSA”) issued a Final Rule to update and modernize the Confidentiality of Alcohol and Drug Abuse Patient Records regulations (“Part 2 Regulations”) and to facilitate information exchange within new health care models. Concurrently, SAMHSA issued a Supplemental Proposed Rule to propose additional clarifications to the Part 2 Regulations as amended by the Final Rule. *SAMHSA is providing a 30-day comment period for the Supplemental Proposed Rule; accordingly, comments are due by February 17, 2017.*

I. Areas for Comment in the Supplemental Proposed Rule

SAMHSA is seeking comments on its additional proposals to address and clarify questions regarding restrictions on lawful holders¹ and their contractors, subcontractors and legal representatives² use and disclosure of Part 2-covered data for purposes of carrying out payment, health care operations, and other health care related activities.

Specifically, SAMHSA seeks comments on its proposals to:

- (1) Retain in regulation the notice found in § 2.32 regarding re-disclosure of Part 2 data but consider whether it would be appropriate to add an abbreviated notice and in which circumstances the shorter notice may be warranted;
- (2) Further revise § 2.33 regarding disclosures permitted with written consent in order to define and limit the circumstances in which certain disclosures for the purposes of payment and health care operations can be made; and
- (3) Further revise § 2.53 regarding disclosures related to audits and evaluations to expressly address further disclosures by contractors, subcontractors, and legal representatives for purposes of carrying out a Medicaid, Medicare, or Children’s Health Insurance Program (“CHIP”) audit or evaluation.

SAMHSA seeks to understand the implications of these proposed changes on the privacy and confidentiality of records concerning substance use disorder diagnosis, prognosis and treatment, and referral for treatment as well as the regulatory and financial impact, if any, of these proposals.

¹ A “lawful holder” of Part 2 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 prohibition on re-disclosure notice) or as permitted under the Part 2 statute, regulations, or guidance and, therefore, is bound by 42 C.F.R. Part 2.

² Contractors, subcontractors, and legal representatives that would receive data from a lawful holder would in turn become lawful holders upon receipt of such data, and, as such, would themselves be subject to the Part 2 requirements.

SAMHSA also seeks comments on the following two areas for its consideration in future rulemaking and guidance:

- (1) Additional purposes for which lawful holders should be able to disclose Part 2 patient identifying information; and
- (2) Further subregulatory guidance that SAMHSA and other agencies could provide to help facilitate implementation of 42 C.F.R. Part 2 in the current healthcare environment.

II. Proposed Revisions to the Part 2 Regulations

a. Section 2.32, Prohibition on Re-Disclosure

The Part 2 Regulations at § 2.32 (as finalized in the Final Rule) include notice language that must be included with each disclosure made with the patient's written consent. Specifically, each disclosure must be accompanied with the following written statement:

This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR Part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65.

SAMHSA does not propose changes to the language in this notification statement, but SAMHSA does seek comments on whether it would be appropriate to also add a shorter abbreviated statement to be used in certain circumstances (e.g., for particular types of disclosures or technical systems) where such a shorter notice may be warranted. SAMHSA suggests that an abbreviated statement could read as follows:

Data is subject to 42 CFR part 2. Use/disclose in conformance with part 2.

b. Section 2.33, Disclosures Permitted with Written Consent

The part 2 Regulations at § 2.33 (as finalized in the Final Rule) state the following:

If a patient consents to a disclosure of their records under § 2.31, a program may disclose those records in accordance with that consent to any person identified in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 2.34 and 2.35, respectively.

SAMHSA proposes to revise this regulatory language slightly, to add language under a new § 2.33(b) to explicitly list and limit the specific types of activities for which any lawful holder of part 2 patient identifying information would be allowed to further disclose the minimal information necessary for specific payment and health care operations activities, and to add language under a new § 2.33(c) requiring that lawful holders that engage contractors and subcontractors to carry out payment and the described health care operations that will entail using or disclosing part 2 patient identifying information include specific contract and subcontract provisions (or through a comparable instrument) requiring contractors and subcontractors to comply with the provisions of part 2.

Specifically, SAMHSA proposes to revise the part 2 Regulations at § 2.33 as follows (the new language in paragraph (a) is underlined; paragraphs (b) and (c) are entirely new):

(a) If a patient consents to a disclosure of their records under § 2.31, a program may disclose those records in accordance with that consent to any person or category of persons identified or general designated in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 2.34 and 2.35, respectively.

(b) If a patient consents to a disclosure of their records under § 2.31 for payment and/or health care operations activities, a lawful holder who receives such records under the terms of the written consent may further disclose those records as may be necessary for its contractors, subcontractors, or legal representatives to carry out payment and/or the following health care operations on behalf of such lawful holder. Disclosures to contractors, subcontractors, and legal representatives to carry out other purposes are not permitted under this section. In accordance with § 2.13 (a), disclosures under this section must be limited to that information which is necessary to carry out the stated purpose of the disclosure.

(1) Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing and related health care data processing

(2) Clinical professional support services (e.g., quality assessment and improvement; initiatives, utilization review and management services);

(3) Patient safety activities;

- (4) Activities pertaining to:
 - (i) The training of student trainees and health care professionals;
 - (ii) The assessment of practitioner competencies; and
 - (iii) The assessment of provider and/or health plan performance;
 - (iv) Training of non-health care professionals;
- (5) Accreditation, certification, licensing, or credentialing activities;
- (6) Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care;
- (7) Third-party liability coverage
- (8) Activities related to addressing fraud, waste and abuse;
- (9) Conducting or arranging for medical review, legal services, and auditing functions;
- (10) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating, including formulary development and administration, development or improvement of methods of payment or coverage policies;
- (11) Business management and general administrative activities, including, but not limited to, management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations;
- (12) Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;
- (13) Resolution of internal grievances;
- (14) The sale, transfer, merger, consolidation, or dissolution of an organization;
- (15) Determinations of eligibility or coverage (e.g. coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;
- (16) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(17) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges.

(c) Lawful holders who wish to disclose patient identifying information pursuant to subsection (b) of this section must enter into a written contract with the contractor (or appropriate comparable instrument in the case of a legal representative retained voluntarily by the lawful holder), which provides that the contractor and any subcontractor or legal representative are or will be fully bound by the provisions of part 2 upon receipt of the patient identifying data, and, as such that each disclosure shall be accompanied by the notice required under § 2.32. In making such disclosure, the lawful holder should specify permitted uses of patient identifying information consistent with the written consent, by the contractor and any subcontractors or legal representatives to carry out the payment and health care operations activities listed in the preceding subparagraph, require such recipients to implement appropriate safeguards to prevent unauthorized uses and disclosures and require such recipients to report any unauthorized uses, disclosures, or breaches of patient identifying information to the lawful holder. The lawful holder should only disclose information to the contractor or subcontractor or legal representative that is necessary for the contractor or subcontractor to perform its duties under the contract. Also, the contract does not permit a contractor or subcontractor or legal representative to re-disclose information to a third party unless that third party is a contract agent of the contractor or subcontractor, helping them provide services described in the contract, and only as long as the agent only further discloses the information back to the contractor or lawful holder from which the information originated.

Based on these proposed revisions, SAMHSA is clarifying that it will consider certain payment or health care operations-related activities permissible for lawful holders to disclose to contractors, subcontractors, or legal representatives as long as the activities are consistent with the stated purpose of the patient's written consent. SAMHSA notes that the list of activities related to payment and health care operations included in § 2.33(b) is similar to the HIPAA Privacy Rule's definition of the terms "payment" and "health care operations," although SAMHSA is not adopting those definitions in their entirety. Further, the payment and health care operations activities listed in § 2.33(b) does not include activities that SAMHSA considers to be related to the patient's diagnosis, treatment, or referral for treatment because SAMHSA believes it is important to maintain patient choice in disclosing information to health care providers with whom they will have direct contact. Accordingly, **this provision will not cover care coordination or case management** and the proposal provides that disclosures to contractors, subcontractors, and legal representatives to carry out other purposes are not permitted under this section.

SAMHSA specifically seeks comments on whether the proposed listing of explicitly permitted activities is adequate and appropriate to ensure the health care industry's ability to conduct necessary payment and the described health care operational functions, while still affording adequate privacy protections for the individuals who were diagnosed, treated, or referred for

treatment for substance use disorders. In addition, SAMHSA seeks comments on the proper mechanisms to convey the scope of the consent to lawful holders, contractors, subcontractors, and legal representatives, including those who are downstream recipients of part 2 patient identifying information given current electronic data exchange technical designs.

c. Section 2.53, Audit and Evaluation

In the Final Rule, SAMHSA made clear that disclosures of patient identifying information to accountable care organizations (“ACOs”) and similar CMS-regulated entities to carry out Medicare, Medicaid and CHIP audit and evaluation activities are permitted. SAMHSA proposes to further amend § 2.53 to make clear that the individual or entity receiving part 2 patient identifying information for audit and evaluation or quality improvement purposes is permitted to further disclose this information to contractor(s) or subcontractor(s) to complete these activities.

Specifically, SAMHSA proposes to revise the part 2 Regulations at § 2.53 as follows (new language is underlined and deleted language is stricken out):

(a) Records not copied or removed. If patient records are not downloaded, copied or removed from the part 2 program premises or forwarded electronically to another electronic system or device, patient identifying information, as defined in § 2.11, may be disclosed in the course of a review of records on the part 2 program premises to any individual or entity who agrees in writing to comply with the limitations on re-disclosure and use in paragraph (d) of this section and who:

(1) Performs the audit or evaluation on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the ~~part 2~~ program or is authorized by law to regulate ~~it's~~ the activities of the part 2 program or those of the lawful holder; or

(ii) Any individual or entity who provides financial assistance to the part 2 program, which is a third-party payer covering patients in the part 2 program, or which is a quality improvement organization performing a utilization or quality control review; or

(2) Is determined by the part 2 program to be qualified to conduct an audit or evaluation of the part 2 program.

(b) Copying, removing, downloading, or forwarding patient records. Records containing patient identifying information, as defined in § 2.11, may be copied or removed from a part 2 program premises or downloaded or forwarded to another electronic system or device from the part 2 program's electronic records by any individual or entity who:

(1) Agrees in writing to:

(i) Maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16;

(ii) Retain records in compliance with applicable federal, state, and local record retention laws; and

(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and

(2) Performs the audit or evaluation on behalf of:

(i) Any federal, state, or local governmental agency which provides financial assistance to the ~~part 2~~ program or is authorized by law to regulate ~~its~~ the activities of the part 2 program or those of the lawful holder; or

(ii) Any individual or entity ~~who~~ which provides financial assistance to the part 2 program, which is a third-party payer covering patients in the part 2 program, or which is a quality improvement organization performing a utilization or quality control review, or such individual's or entity's or quality improvement organization's contractors, subcontractors, or legal representatives.

(c) Medicare, Medicaid, Children's Health Insurance Program (CHIP), or related audit or evaluation. (1) Patient identifying information, as defined in § 2.11, may be disclosed under paragraph (c) of this section to any individual or entity for the purpose of conducting a Medicare, Medicaid, or CHIP audit or evaluation, including an audit or evaluation necessary to meet the requirements for a Centers for Medicare & Medicaid Services (CMS)-regulated accountable care organization (CMS-regulated ACO) or similar CMS-regulated organization (including a CMS-regulated Qualified Entity (QE)), if the individual or entity agrees in writing to comply with the following:

(i) Maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16;

(ii) Retain records in compliance with applicable federal, state, and local record retention laws; and

(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section.

(2) A Medicare, Medicaid, or CHIP audit or evaluation under this section includes a civil or administrative investigation of a part 2 program by any federal, state, or local government agency with oversight responsibilities for Medicare, Medicaid, or CHIP and includes administrative enforcement, against the part 2 program by the government agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

(3) An audit or evaluation necessary to meet the requirements for a CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) must be conducted in accordance with the following:

(i) A CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) must:

(A) Have in place administrative and/or clinical systems; and

(B) Have in place a leadership and management structure, including a governing body and chief executive officer with responsibility for oversight of the organization's management and for ensuring compliance with and adherence to the terms and conditions of the Participation Agreement or similar documentation with CMS; and

(ii) A CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) must have a signed Participation Agreement or similar documentation with CMS, which provides that the CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE):

(A) Is subject to periodic evaluations by CMS or its agents, or is required by CMS to evaluate participants in the CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) relative to CMS-defined or approved quality and/or cost measures;

(B) Must designate an executive who has the authority to legally bind the organization to ensure compliance with 42 U.S.C. 290dd-2 and this part and the terms and conditions of the Participation Agreement in order to receive patient identifying information from CMS or its agents;

(C) Agrees to comply with all applicable provisions of 42 U.S.C. 290dd-2 and this part;

(D) Must ensure that any audit or evaluation involving patient identifying information occurs in a confidential and controlled setting approved by the designated executive;

(E) Must ensure that any communications or reports or other documents resulting from an audit or evaluation under this section do not allow for the direct or indirect identification (e.g., through the use of codes) of a patient as having or having had a substance use disorder; and

(F) Must establish policies and procedures to protect the confidentiality of the patient identifying information consistent with this part, the terms and conditions of the Participation Agreement, and the requirements set forth in paragraph (c)(1) of this section.

(4) Program, as defined in § 2.11, includes an employee of, or provider of medical services under the program when the employee or provider is the subject of a civil investigation or administrative remedy, as those terms are used in paragraph (c)(2) of this section.

(5) If a disclosure to an individual or entity is authorized under this section for a Medicare, Medicaid, or CHIP audit or evaluation, including a civil investigation or

administrative remedy, as those terms are used in paragraph (c)(2) of this section, the individual or entity may further disclose the patient identifying information that is received for such purposes to its contractor(s) or subcontractor(s) to carry out the audit or evaluation, and then a quality improvement organization which obtains the such information under paragraph (a) or (b) of this section may disclose the information to that individual or entity (or, to such individual's or entity's contractors, subcontractors, or legal representatives, but only for the purposes of conducting a Medicare, Medicaid, or CHIP audit or evaluation this section.

(6) The provisions of this paragraph do not authorize the part 2 program, the federal, state, or local government agency, or any other individual or entity to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the audit or evaluation as specified in paragraph (c) of this section.

(d) Limitations on disclosure and use. Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under § 2.66.

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