42 CFR Part 2 – Final Rule

Comparison Chart – 1987 rule, 2017 updated final rule, and HIPAA

Revised 2/23/2017

Acronyms:

HIPAA: Health Information Portability and Accountability Act (and its implementing regulations)
PHI: Protected Health Information
TPHO: "treatment, payment or healthcare operations"
HIE: Health information exchange

	42 CFR Part 2 (*1987 Rule*)	**42 CFR Part 2 (*Updated Final Rule*)**	**HIPAA**
Applicability (covered entities)	Part 2 applies to any individual or entity that is federally assisted and holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment. This includes specialty facilities and identified units/personnel within general medical facilities who meet the criteria. Any provider that has a DEA X# is considered federally assisted[1] *Via SAMHSA: "Accordingly, primary care providers who do not work in general medical care facilities meet Part 2's definition of a program if their **principal practice** consists of providing alcohol or drug abuse diagnosis, treatment or referral for treatment, and they hold themselves out as providing the same. If their principal practice consists of providing alcohol or drug abuse diagnosis, treatment or referral for treatment, but they do not hold themselves out as providing those services, then it is likely that they would not meet the definition of a program.* *The phrase "holds itself out" is not defined in the regulations, but could mean a number of things, including but not limited to state*	SAMHSA will continue to apply the 42 CFR Part 2 regulations to a program that is federally assisted and holds itself out as providing, and provides, SUD diagnosis, treatment, or referral for treatment. SAMHSA has finalized the new definition of a covered program: "Program means: (1) An individual or entity (other than a general medical facilities) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or (2) An identified unit within a general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or (3) Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers."	Any health plan, health care clearinghouse, or provider who electronically transmits any health information in connection with transactions for which HHS has adopted standards.

[1] http://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-faqs

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	licensing procedures, advertising or the posting of notices in the offices, certifications in addiction medicine, listings in registries, internet statements, consultation activities for non-"program" practitioners, information presented to patients or their families, or any activity that would lead one to reasonably conclude that the provider is providing or provides alcohol or drug abuse diagnosis, treatment or referral for treatment." [2] ***Note: APA has interpreted the regulations and guidance from SAMHSA to not cover general psychiatrists who treat addiction (via OBOT/MAT or otherwise) at an abundance of less than a majority of their practice. SAMHSA has not pushed back on this interpretation, and we are not aware of any Part 2 enforcement actions against general psychiatrists who would not generally be considered to be "Part 2 covered programs" under current law and current understanding.***	SAMHSA has established the definition of "holds itself out "and is defined as any activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder diagnosis, treatment, or referral for treatment including but not limited to: • Authorization by the state or federal government (e.g. licensed, certified, registered) to provide, and provides, such services, • Advertisements, notices, or statements relative to such services, or • Consultation activities relative to such services."	
Consent requirements	With limited exceptions, Part 2 requires patient consent for disclosures. The consent form is required to include the name or title of the individual or the name of the organization to which disclosure is to be made. The limited exceptions encompass medical emergency, court order, notification to law enforcement due to crimes on program premises or against program personnel, and certain state laws reporting **<u>Blanket consent?</u>** Technically possible, but highly limited due to the fact that you'd have to re-initiate blanket consent if any new provider, program, facility etc. is newly added to the recipient list.	Current regulations do not include a way for patients to determine "to whom" their records have been disclosed. SAMHSA's final rule finalizes the provision that includes a general designation in the "To Whom" field that allows the disclosure of information to individuals or entities as long as those entities have a treating provider relationship with the patient. The final rule allows for additional options for patients to complete the "To Whom" section. Patients may now include 1) a name of an individual, 2) name of entity that has a "treating provider relationship" with the patient, 3) name that the patient does not have a treating provider relationship but is a third-party payer, and/or 4) name of entity that does not have a treating	HIPAA generally permits the disclosure of protected health information without patient consent or authorization for the purposes of "treatment, payment, or healthcare operations" (TPHO). A notable exception to this is for psychotherapy notes, which must be kept separate from the traditional medical record in order to qualify as psychotherapy note designation and require explicit authorization by a patient for disclosure.

[2] http://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-faqs

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		provider relationship, is not a third party, but includes the name of specific participants, name of the entity participants that have a treating provider relationship, or general designation ("all treating providers"). SAMHSA requires that the compliant consent include the date, event, condition that the consent will expire unless terminated before those listed. For instance, the consent form can designate an HIE (specifying the name of the HIE entity) as long as a class of individuals and or/entity participants with a provider relationship are named. Reviewing the full text of the "to whom" designation (page 13-16, section H.a.1 of the notice of proposed rulemaking) as well as its associated explanatory chart is advisable. To balance the flexibility of allowing a general designation in the "To Whom", SAMHSA now requires that upon request a patient who includes a general designation on the consent form may obtain a list of entities to which their information has been disclosed. The final rule determined that there is no timeframe for compliance; however, entities must be capable of providing a List of Disclosures upon request in order to choose to have the option of disclosing information outlined in the general designation on a consent form. SAMHSA requires that the consent form contain statements that the patient understands the terms of the consent and his or her right to obtain information on the disclosures. Section 2.31, paragraph (2) of the "for whom" section of the provision discussing the disclosures with patient consent states requires that the specific name(s) or general designation(s) of the part 2 program that is	

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		permitted to make the disclosure must be named. Finally, SAMHSA requires the consent form to explicitly describe the SUD-related information to be disclosed. The type of information requested must have sufficient specificity to allow for appropriate compliance by the disclosing entity (e.g., medications and dosages, lab tests, substance use history summaries). Entities creating the consent may include a free text space, or provide choices. A patient consenting to disclose "all of my substance use disorder information" is acceptable as long as more granular options are included.	
Prohibitions on re-disclosure	Federal rules prohibit recipients of disclosures from covered entities from making any further disclosure of the information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains 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 this link (question 6) for further detail on redisclosure and the narrow circumstances regarding "otherwise permitted" Part 2-compliant redisclosures	SAMHSA clarifies that the prohibition on re-disclosure provision *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, and allows other health-related information shared by the part 2 program to be re-disclosed, if permissible under the applicable law. For example, if an individual receives substance use disorder treatment from a part 2 program and also receives treatment for a health condition such as high blood pressure, the individual's record would include information unrelated to their substance use disorder (i.e., high blood pressure). Part 2 does not prohibit re-disclosure of the information related to the high blood pressure as long as it does not include information that would identify the individual as having or having had a substance use disorder. However, illnesses that are brought about by drug or alcohol abuse may reveal that a patient has a substance use disorder. For example, cirrhosis of the liver or pancreatitis could reveal	HIPAA authorization must include a statement that information used or disclosed pursuant to an authorization may be subject to re-disclosure by the recipient and no longer protected by the rule. HIPAA's minimum necessary requirements generally apply to the circumstances of redisclosure.

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		a substance use disorder. Also, if a prescription for a medication used for substance use disorder treatment is revealed without further clarification of a non-substance disorder use (e.g., methadone used for the treatment of cancer), it would suggest that the individual has a substance use disorder and also would be prohibited. If data provenance (the historical record of the data and its origins) reveals information that would identify, directly or indirectly, and individual as having or having had a substance use disorder, the information would be prohibited from being re-disclosed. For example, if the treatment location is a substance use disorder treatment clinic, this information would identify an individual as having had a substance use disorder and is therefore prohibited."	
Medical emergency	In cases of "immediate threat to the health or safety of an individual or the public" Part 2 permits disclosure to medical personnel. Information in those circumstances may be redisclosed. *"Notifications to medical personnel in a medical emergency: A Part 2 program can make disclosures to medical personnel if there is a determination that a medical emergency exists, i.e., there is a situation that poses an immediate threat to the health of any individual and requires immediate medical intervention [42 CFR §2.51(a)]. Information disclosed to the medical personnel who are treating such a medical emergency may be redisclosed by such personnel for treatment purposes as needed. For additional information regarding disclosures during a medical emergency, see FAQs Numbered 7, 8, and 9 below."*	In the final rule, SAMHSA has aligned the regulatory language with the statutory language regarding the medical emergency exception of 42 CFR part 2 (§ 2.51). SAMHSA has adapted the medical emergency exception to give providers more discretion to determine when a "bona fide medical emergency" (42 U.S.C. 290dd-2(b)(2)(A)) exists. **Section 2.51 of the regulation states that patient identifying information may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency**, in which the patient's prior informed consent cannot be obtained." Immediately following the disclosure, SAMHSA requires the part 2 program to immediately document, in writing, specific information related to the disclosure, including:	Extremely permissive. A good summary can be found within this HHS OCR bulletin.

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		- The name of the medical personnel to whom the disclosure was made ant their affiliation with the health facility - The name of the individual making the disclosure - The date and time of the disclosure - The nature of the emergency SAMHSA also states that a patient identifying information may be made to the Food and Drug Administration (FDA) if there is a reason to believe that the health of the patient may be threatened by an error in the manufacturing, label, or sale of an FDA approved product.	
Audit trail / accounting of disclosures	No explicit right or requirement per limited DGR understanding	Permits the patient to obtain a list of entities that received their information in the previous two years under a general designation consent. Patient requests must be made in writing. The response would need to include the name of the recipient entity, the date of the disclosure, and a brief description of the information disclosed. The entity must respond in 30 or fewer days following the receipt of the written request.	HIPAA established a right for patients to receive an accounting of disclosures of PHI made by a covered entity in the six years prior for ***EXCEPT FOR*** the vast majority of disclosures related to TPHO, for explicitly authorized disclosures, and a number of other areas outlined under 45 CFR 164.528. A proposed rule that would implement the 2009 HITECH Act's establishment of a patient right to receive an accounting of disclosures made through EHRs of TPHO has yet to be finalized and implemented.
Qualified Service Organization	Defines Qualified Service Organization as a person which "provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or	SAMHSA has expanded the definition of Qualified Service Organization (QSO) to include entities that provide population health management services to a Part 2 program.	Under HIPAA this provision is defined as a Business Associate. Under HIPAA health plans, health care clearinghouses, and certain

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	other professional services, or services to prevent or treat child abuse or neglect". The law states that a written agreement must be entered in under which a person acknowledges that receiving and storing this information is bound by all regulations.		heatlh care providers are considered business associates. HIPAA allows covered providers and he4alth plans to disclose PHI if the provider or plan receives statisfactory assurances that the business association will use the information as intended, will safeguard the information from misuse, and will help the covered entity comply with some of the covered entity's duties under HIPAA.
Research	Programs permitted to disclosed or use substance abuse patient information for research activities.	Section 2.52 states that patient identifying information to be disclosed to qualifying personnel for the purpose of conducting scientific research by a Part 2 program or other individuals or entities if that researcher provides documentation that they are meeting all requirements related to protections for human research.	HIPAA allows PHI to be disclosed by a covered entity for research purposes as defined as "a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge". To use or disclose patient identifiable data without consent for purposes of research, a covered entity must obtain IRB or Privacy Board Approval, representations from the researcher that the PHI data will be solely used to prepare a research protocol or similar purposes, representation that the data is necessary for the research, and must provide a data use agreement entered into by the covered entity and the researcher.