CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS REGULATIONS 42 C.F.R. PART 2: SUBPOENA RESPONSE TOOLKIT

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INTRODUCTION

Background and Purpose

The regulations at 42 C.F.R. Part 2 (Part 2) were first promulgated in 1975 and last substantively updated in 1987. Part 2 implements 42 U.S.C.A. § 290dd-2, which protects the confidentiality of information relating to a patient's identity, diagnosis, prognosis, or treatment in connection with any federally assisted program that provides substance abuse education, prevention, training, treatment, rehabilitation, or research. The confidentiality regulations were promulgated in response to stigma and discrimination against people with a substance use disorder (SUD). The intent of Part 2 is to encourage individuals to seek treatment by ensuring that information relating to a person's substance use disorder–including their identity–is protected from disclosure and cannot be released without the patient's consent.

Applicability

Part 2 applies to "federally assisted alcohol and drug abuse programs." For Part 2 to apply to a SUD treatment program, the program must offer SUD education, treatment, or prevention and be regulated or assisted by the federal government. A federally assisted program includes programs that fall into one of the following general categories or programs:

- A program conducted directly by or through a contract with any federal agency;
- A program authorized, certified, licensed, or registered by the federal government, including:
    - a program certified as a provider under the Medicare program;
    - a program authorized to conduct methadone maintenance treatment; or
    - a provider registered with the DEA;
- A program receiving federal funds in any form, including funds that do not directly pay for SUD services, and pass-through federal funds from state or local government; and
- Any program granted tax-exempt status by the IRS or a program allowed tax deductions for contributions by the IRS.

Patient Identity

A patient's identity is protected under Part 2. A program is prevented from releasing any information that would identify a person as an alcohol or drug abuser either directly or through affirmation or verification. Therefore, a program cannot confirm or deny whether a person with a substance use disorder is even a patient without the proper release or unless another Part 2 exception applies. Any

answer to a request for patient information or records must be made in a way that will not affirmatively reveal that an individual has been diagnosed or treated for alcohol or drug abuse.

Written Authorization

Except in very limited circumstances, Part 2 does not permit the disclosure of SUD records unless a patient first provides voluntary, written consent. The disclosure must be in writing; verbal consent is not effective. In addition, Part 2 does not permit a patient to authorize a disclosure to a general classification of organizations; each entity must be specifically named.

The written consent requirement under Part 2 can be met only if the form includes ten required elements. (See Checklist for Written Consent to Disclosures (42 C.F.R. § 2.31) on page 20 for required elements).

Disclosures Without Patient's Consent

Part 2 has limited exceptions for a disclosure without the patient's consent, and they are more limited than what is allowed under the Health Insurance Portability and Accountability Act (HIPAA). Disclosures without a patient's consent are allowed in the following circumstances:

- Communications among program personnel
- Communications between a program and a Qualified Service Organization (QSO)
- Crimes on program premises or against program personnel
    - *Note: There is no exception for complying with a duty to warn unless the threat is made against a program personnel.*
- Reports of suspected child abuse and neglect
    - *Note: The exception allows a disclosure to make the initial report of suspected child abuse or neglect; however, any disclosure for a subsequent investigation is not allowed unless there is a court order or signed authorization.*
- Medical emergencies
    - *Note: This exception only applies when there is an immediate threat to the health of the patient that requires immediate medical intervention. Immediately following the disclosure, the program must document the disclosure in the patient's records, including the name of the medical personnel who received the information, the name of the individual making the disclosure, the date and time of the disclosure, and the nature of the emergency.*
- Scientific research
- Audits and evaluation activities

- *Note: If records are to be copied or removed from the program premises, the auditor must sign a written statement agreeing to certain conditions. See Audit and Evaluation Agreement on page 21.*

- Court order

    - *Note: The court is required to make certain findings, and the court order must contain certain elements. See Sample Court Orders on pages 8-12 and the Checklist for Compliant Court Orders on page 19.*

Minors

Part 2 incorporates applicable state law regarding a minor's ability to consent to treatment when determining whether a minor can authorize the disclosure of his or her SUD information. If a minor patient has the legal capacity to consent to alcohol or drug abuse treatment under state law, then the minor has the legal capacity to consent to the disclosure of information. If state law requires both the minor and parent or guardian to consent to treatment, then any written consent for disclosure must be signed by both the minor and the parent or guardian.

If state law requires parental consent, the fact that a minor sought alcohol or drug abuse treatment may only be communicated to his or her parent or guardian if: (1) the minor gives written consent to do so; or (2) the minor lacks the capacity to make a rational choice regarding consent.

Incompetent and Deceased Patients

Incompetent patients other than minors: If a patient lacks the capacity to manage his or her own affairs, a consent to disclose may be given by the guardian or other person authorized under state law to act on the patient's behalf.

Deceased patients: Written consent or a court order would be required to disclose the information of a deceased patient. For written consent, the executor, administrator, or other personal representative appointed under applicable state law may sign. If there is no such appointment, consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.

Redisclosure

When Part 2 programs disclose information pursuant to a signed consent form, they must include a written statement that the information cannot be re-disclosed. Persons who receive records directly from a program and who are notified of the restrictions on re-disclosure of the records are bound by the Part 2 regulations. See Sample Redisclosure Notice on page 8.

- *Note: Attorneys will sometimes seek oral testimony based on a signed written consent from the client. This can be problematic because the consent form would have to list everyone present at the deposition or in the courtroom. A second problem is the prohibition on redisclosure. The*

consent form only allows disclosure to those people expressly listed on the consent form and would prevent any further use of the oral testimony in transcript form, unless another consent form is executed. For example, if a subpoena for deposition is accompanied by a written consent that lists the court reporter and all attorneys present during the deposition, the prohibition on redisclosure prohibits sending the deposition transcript to an expert witness later. Rather than relying on a written consent form for oral testimony, a court order is recommended instead.

TEMPLATE RESPONSE LETTER TO SUBPOENA WITH NO COURT ORDER OR RELEASE

DATE

NAME
ADDRESS
ADDRESS

Re: Request for Records in Case No: _____

Dear _____:

[Provider] recently received a subpoena for substance use disorder records in relation to the above-referenced matter. As you may already know, [Provider] is a behavioral health treatment program and is governed by federal and state laws that address the privacy and confidentiality of our clients and their records. Unfortunately, [Provider] cannot comply with your subpoena for records because it was not accompanied by a court order or by a written and signed authorization.

The federal confidentiality laws and regulations governing the release of substance use disorder information prohibit us from disclosing information in response to a subpoena unless a court also issues an order in compliance with the procedures and standards set forth in 42 C.F.R. Part 2. The requirements for any court order authorizing the disclosure of substance abuse records are set forth in 42 C.F.R. § 2.64 and 42 C.F.R. § 2.65. In the alternative, any subpoena would have to be accompanied by a written authorization from the client whose information is being requested. The requirements for written authorizations are found at 42 C.F.R. § 2.31.

[Provider] would like to comply with your request for information, but we must ensure we are acting in accordance with all federal and state confidentiality requirements. Without a valid release or court order, [Provider] cannot confirm or deny whether the individual is or ever was a participant in one of our programs. If you should have any further questions, please do not hesitate to contact _____.

Sincerely,

[NAME]
Medical Records Clerk

REDISCLOSURE NOTICE REQUIRED BY 42 C.F.R. § 2.32

Prohibition on Redisclosure of Confidential Information

In accordance with 42 C.F.R. § 2.32:

This notice accompanies a disclosure of information concerning a patient in alcohol or drug treatment, made to you by the consent of such patient. 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.

SAMPLE COURT ORDER: PROTECTIVE ORDER FOR ORAL TESTIMONY

STATE OF _____
FOR THE COUNTY OF _____

In re:	)	CASE NO. XXXXX
	)	
XXXXXX,	)	
	)	**COURT ORDER FOR DISCLOSURE OF**
Petitioner	)	**PROTECTED PATIENT RECORDS IN**
	)	**WITNESS TESTIMONY TO COURT**
	)	
	)	
	)	
vs.	)	
	)	
XXXXXX,	)	
Respondent		

1. Pursuant to 42 C.F.R. Part 2 and applicable state law, this Court authorizes XXXXXXXXXXXX, an [employee/contractor/consulting physician] of the [Name of Part 2 Program] in [City, State] (the "Clinic") to testify regarding protected patient records in compliance with civil subpoenas.
2. The testimony is to be pursuant to subpoenas served by counsel for Respondent XXXXXXXXXXXX, the individual to whom the testimony and records relate. Respondent has agreed in writing to this testimony and this Court Order is necessary in order to effectuate that agreement in compliance with the requirements of 42 C.F.R. Part 2, § 2.64.
3. The Court finds that the disclosure is in connection with litigation in which the patient will offer testimony or other evidence pertaining to the content of the confidential communications.
4. The Court further finds that other ways of obtaining the protected testimony and records would not be effective, and the public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.
5. Disclosure shall be limited to [XXXXXXXXX].

6. **No testimony regarding other patients of the Clinic shall be allowed and counsel is hereby Ordered not to ask any questions calling for such information.**
7. The protected patient records disclosed pursuant to the subpoena shall be disclosed only to those persons whose need for information is the basis for the order.
8. The Court shall take all measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services, which may include sealing the record from public scrutiny, taking testimony in a closed courtroom, or taking other appropriate measures to ensure that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, the person holding the record, or appropriate Court personnel in the fulfillment of their duties.
9. A copy of this Order shall be provided to the [Name of the Part 2 Program].

IT IS SO ORDERED.

DATED:_____ _____

[Name]

Judge of _____ Court

SAMPLE COURT ORDER:
PROTECTIVE ORDER FOR RECORDS IN A CRIMINAL CASE

STATE OF _____
IN THE CIRCUIT COURT OF THE ___ JUDICIAL CIRCUIT
COUNTY OF _____

_____,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No.
	)	
_____,	)	
	)	
Defendant.	)	

ORDER

This matter coming to be heard before the Honorable _____, the parties being present or represented by counsel, and the Court being fully advised of the premises,

IT IS HEREBY ORDERED THAT:

[Provider] shall release the following records **[specify records requested]** regarding **[person's name]**, seen on or about **[specify dates of treatment]**, to the following person or entity: **[person requesting records]**.

In entering this order, this Court finds that the crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect. The Court further finds good cause exists for disclosure of the records because there is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution and that other ways of obtaining the information are not available or would not be effective. The Court further finds that potential injury to the patient, to the physician-patient relationship, and to the ability of the program to provide services to other patients is outweighed by the public interest and the need for the disclosure.

The disclosure of records is limited to the parties of the above-captioned cause, all of whom have a need for the information contained within the records. The disclosure of information must be limited to those records specified above. Furthermore, the disclosure is limited to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution. Use of the records will be limited to the investigation and prosecution of an extremely serious crime or suspected crime.

This order shall expire upon the closing of said court proceedings or **[date]**, whichever is sooner.

Dated:_____ By:_____

SAMPLE COURT ORDER: PROTECTIVE ORDER FOR RECORDS IN A CIVIL CASE

STATE OF _____
IN THE CIRCUIT COURT OF THE ___ JUDICIAL CIRCUIT
COUNTY OF _____

,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No.
	)	
,	)	
	)	
Defendant.	)	

ORDER

This matter coming to be heard before the Honorable _____, the parties being present or represented by counsel, and the Court being fully advised of the premises,

IT IS HEREBY ORDERED THAT:

[Provider] shall release the following records **[specify records requested]** regarding **[person's name]**, seen on or about **[specify dates of treatment]**, to the following person or entity: **[person requesting records]**.

In entering this order, this Court finds that good cause exists for the disclosure of the records because other ways of obtaining the information are not available or would not be effective. Further, this Court finds that the public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship, and the treatment program.

The disclosure of records is limited to the parties of the above-captioned cause, all of whom have a need for the information contained within the records. The disclosure of information must be limited to those records specified above. The records and transcripts of any proceeding where the disclosed records will be introduced will be sealed from public viewing.

This order shall expire upon the closing of said court proceedings or **[date]**, whichever is sooner.

Dated:_____ By:_____

SAMPLE MEMORANDUM OF LAW FOR OBJECTING TO A NONCOMPLIANT SUBPOENA

CASE TYPE:

STATE OF	DISTRICT COURT
COUNTY OF	JUDICIAL DISTRICT
John Doe Plaintiff, vs. Jane Roe Defendant.	File No.: **Template:** **Third-Party [Name of Part 2 Program]'s Opposition to Motion to Compel Compliance With Subpoena** **Or** **Third-Party [Name of Part 2 Program]'s Motion for Protective Order**

ARGUMENT

I. [INSERT JURISDICTION-SPECIFIC LEGAL STANDARD FOR MOTION]

II. FEDERAL LAW PROHIBITS [NAME OF PART 2 PROGRAM] FROM RESPONDING TO THE SUBPOENA.

Federal regulations provide blanket confidentiality protection covering all "[r]ecords[1] of the identity, diagnosis, prognosis, or treatment of any patient" which are maintained in connection with any drug or alcohol abuse education, treatment, or rehabilitation program that is "conducted, regulated, or directly or indirectly assisted by any department or agency of the United States." 42 C.F.R. § 2.1 *et seq*. ("42 C.F.R. Part 2"). The rationale behind this broad shield is simple: "Congress felt that 'the strictest adherence' to the confidentiality provision was needed, lest individuals in need of drug abuse treatment be dissuaded from seeking help." *Ellison v. Cocke County, Tenn.*, 63 F.3d 467, 471 (6th Cir. 1995). Accordingly, patient records are only discoverable in civil litigation if: (1) the patient provides appropriate consent to disclosure; or (2) an appropriate court order authorizes the production of patient information. 42 C.F.R. §§ 2.1(b), 2.2(b), 2.31, and 2.61; *see Carr v. Allegheny Health Educ. & Research Foundation*, 933 F.Supp 485, 487 (W.D.Pa. 1996). Moreover, the protections of 42 C.F.R. Part 2, and the requirements that a party must satisfy in order to obtain disclosure of such records, must be strictly applied in all cases. 42 C.F.R. § 2.13(b) ("The restrictions on disclosure and use in these regulations apply whether the holder of the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement or other official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by these regulations.").

Due to the nature of its treatment and rehabilitation services, all patient information in [Name of Part 2 Program]'s possession falls within the ambit of these regulations. *See* 42 C.F.R. § 2.12(b) (defining "federally assisted" alcohol abuse and drug abuse programs subject to the regulations). Indeed, when responding to a subpoena, [Name of Part 2 Program] cannot even confirm *whether* a particular individual is or was a patient at one of its facilities in the absence of a satisfactory patient consent or appropriate court order permitting it to do so. 42 C.F.R. § 2.13(c).

[1] Importantly, "records" include "any information, whether recorded or not, which . . . would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such an identification by another person." 42 C.F.R. § 2.12. Accordingly, these restrictions pertain to testimony as well as documents.

A. Movant Has Not Obtained Appropriate Consent From The Purported Patient.

Even where a patient consents to disclosure of records, that consent must satisfy numerous requirements before the party possessing those records may release them. A patient's consent must be in writing, and must, at a minimum, include the following elements:

> (1) The specific name or general designation of the program or person permitted to make the disclosure.
>
> (2) The name or title of the individual or the name of the organization to which disclosure is to be made.
>
> (3) The name of the patient.
>
> (4) The purpose of the disclosure.
>
> (5) How much and what kind of information is to be disclosed.
>
> (6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 2.15 in lieu of the patient.
>
> (7) The date on which the consent is signed.
>
> (8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.
>
> (9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

42 C.F.R. § 2.31. "[T]he law makes clear that when consent is given, the presumption is against general waivers of confidentiality, and instead, that patients have complete control over the terms of any consent they may grant." *Fannon v. Johnston*, 88 F.Supp.2d 753, 761 (E.D.Mich. 2000). Accordingly, a patient may only provide consent to the disclosure and use of records for a particular purpose, and the recipient of such information cannot use it in any other civil, criminal, administrative, or legislative proceedings. *Id.*; 42 C.F.R. §§ 2.13(a) and 2.32.

B. Movant Has Not Obtained An Appropriate Court Order.

A court order authorizing the disclosure of confidential information regarding a patient's drug or alcohol treatment "is contemplated only under narrow circumstances." *Carr*, 933 F.Supp at 487. Moreover, an order authorizing the use or disclosure of patient information is "a unique kind of court order." 42 C.F.R. § 2.61. "Such an order does not compel disclosure," it only *permits* disclosure. Even if a court issues an order authorizing disclosure of patient records, the moving party must also employ a "subpoena or a similar legal mandate" in order to actually compel disclosure of the authorized information. *Id.*; 42 C.F.R. § 2.3. Accordingly, an order authorizing the disclosure of records has no power to compel production absent a subpoena. 42 C.F.R. § 2.61. And, similarly, a subpoena has no power to compel production of patient records absent an appropriate order authorizing disclosure of the records sought by the subpoena. *Id.*

In order to obtain <u>any</u> information regarding a patient, the party seeking disclosure must demonstrate "good cause" for obtaining that information. 42 C.F.R. §§ 2.1(b)(2)(C), 2.2(b)(2)(C). The party seeking disclosure always bears the burden of demonstrating that "good cause" exists. *Fannon*, 88 F.Supp.2d at 757; *Megonnell v. Infotech Solutions, Inc.*, 1:07-cv-02339, 2009 WL 3857456, at *3 (M.D.Pa., Nov. 18, 2009). At a minimum, in order to establish good cause, the moving party must demonstrate: "(1) Other ways of obtaining the information are not available or would not be effective; and (2) The public interest and the need for disclosure outweigh the potential injury to the patient, to the physician-patient relationship and the treatment services." 42 C.F.R. § 2.64(d). In determining whether to order the disclosure of records, "[c]ourts applying these statutes and regulations have noted there is a strong presumption against disclosing records of the kind covered by the statute and regulations, and the privilege afforded to them should not be abrogated lightly." *McCloud v. The Bd. Of Dir. of Geary Comm. Hosp.*, 06-1002-MLB, 2006 WL 2375614, at *4 (D.Kan. Aug. 16, 2006).

Parties seeking the "disclosure of confidential communications made by a patient to a program in the course of diagnosis, treatment, or referral for treatment" must satisfy even more onerous criteria. 42 C.F.R. § 2.63(a). Specifically, a court may authorize disclosure of communications made by a patient to a care provider only if:

> (1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;
>
> (2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as one that directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or
>
> (3) The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.[2]

Id. "Thus, if the information sought contains the patient's 'confidential communications' to the program staff, the party seeking the records must satisfy both the 'good cause' standard in § 2.64(d) and [demonstrate one of the three] requirements of § 2.63(a)."[3] *Ricchuite v. Johnson*, 1:14CV-00104-GNS, 2015 WL 5673126, at *3 (W.D.Ky. July 10, 2015).

Finally, even where a court issues an order authorizing disclosure, such an order must be narrowly tailored. Specifically, the order must:

> (1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order;

[2] Application of 42 C.F.R. § 2.63(a)(3) is case-specific. *Fannon*, 88 F.Supp.2d at 760. In other words, the patient's act of offering testimony or evidence pertaining to the content of confidential communications must occur in the same proceeding as the one in which the moving party seeks disclosure of patient records. The fact that a patient may have offered testimony, introduced evidence, or otherwise disclosed confidential communications in one proceeding or setting does not provide a basis for seeking disclosure of those communications in any other proceeding. *Id*.

[3] In addition to satisfying the substantive requirements of 42 C.F.R. Part 2, the moving party must also satisfy certain procedural requirements. Those procedural requirements include: (1) the application for an order authorizing disclosure of patient records must use a fictitious name to refer to the patient, and cannot contain any patient-identifying information; (2) both the patient and the party holding the records must receive adequate notice of the application for disclosure and an opportunity to file a written response; and (3) any hearing, oral argument, or review of evidence related to the application must be held in a private setting, such as the Court's chambers. 42 C.F.R. § 2.64(b) and (c).

> (2) Limit disclosure to those persons whose need for information is the basis for the order; and
>
> (3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

42 C.F.R. § 2.65(e); *see also* 42 C.F.R. § 2.13(a) ("Any disclosure made under [42 C.F.R. Part 2] must be limited to that information which is necessary to carry out the purpose of the disclosure.").

III. [IF APPLICABLE: STATE LAW PROHIBITS [NAME OF PART 2 PROGRAM] FROM RESPONDING TO THE SUBPOENA.]

Even if a party seeking disclosure of patient records is able to satisfy the requirements of 42 C.F.R. Part 2, it still may not be entitled to receive that information. Rather, the party seeking disclosure must also satisfy all state laws governing the disclosure and use of confidential information. 42 C.F.R. § 2.20.

[INSERT STATE LAW ARGUMENT]

CHECKLIST FOR COMPLIANT COURT ORDERS

Civil Court Order (42 C.F.R. § 2.64)

- ☐ Court finds that good cause exists.
- ☐ Court finds that other ways of obtaining the information are not available or would not be effective.
- ☐ Court finds that the public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship, and the treatment services.
- ☐ Court order limits disclosure to those parts of the patient's record which are essential to fulfill the objective of the order.
- ☐ Court order limits the disclosure to those persons who need the information.
- ☐ Court order includes such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services.

Criminal Court Order (42 C.F.R. § 2.65)

- ☐ Court finds that the crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.
- ☐ Court finds that there is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.
- ☐ Court finds that other ways of obtaining the information are not available or would not be effective.
- ☐ Court finds that the potential injury to the patient, to the physician-patient relationship, and to the ability of the program to provide services to other patients is outweighed by the public interest and the need for the disclosure.
- ☐ Court order limits disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order.
- ☐ Court order limits disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of extremely serious crime or suspected crime specified in the application.
- ☐ Court order includes such other measures as are necessary to limit disclosure and use to the fulfillment of only that public interest and need found by the court.

CHECKLIST FOR WRITTEN CONSENT TO DISCLOSURES (42 C.F.R. § 2.31)

Checklist for Substance Use Disorder Records

- ☐ The consent to disclosure is written and not verbal.
- ☐ The specific name or general designation of the program or person permitted to make the disclosure.
- ☐ The name or title of the individual or the name of the organization to which disclosure is to be made.
- ☐ The name of the patient.
- ☐ The purpose of the disclosure.
- ☐ How much and what kind of information is to be disclosed.
- ☐ The signature of the patient:
    - o If the patient is a minor, the signature of a person authorized to give consent, or
    - o If the patient is incompetent or deceased, the signature of a person authorized to sign in lieu of the patient.
- ☐ The date on which the consent is signed.
- ☐ A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to disclose information has already acted in reliance on it.
- ☐ Expiration date (or expiring event or condition).

AUDIT AND EVALUATION AGREEMENT PURSUANT TO 42 C.F.R. § 2.53(b)

Audit and Evaluation Agreement Pursuant to 42 C.F.R. § 2.53(b)

Name of Individual: _____ Name of Agency/Organization:_____

Agency/ Organization Address:_____

Purpose of Visit: _____

Type of Review: ☐ On Site ☐ Off Site

If On Site, Length of Visit: From _____ To _____

If Off Site, Records Will Be: Copied _____ Removed_____

I, _____(name of individual conducting audit or evaluation) agree as follows:

Client information and records will be maintained in accordance with the security requirements stated in 42 C.F.R. §2.16 (mandating the records be maintained in a secure room, locked file cabinet, or safe when not in use, and that procedures be used to control the access to and use of these records).

All client information and records will be destroyed upon completion of the audit or evaluation activities.

Client information and records received from [Provider] for this audit will not be redisclosed to any other person or entity and will only be used to carry out audit or evaluation activities.

The Auditing Agency also acknowledges that it may have access to confidential and proprietary information of the [Provider]. The term "confidential and propriety information" shall include all business, financial, medical, or technical information relating to the [Provider's] operations, including but not limited to: computer software systems; record keeping forms and manuals; company policies, procedures, and protocols; training manuals and materials; financial information; client fees and charges; client medical records; and case histories and billing information.

The Auditing Agency hereby agrees that it will not, without the prior express written consent of the [Provider], disclose directly or indirectly any confidential or proprietary information. In the event the Auditing Agency is required by law or court order to disclose such information, the Auditing Agency will give the [Provider] prompt notice of such mandate so the [Provider] can seek an appropriate protective order.

In the event of a breach or threatened breach by the Auditing Agency of the provisions of this agreement, the [Provider] shall be entitled to an injunction restraining the Auditing Agency from disclosing, in whole or in part, the confidential or proprietary information of the [Provider] and from rendering any services to any entity to whom such information has been disclosed or may be disclosed. Nothing herein shall be construed as prohibiting the [Provider] from pursuing any other remedies available to it for such breach or threatened breach, including the recovery of damages from Auditing Agency.

_____ _____

Signature of Individual Conducting Audit or Evaluation Signature of Program Director

Date: _____ Date: _____

SOP FOR RESPONDING TO MEDICAL RECORD REQUESTS FOR SUBSTANCE ABUSE TREATMENT RECORDS

STANDARD OPERATING PROCEDURE
Responding to Medical Record Requests

Policy: This SOP supports the Information Management Plan.

Purpose: It is [Provider] policy to respond to subpoenas, court orders, and other requests for records in accordance with state and federal law, specifically 42 C.F.R. Part 2, [insert relevant state law], and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Procedures for responding to subpoenas and disclosing client information in a manner that complies with state and federal law is listed below.

Scope: This SOP applies to any staff responding to subpoenas or disclosing client information.

CAUTIONARY NOTE: THIS IS A GENERALIZED PROCEDURE FOR HANDLING SUBPOENAS AND REQUEST FOR RECORDS. IMPROPERLY DISCLOSING CLIENT INFORMATION OR IGNORING A COURT ORDER CAN HAVE SERIOUS CONSEQUENCES, INCLUDING FINES AND IMPRISONMENT. IF STAFF HAVE ANY QUESTIONS OR CONCERNS, THEY SHOULD CONTACT THE MANAGER OF MEDICAL RECORDS OR GENERAL COUNSEL.

Definitions:

[Provider] receives several different types of records requests. Requests for records can be classified into one of the following categories:

1) **Subpoena:** A legal document issued by an attorney requiring someone to appear and give testimony.
2) **Subpeona Duces Tecum:** A legal document issued by an attorney requiring a person or entity to produce records.
3) **Court Order:** A written legal document issued and signed by a judge directing a person or entity to do something. A court order is different than a subpoena. A subpoena can be issued by an attorney without a judge's signature. A court order can only be issued and signed by a judge.
4) **Audit:** An official inspection of an organization's records or accounts, typically by a government agency.
5) **Request for Records with Signed Authorization or Release:** Any other request for records from an outside person or agency that is accompanied by a signed consent/authorization form or signed release of information.
    - *Note: A client's request for his or her own records is outside the scope of this SOP. Please refer to your agency's SOP for handling a client's request for his or her own records.*

Procedure Overview:

1. **Document in the Client's record.** The Medical Records clerk or designee shall document the receipt of each subpoena, court order, or request for records in the client record.

2. **Determine whether the Client has records at [Provider].** If the person who is the subject of the subpoena or records request was not a client or does not have any records,[Provider] can confirm the person was never a client and can send a letter indicating that [Provider] does not have any records for the person.

3. **Determine whether the Client previously signed a release.** Upon receipt of a subpoena or request for records, check the client's record to determine whether the client has signed an authorization that includes the person or entity that is requesting the records. If so, follow the appropriate procedures as outlined below for determining if the authorization is valid.

4. **Classify the request.** Determine which of the above categories the request fits into: Subpoena; Subpoena Duces Tecum; Request for Records with Signed Authorization or Release; or Audit. Follow the steps below for the specific type of request.

    - *Note: There is no standardized form for the above documents. All subpoenas and requests for records will vary in format. The only way to determine what category a request falls into is by reading the entire document.*

    - *Note: A client's request for his or her own records is outside the scope of this SOP. Please refer to your agency's SOP for handling a client's request for his or her own records.*

Subpoena for Testimony

A subpoena that requests testimony will require a witness, usually specified by name, to appear at a specific time to testify at a deposition or court hearing. All subpoenas that require testimony should be forwarded to General Counsel. General Counsel will determine if the subpoena is legally sufficient to compel testimony, will discuss the anticipated testimony with the attorney who issued the subpoena, and will schedule a witness preparation session with the staff member who is being asked to give testimony.

Subpoena Duces Tecum (Subpoena for Records)/Court Orders

Under the [state] and Federal Privacy/Confidentiality Rules, [Provider] may NOT release any records in response to a subpoena UNLESS one of the following applies:

1) The client has signed an authorization allowing [Provider] to release the records; or
2) A court order signed by a judge directs [Provider] to produce the records.

If a subpoena is accompanied by an authorization for release of records signed by the client, use the procedure below for "Request for Records with Authorization/Signed Release" to determine if authorization is valid.

> *Note: A subpoena and court order are two different legal documents. See Definitions section above.*

Determine if the Subpoena is for Substance Abuse or Mental Health Records. The requirements for a court order are different for substance abuse records than for mental health records. To determine what legal requirements apply, review the subpoena to determine what records are being sought. If the subpoena requests both substance abuse and mental health records, the court order must comply with legal requirements for both types of records.

For a substance abuse records, the Court Order must:

- Reference the Federal Privacy/Confidentiality protections (42 C.F.R. § 2.64 and 42 C.F.R. § 2.65);
- Limit disclosure to only those parts of the record that are needed;
- Limit disclosure to only those persons who need the information; and
- Limit the use of the records.

See the Checklist for Compliant Court Orders on page 19 for additional information.

For a mental health records, the Court Order must:

- [Insert requirements from any state-specific mental health confidentiality laws]

If the Court Order is sufficient, produce only the records specified in the Subpoena and Court Order to only those parties specified in the Subpoena and Court Order. If there is a difference between the records requested by the subpoena and the records requested by the Court Order, determine which request is more narrow and more specific and comply with that request. If there is no Court Order or if the Court Order is insufficient, send the Response Letter to Subpoena with No Court Order or Release found on page 7.

Request for Records with a Signed Authorization or Release

First, determine if the consent/authorization/release is valid. For purposes of this section, a "consent" refers to any document signed by the client authorizing the disclosure of his or her records. This document may be titled "Consent", "Authorization", or "Release of Information."

[Provider] may disclose client records and other information if the client has signed a valid authorization that has not expired or been revoked. If the request or authorization seeks both substance abuse and mental health records, the authorization must comply with legal requirements for both types of records.

For a substance abuse client, the Federal Confidentiality Rules (specially, 42 C.F.R. § 2.31) require that a valid consent form be in writing and contain specified parts. Use the Checklist for Written Consent to Disclosures (42 C.F.R. § 2.31) on page 20 to determine if the consent is valid. If the consent is valid, then [Provider] can release ONLY the information listed in the client consent.

For a mental health client, the [insert relevant state law governing release of mental health records], requires a valid consent form must be in writing and must contain specific information. Use the

Checklist for Written Consent to Disclosures (42 C.F.R. § 2.31) on page 20 to determine if the consent is valid.

If the consent is invalid because (i) it does not contain all of the required information or (ii) it has expired or has been revoked, then [Provider] cannot release any of the requested information. The consent does not have to be on [Provider's] specific form; however, it must meet all of the elements outlined above. If the consent is invalid or expired, send Response Letter to Subpoena with No Court Order or Release as provided on page 7.

Deceased Clients:
HIPAA, 42 C.F.R. Part 2 and State Confidentiality and Privacy Regulations still apply to the records of deceased individuals. HIPAA applies to a deceased individual for a period of 50 years. 42 C.F.R. Part 2 and applicable state regulations have specific limitations as follows:

- ***Substance Abuse Clients:*** In order to release records of deceased clients under 42 C.F.R. Part 2 for a deceased client, written consent to the disclosure is required from the executor, administrator, or other personal representative appointed under applicable State law. If there is no such appointment, the consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family. (42 C.F.R. 2.15(b)(2)).

- ***Mental Health Clients:*** [insert state specific law]

Audits, Investigations, and Inspections

An audit is an official inspection of an organization's records or accounts, typically by a government agency. Sometimes, but not always, these requests are received from government organizations such as the Centers for Medicare & Medicaid Services (CMS), [insert state agencies]. Insurance companies and managed care companies can also request audits.

All audits should be immediately forwarded to the Corporate Compliance Department.

If an auditor or outside agency requests copies of records, they must agree in writing to:

- Maintain the patient identifying information in accordance with the security requirements provided in 42 C.F.R. § 2.16;
- Destroy all of the patient identifying information upon completion of the audit or evaluation; and
- Comply with the limitations on disclosure and use in 42 C.F.R. §2.53(d).

See Audit and Evaluation Agreement on page 21.

Producing Records

If the Court Order or Authorization to Release Records is valid, produce only the specified records to only the specified people or entities.

Minimum Necessary:
Each record request shall be reviewed for compliance with the minimum necessary standard. This standard means that only the information that is reasonably necessary to achieve the purpose of the disclosure shall be provided. For example, if a client's treatment plan is requested by a third party for whom there is a valid release, only the treatment plan shall be provided, not the client's entire chart consisting of other treatment records. [Provider] shall not disclose an entire medical record, except when the entire medical record is reasonably necessary to accomplish the purpose of the request.

If the Court Order or Authorization is valid, then [Provider] can release ONLY the information listed in the subpoena or records request. It is important that [Provider] DOES NOT release documents from any outside, non-[Provider] entities. ONLY [Provider] RECORDS MAY BE PRODUCED.

A Court Order or Records Request may require that the records be produced to (i) the party who is requesting the records; or (ii) the judge presiding over the case. If the Court Order or Records Request specifies that records should only be produced to the judge, such records should be sent directly to the judge in an envelope marked "Confidential." If records are sent to the judge, the records should not be produced to either attorney. It is important to read the subpoena and court order for any instructions regarding the production of records.

If records are to be produced, [Provider] will notify the person who requested the records of the copying costs. Prior to producing records, [Provider] will secure payment for the records. Records will not be released until payment is received.

[Insert table of copying costs approved by state law]

After securing proper payment, records will be produced to the parties specified in a valid Court Order or Records Request. The requested records will be sent via fax, United States Postal Service, or uploaded to a secure website. Email may only be used if the email is sent encrypted and if the client agrees to and assumes the risks associated with sending records by email. The Medical Records Clerk or other facility designee shall document the release of client information in the client file.