

**Welfare Reform and Substance
Abuse Treatment
Confidentiality:
General Guidance for
Reconciling
Need to Know and Privacy**

Technical Assistance Publication Series

24

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Foreword

The need for this guidance emerged from a series of four regional State Team-Building Workshops held on welfare reform and its relationship to substance abuse treatment. These workshops, sponsored by the Center for Substance Abuse Treatment's (CSAT) Division of State and Community Assistance, were conducted from July through October 1997. They were attended by representatives of both substance abuse treatment and welfare systems within each participating State. These representatives identified a mutual goal at the workshops: namely, assisting shared clients in overcoming substance abuse issues which create barriers to the clients' ability to work.

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWA) (Public Law 104-193) has challenged States to help their citizens leave welfare and become employed. As a consequence, States are now trying harder than ever to prepare welfare clients to enter and succeed in the workforce. Among the barriers to work identified in research regarding welfare clients are drug and alcohol problems. This Technical Assistance Publication (TAP) provides broad guidance on how two systems—the substance abuse treatment and welfare systems—can share information on their mutual clients.

The goal of this TAP is to assist State alcohol and other drug agencies, substance abuse treatment providers, and welfare officials in addressing confidentiality issues with respect to these shared clients. It familiarizes welfare agency staff with protections about which they may be unaware. It discusses key issues such as how and when disclosure is possible and it provides practical tips to surmount real or perceived obstacles.

Confidentiality laws relating to treatment for substance abuse—defined as abuse of alcohol or other drugs—were originally enacted to encourage substance abusers to seek assistance without fear of public disclosure of their abuse, including disclosure of records of their treatment that could attach for life. Federal regulations that protect the identities of persons in substance abuse treatment have their genesis in two statutes of the early 1970's: first, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of

1970; and second, the Drug Abuse Prevention, Treatment and Rehabilitation Act of 1972. These two statutes were implemented by regulations issued in 1975 by the U.S. Department of Health, Education, and Welfare (DHEW). Revised in 1987 by DHEW's successor, the U.S. Department of Health and Human Services, the regulations are set out at title 42, part 2, of the Code of Federal Regulations.

The confidentiality statutes and regulations were later consolidated by Congress within the Public Health Service Act—now title 42, section 290dd-3 of the United States Code (42 U.S.C. §290dd-2). In this TAP, references to the confidentiality law or regulations mean the regulations at title 42, part 2, of the Code of Federal Regulations (42 CFR Part 2). The Federal confidentiality law and regulations are presented as Appendix A.

On behalf of the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration, I hope that this TAP will promote compliance with the Federal confidentiality regulations by both substance abuse treatment and welfare officials, as well as facilitate interactions between the two systems.

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I. Introduction

The purpose of this document is to provide guidance in resolving issues related to the confidentiality of patient/client information that are faced by alcohol and other drug agencies, substance abuse treatment providers, and welfare officials charged with implementing State responses to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWA) (Public Law 104-193). These parties confront several issues related to confidentiality as they collaborate in helping their shared clients overcome substance abuse problems that create barriers to the clients' ability to work.

The Federal alcohol and drug confidentiality law requires covered programs that provide alcohol or drug abuse diagnosis, treatment, or referral for treatment to strictly maintain the confidentiality of substance abuse patient records. This law (42 U.S.C. §290dd-2) and its accompanying regulations (42 CFR Part 2) came about because the U.S. Congress recognized that these safeguards on privacy serve the important purpose of encouraging persons to seek treatment by preventing the disclosure of information related to their substance abuse diagnosis and treatment. (For the full text of the Federal law and regulations, see Appendix A.)

The Federal confidentiality law and regulations have proved to be both remarkably effective and practical in protecting patients from the potential harm of unwarranted disclosures while permitting the release of information in appropriate circumstances. Increasingly, however, the substance abuse treatment field is being called upon to interact and communicate with outside entities, including staff of welfare agencies who are not familiar with these protections or how to utilize the provisions authorizing appropriate disclosures.

The PRWA has challenged States to help their citizens leave welfare and enter the workforce. In order to do this, States are having to help "harder-to-serve" welfare clients prepare to enter—and succeed in—the workforce. Among the barriers facing such clients identified in the research are drug and alcohol problems.

Both welfare clients and officials believe that treatment services are important to welfare reform. Providing substance abuse treatment and prevention services can help States meet their welfare reform goals both by moving substance abusing welfare recipients to sobriety/work and by averting inter-generational substance and welfare dependence among young people. As a result, both systems increasingly understand and appreciate the benefits that will accrue from working together effectively.

For a successful collaboration between substance abuse services and welfare systems to occur, both systems must address the implications of the Federal confidentiality law for communication of patient information. How can necessary disclosures be made between the two systems without violating the confidentiality rules?

This document promotes and facilitates compliance with the Federal confidentiality law by both substance abuse and welfare agencies, while permitting communication and linkages between the substance abuse and adult welfare systems essential to successful implementation of welfare reform.

This document was developed for the following audiences:

- C staff of State agencies responsible for funding and evaluating substance abuse treatment and prevention programs;
- C staff of substance abuse treatment and prevention programs, including clinical directors, counselors, nurses and administrative personnel; and
- C welfare officials responsible for interacting with welfare recipients with or at risk for substance abuse problems.

The document describes the basic provisions of Federal confidentiality law and outlines the key confidentiality issues pertaining to the substance abuse treatment system and the welfare system. The Federal confidentiality law and regulations are presented in Appendix A; sample patient consent and other forms are presented in Appendix B.

The Federal confidentiality law discussed here applies only to substance abuse patient records and not to records of other health or mental health services. For example, the child welfare system is also undergoing change nationally, but confidentiality issues pertaining exclusively to clients within that system are not included in the scope of this guidance.

II. Confidentiality of Alcohol and Drug Abuse Patient Records: The Basics

Federal law (42 U.S.C. §290dd-2) and regulations (42 CFR Part 2) afford substance abuse treatment client records special privacy protection out of recognition that the confidentiality of such records must be scrupulously protected if individuals are to be encouraged to enter and stay in treatment.

These are the basic provisions of the Federal confidentiality law and regulations:

C Except under certain specified conditions, there is a prohibition on disclosure of records or other information concerning a patient in a Federally assisted program. (See 42 CFR §2.11 for definition of “program” and §2.12(b) for the meaning of “Federally assisted.”) The prohibition applies regardless of whether the person seeking the information already has it, has other means of obtaining it, enjoys official status, has obtained a subpoena or even a warrant, or is authorized by State law (42 CFR §2.13(b)).

C Under certain conditions, limited disclosures are permitted. These fall into nine categories: (1) when there is written consent from the patient;

(2) when the disclosures are for the purpose of internal communications; (3) when there is no patient-identifying information; (4) when there is a medical emergency; (5) when there is a court order; (6) when the person involved has committed a crime at program or against program personnel; (7) when the disclosure is for research/audit and evaluation; (8) when the disclosure is for child abuse and neglect reporting; and (9) when there is a Qualified Service Organization agreement (QSOA).

C Most disclosures are permissible if a patient has signed a valid consent form that has not expired or been revoked. A proper patient consent form must be in writing and contain each of the following nine elements (42 CFR §2.31):

1. the name of the program making the disclosure;
2. the name of the individual or organization that will receive the disclosure;
3. the name of the patient;
4. the purpose or need for the disclosure;
5. how much and what kind of information will be disclosed;
6. a statement that the patient may revoke the consent at any time;
7. the date, event, or condition upon which consent expires if not revoked;
8. the signature of the patient; and
9. the date on which the consent is signed.

General release forms and other forms that do not contain all the above nine elements are *not* valid for the purpose of authorizing disclosure of substance abuse patient records.

- C Familiarity with the Federal confidentiality provisions is essential to anyone directly or indirectly involved with substance abuse treatment, because the unknowing proceed at peril of criminal and civil liability. Violating the regulations is punishable by a fine of up to \$500 for a first offense or up to \$5,000 for each subsequent offense (42 CFR §2.4).

III. Confidentiality and Welfare: The Key Areas

It is essential to understand that the Federal confidentiality law and regulations *do* permit disclosures to the welfare system of the records of patients receiving substance abuse treatment in most circumstances, as long as the Federal confidentiality requirements are followed scrupulously. Typically, this means obtaining the written consent of the patient to authorize the disclosure. Key areas for welfare caseworkers and substance abuse treatment providers who work with welfare recipients are discussed further below:

- C disclosure of substance abuse diagnosis and treatment information from the treatment system to the welfare system;
- C disclosure of substance abuse testing and screening information from the welfare system to the treatment system;
- C reporting of attendance in—and failure to attend—a substance abuse treatment program to the welfare system;
- C patient/client revocation of consent;

- C reporting a substance abuse patient’s relapse to the welfare system;
- C combined case planning between substance abuse staff and welfare caseworkers;
and
- C Qualified Service Organization agreements (QSOAs) between treatment and welfare systems.

1. Disclosure of Substance Abuse Diagnosis and Treatment Information From the Treatment System to the Welfare System

Information concerning a patient’s diagnosis and treatment is covered by the Federal confidentiality law and regulations; disclosure can be made only with the patient’s written consent or other appropriate legal authorization.

The Federal confidentiality law and regulations state that information obtained by Federally assisted substance abuse programs regarding an individual’s substance abuse drug treatment, and the “diagnosis” of a patient’s substance abuse (defined as “any reference to an individual’s alcohol or drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment”), are covered by the confidentiality protections (42 CFR §2.11 and 2.12(a)(ii)). Thus, a substance abuse program must obtain the written consent of the patient or obtain other authorization, as prescribed by the law and regulations, before it can make any disclosure of information related to treatment and/or a diagnosis.

Substance abuse programs can disclose to the welfare system information about treatment services only with the written consent of the patient (42 CFR Subpart C) or with other authorization such as a court order issued in accordance with 42 CFR Subpart D. Similarly, whenever a treatment program makes a diagnosis (or “clinical assessment”) to determine if an individual has a substance abuse problem, it can communicate information related to that diagnosis to the welfare system only with the written consent of the patient or with other

authorization. These rules remain in force even if the welfare system referred the individual for diagnosis and treatment, and even if the welfare system *mandated* the individual to obtain one or both of those services.

In the great majority of situations involving communication of treatment or diagnostic information, written consent will be the vehicle that authorizes disclosure of information from the substance abuse treatment provider to the welfare agency. Written consent is valid for the purpose of authorizing disclosure of substance abuse patient information covered by the Federal confidentiality law only if it contains all nine elements required by §2.31 of the regulations (see discussion above).

Section 2.12(a)(1) states that the confidentiality law and regulations govern information disclosed by a “Federally assisted drug abuse...or...alcohol abuse program.” In addition, §2.11 defines a covered “program” as “an individual or entity. . . who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment . . .”

A patient consent form that would authorize a treatment program to communicate information concerning the diagnosis and treatment of substance abuse to the welfare system is presented in Appendix B (Sample Form #1).

In some jurisdictions, the welfare agency itself employs specialists in substance abuse problems who assess and diagnose welfare recipients and then refer

those with substance abuse problems to treatment. Such specialists are covered by the Federal confidentiality law and regulations, so they would need consent forms signed by the individuals they diagnose before the results could be communicated to any other section of the welfare agency.

The welfare and treatment systems can work together to enhance their ability to obtain consent and minimize confusion and misunderstanding.

A little collaboration can go a long way in reducing confusion and improving the working relationships between the welfare and substance abuse treatment systems.

Practical Tip: Only the party (or parties) named on a consent form can obtain information from the treatment program, directly or indirectly. Thus, if a welfare case worker wishes to disclose to another party information obtained via a consent form, the case worker would need to obtain, from the client, an additional consent form permitting the specific disclosure before making the redisclosure. The best way to avoid these types of paperwork headaches is to make sure that everyone who will need to receive the information is listed (by name or descriptively) on the initial consent form. The Federal regulations allow consent forms to authorize disclosures to multiple parties where all the other elements are identical. A multiparty consent form is presented in Appendix B (Sample Form #2).

Practical Tip: As long as the patient consent form contains all nine elements required by the Federal confidentiality law and regulations, it does not matter who presented the form to the patient for signature. Thus, the welfare and substance abuse treatment systems could collaborate on the development of a common form and then use that form routinely whenever information will be needed. The welfare system could have the patient sign the form whenever it refers recipients to treatment or requires that an individual receive treatment in order to receive welfare. The treatment system could rely on that same consent to disclose back to the welfare agency.

Whenever a disclosure is made with the patient's written consent, the treatment program making the disclosure must include with the information conveyed a notice that redisclosure is prohibited without further authorization. Such a notice is presented in Appendix B (Sample Form #3). The prohibition does not apply to sharing the information with others within the welfare agency who are included as recipients on the consent form.

2. Disclosure of Substance Abuse Testing and Screening Information From the Welfare System to the Treatment System

Alcohol and drug testing that is not conducted as part of a diagnosis or treatment for an alcohol or other drug problem is not covered by Federal confidentiality rules; information related to a test conducted as part of a diagnosis or treatment is covered.

The Federal confidentiality law and regulations provide that information gathered by a "program" as defined in §2.11 CFR incident to diagnosis, treatment or referral for treatment, is covered. Therefore, if a welfare agency is a program as defined in §2.11 and it conducts a urine test, blood alcohol count, or other test for purposes *other than a diagnosis or treatment regimen*, any information related to that test is *not* covered by the Federal confidentiality regulations. In that situation, the welfare agency could communicate information about the test results without needing to obtain consent or any other authorization under the Federal confidentiality regulations.

The Federal confidentiality law and regulations *would* apply if the welfare agency were a "program" as defined in §2.11 CFR *and* the test was conducted as part of developing a diagnosis or in the course of referring for treatment services. If covered, the welfare program must obtain the written consent of the patient or obtain other authorization as prescribed by the Federal regulations before it can make any disclosure of information related to treatment and/or a diagnosis.

Information gathered in a "prescreen" for the purpose of referring an individual for a diagnosis

is not covered by the Federal law and regulations.

Increasingly, many welfare agencies are instituting a "screen" or "prescreen" procedure to identify welfare recipients who may have alcohol and other drug problems that could create a barrier to work. Individuals identified by this screening mechanism as possibly having an alcohol or other drug problem are then referred to a specialist whose job is to diagnose and, if the diagnosis reveals a substance abuse problem, refer the individual for treatment. Since the information gathered through the screening or prescreening process does not constitute a diagnosis and is not gathered for "the purpose of treatment or referral for treatment," it is not covered by the Federal confidentiality rules. Thus, information gathered from the screen or prescreen may be communicated without restriction and without the written consent of the individual or any other authorization.

Practical Tip: If a welfare agency fits the definition of a "program" as defined in §2.11 CFR, the key issue in this analysis is whether a substance abuse specialist determined that the individual has an alcohol or drug problem. If such a determination was made, then the information gathered and the report generated is confidential under the Federal requirements. But if no determination was actually made as to whether the individual had a substance abuse problem, and instead an attempt was made simply to identify individuals who should *be assessed for a diagnosis* because they *might* have a problem, then nothing has been done that is covered by the Federal confidentiality law and regulations.

3. Reporting of Attendance in—and Failure To Attend—Substance Abuse Programs to the Welfare System

Substance abuse programs may report a welfare recipient's attendance and or failure to attend treatment to the welfare system as long as a valid written consent signed by the patient is in effect.

Information about a welfare recipient's participation in substance abuse treatment can be disclosed to the welfare system or any other person or organization as long as the patient has signed a written consent form authorizing the disclosure. This includes information that may be detrimental to the patient in the sense that it could lead to termination of welfare benefits or other sanctions, including such facts as the failure of the individual to comply with treatment or leaving the program without permission before completion of treatment.

A substance abuse patient is allowed to revoke consent under §2.31(a)(8) CFR. If a patient does this, the consent is no longer valid “except to the extent that the program or person which is to make the disclosure has already acted in reliance on it.” That subsection of the Federal regulations states that “[a]cting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third-party payer.”

Thus, to the extent that the welfare system is a “third-party payer” providing payment to the program for the welfare recipient's treatment, and the program relied on the consent to enable it to obtain payment, the treatment program can (but is not required to) continue making disclosures to the welfare system for purposes of obtaining payment for past services even after a patient revokes consent.

However, a program that continues to provide services after a patient has revoked a consent to the welfare system does so at its own financial peril. Since the consent was already revoked when it provided these services the program is not relying on the consent and thus cannot make a disclosure to the welfare system for the purpose of obtaining payment.

Practical Tip: A consent form is only in place until the date, event, or condition on which it expires (or the patient/client revokes consent), so it is a good idea to make sure that the expiration set forth on the consent form is sufficiently far in the future to ensure that the welfare system can receive appropriate information as needed. For example, if the consent expires when the patient/client leaves treatment, a treatment program would be unable to report to the welfare system that a patient/client left *before* completion of treatment since the consent would have expired the moment he or she left the program. It would be more advisable to have the consent contain an end date that is flexible, reasonable, and fits relevant circumstances such as, “30 or 60 days after treatment ends” or “when the patient/client is no longer eligible for welfare benefits.”

4. Patient/Client Revocation of Consent

Some welfare agencies are concerned about how to handle the situation if a patient/client revokes consent. As noted, treatment programs that relied on a consent for disclosure to the welfare system, consistent with §2.31(a)(8) CFR, are permitted to continue making disclosures to the welfare system as a third-party payer even if the client attempts to revoke that consent. For example, the treatment program has extended services in reliance on a consent that enables the welfare system to reimburse the program for treatment services. Substance abuse programs and welfare agencies should be aware of and use this provision when appropriate.

Practical Tip: Though revocation of patient consent is rare, in those situations where it does occur, there are ways in which substance abuse programs and welfare agencies can still continue their working relationship. While effective revocation of patient consent precludes a substance abuse program from making any further disclosures, such as whether the patient is still in treatment, welfare agencies that have been receiving information and then abruptly run into a “wall of silence” can make an educated surmise that the client may have revoked consent. The welfare agency could then approach the individual, ask why the flow of information has stopped and, where appropriate, require that verification of treatment status be provided or eligibility for benefits will end.

5. Reporting a Substance Abuse Patient’s Relapse to the Welfare System

Unfortunately, patients in substance abuse treatment sometimes have relapses. For most patients who have relapses, treatment will continue or resume.

Substance abuse treatment programs may report information about a patient’s treatment, including any relapse, to welfare officials if that information is covered by a valid written consent form signed by the patient. The same issues involving communication of treatment information and revocation of consent discussed previously would similarly apply to information about a patient’s relapses.

Practical Tip: Relapse information is subject to the same confidentiality protections as other treatment information. For many welfare agencies, the key information needed is whether the welfare recipient is proceeding satisfactorily in treatment—and satisfactory progress can include relapse as long as the patient remains in or resumes treatment—rather than whether a patient has relapsed.

6. Combined Case Planning Between Substance Abuse Staff and Welfare Caseworkers

The success of a client's transition to work will involve collaborative planning between substance abuse counselors and welfare caseworkers. Most of the discussion between substance abuse staff and welfare caseworkers necessary for joint case planning will be permissible via a properly authorized consent form. It is often useful to tell a client that his case and progress will be discussed at periodic meetings (or conference calls, etc.) between substance abuse treatment and welfare staff.

It is useful to explain to the client who specifically will participate in such discussions. It is also a good idea to explain that, unless authorized by the client's consent form, information from such a discussion cannot be further disclosed.

Practical Tip: To avoid repeated paperwork and confusion, it is useful to have the client complete a multiparty consent form that lists all the potential people who would be involved in case planning meetings. Multiparty consent forms such as the one shown in Appendix B (Sample Form #2) can be designed to fit any case planning meeting. A Qualified Service Organization agreement (QSOA) between a substance abuse treatment program and a service organization may also be used to conduct combined case planning. QSOAs are described in the section that follows.

7. Qualified Service Organization Agreements (QSOAs) Between

Treatment and Welfare Systems

Substance abuse treatment programs may disclose information to a “Qualified Service Organization” without the patient’s consent (§2.12(c)(4) CFR). A service organization is an organization that provides services to the substance abuse program. An agreement between a treatment program and a Qualified Service Organization is a “Qualified Service Organization agreement,” or QSOA. For an illustration of such an agreement, see Appendix B (Sample Form #4).

A QSOA permits patient-identified communication between the substance abuse treatment program and the service organization without individual client consent as long as the disclosure is for the purpose of enabling the service organization to provide a service to the treatment program and so long as the information is only disclosed back to the treatment program. In entering the QSOA, the service organization agrees to be bound by the provisions of 42 CFR Part 2 and to resist in court any effort to obtain access to information which would not be permitted by Federal confidentiality regulations.

Practical Tip: Although the case planning discussions could be conducted using consent forms, they would also be permissible using a QSOA as long as the information is not redisclosed beyond the welfare agency and the treatment program, unless further authorization were to be obtained. The rationale for a QSOA in this circumstance is that the service provided to the program is the benefit of having coordinated planning with welfare staff. The QSOA requires the signatures of the director of the substance abuse treatment program and the head of the welfare agency. However, reimbursement by the welfare system for substance abuse treatment is not a “service” being provided to the treatment organization. It is payment for a service being rendered by the treatment program. Thus, in order to make disclosures to the welfare agency for the purpose of recovering reimbursement for treatment, a program needs to obtain the client’s written consent as discussed above.

IV. Essential Considerations

1. Relationship with State Law

In using this guidance, the reader should be aware that, apart from the Federal confidentiality law, States may have laws and regulations that govern the confidentiality of patient records for individuals who are receiving substance abuse treatment services. In instances in which a State's confidentiality law is *more* restrictive than the Federal law, a program must follow the stricter State law. In instances where a State's confidentiality law is *less* protective of confidentiality than the Federal law, however, the Federal law controls. Only rarely is there an irreconcilable conflict between Federal and State law. (See §2.20 CFR in Appendix A for a discussion of the relationship of Federal and State confidentiality laws.)

2. Assistance of Legal Counsel

Because the primary responsibility for compliance with the Federal confidentiality law and regulations lies with the program and its staff, it would be advisable for these guidelines to be thoroughly discussed with the program's legal counsel. Likewise, readers are advised to seek the advice of legal counsel when designing letters and forms based on the samples provided here or when questions arise concerning any of the issues discussed in this guidance.

Appendix A—The Federal Confidentiality Law and Regulations

Appendix A—The Federal Confidentiality Law and Regulations

SUBCHAPTER A—GENERAL PROVISIONS

PART 1 [RESERVED]

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

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AUTHORITY: Sec. 408 of Pub. L. 92–255, 86 Stat. 79, as amended by sec. 303 (a), (b) of Pub. L. 93–282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94–237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94–581, 90 Stat. 2852; sec. 509 of Pub. L. 96–88, 93 Stat. 695; sec. 973(d) of Pub. L. 97– 35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98–24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290ee–3) and sec. 333 of Pub. L. 91–616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93–282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94–581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L.

98–24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290dd–3), as amended by sec. 131 of Pub. L. 102–321, 106 Stat. 368, (42 U.S.C. 290dd–2).

SOURCE: 52 FR 21809, June 9, 1987, unless otherwise noted.

Subpart A—Introduction

§ 2.1 Statutory authority for confidentiality of drug abuse patient records.

The restrictions of these regulations upon the disclosure and use of drug abuse patient records were initially authorized by section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175). That section as amended was transferred by Pub. L. 98–24 to section 527 of the Public Health Service Act which is codified at 42 CFR Ch. I (10-1-97 Edition § 2.2 at 42 U.S.C. 290ee–3. The amended statutory authority is set forth below:

§ 290ee–3. CONFIDENTIALITY OF PATIENT RECORDS.

(a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent,

the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) *Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a p a t i e n t o r t o conduct any investigation of a patient.

(d) *Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) *Armed Forces and Veterans' Administration; interchange of records; report of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces. The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) *Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be

fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

(g) Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders

Except as provided in subsection (h) of this section, the Secretary, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(3) of Pub. L. 94-581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of drug abuse patient records under Title 38 was moved from 21 U.S.C. 1175 to 38 U.S.C. 4134.)

§ 2.2 Statutory authority for confidentiality of alcohol abuse patient records.

The restrictions of these regulations upon the disclosure and use of alcohol abuse patient records were initially authorized by section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582). The section as amended was transferred by Pub. L. 98-24 to section 523 of the Public Health Service Act which is codified at 42 U.S.C. 290dd-3. The amended statutory authority is set forth below:

§ 290dd-3. CONFIDENTIALITY OF PATIENT RECORDS

(a) Disclosure authorization

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the

United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Prohibition against use of record in making criminal charges or investigation of patient

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) Continuing prohibition against disclosure irrespective of status as patient

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) Armed Forces and Veterans' Administration; interchange of record of suspected child abuse and neglect to State or local authorities

The prohibitions of this section do not apply to any interchange of records—

- (1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or
 - (2) between such components and the Armed Forces.
- The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) Penalty for first and subsequent offenses

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

(g) Regulations of Secretary; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders

Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection(b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(4) of Pub. L. 94–581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of alcohol abuse patient records under Title 38 was moved from 42 U.S.C. 4582 to 38 U.S.C. 4134.)

§ 2.3 Purpose and effect.

(a) Purpose. Under the statutory provisions quoted in §§ 2.1 and 2.2, these regulations impose restrictions upon the disclosure and use of alcohol and drug abuse

patient records which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program. The regulations specify:

- (1) Definitions, applicability, and general restrictions in subpart B (definitions applicable to § 2.34 only appear in that section);
- (2) Disclosures which may be made with written patient consent and the form of the written consent in subpart C;
- (3) Disclosures which may be made without written patient consent or an authorizing court order in subpart D; and
- (4) Disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders in subpart E.

(b) Effect. (1) These regulations prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstance exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

(2) These regulations are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.

(3) Because there is a criminal penalty (a fine—see 42 U.S.C. 290ee–3(f), 42 U.S.C. 290dd–3(f) and 42 CFR 2.4) for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute (see *M. Kraus & Brothers v. United States*, 327 U.S. 614, 621–22, 66 S. Ct. 705, 707–08 (1946)).

§ 2.4 Criminal penalty for violation.

Under 42 U.S.C. 290ee–3(f) and 42 U.S.C. 290dd–3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

§ 2.5 Reports of violations.

(a) The report of any violation of these regulations may be directed to the United States Attorney for the judicial district in which the violation occurs.

(b) The report of any violation of these regulations by a methadone program may be directed to the Regional Offices of the Food and Drug Administration.

Subpart B—General Provisions

§ 2.11 Definitions.

For purposes of these regulations:

Alcohol abuse means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

Drug abuse means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user.

Diagnosis means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment.

Disclose or disclosure means a communication of patient identifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

Informant means an individual:

(a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the request of a law enforcement agency or official: and

(b) Who at the request of a law enforcement agency or official observes one or more patients or employees of the program for the purpose of reporting the information obtained to the law enforcement agency or official.

Patient means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

Patient identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.

Person means an individual, partnership, corporation, Federal, State or local government agency, or any other legal entity.

Program means:

(a) An individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(b) An identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(c) Medical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers. (See § 2.12(e)(1) for examples.)

Program director means:

(a) In the case of a program which is an individual, that individual:

(b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to act as chief executive of the organization.

Qualified Service Organization means a person which:

(a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(b) Has entered into a written agreement with a program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the programs, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

Records means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

Third party payer means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

Treatment means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient.

Undercover agent means an officer of any Federal, State, or local law enforcement agency who enrolls in or becomes an employee of a program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

[52 FR 21809, June 9, 1987, as amended by 60 FR 22297, May 5, 1995]

§ 2.12 Applicability.

(a) *General*—(1) *Restrictions on disclosure*. The restrictions on disclosure in these regulations apply to any information, whether or not recorded, which:

(i) 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; and

(ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date) for the purpose of treating alcohol or drug abuse, making a diagnosis for that treatment, or making a referral for that treatment.

(2) *Restriction on use*. The restriction on use of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290ee-3(c), 42 U.S.C. 290dd-3(c)) applies to any information, whether or not recorded which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date), for the purpose of treating alcohol or drug abuse, making a diagnosis for the treatment, or making a referral for the treatment.

(b) *Federal assistance*. An alcohol abuse or drug abuse program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (c)(2) of this section relating to the Veterans' Administration and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:

- (i) Certification of provider status under the Medicare program;
 - (ii) Authorization to conduct methadone maintenance treatment (see 21 CFR 291.505); or
 - (iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse;
- (3) It is supported by funds provided by any department or agency of the United States by being:

- (i) A recipient of Federal financial assistance in any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities; or
 - (ii) Conducted by a State or local government unit which, through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or
- (4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) *Exceptions*—(1) *Veterans' Administration*. These regulations do not apply to information on alcohol and drug abuse patients maintained in connection with the Veterans' Administration provisions of hospital care, nursing home care, domiciliary care, and medical services under title 38, United States Code. Those records are governed by 38 U.S.C. 4132 and regulations issued under that authority by the Administrator of Veterans' Affairs.

(2) *Armed Forces*. These regulations apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

- (i) Any interchange of that information within the Armed Forces; and
- (ii) Any interchange of that information between the Armed Forces and those components of the

Veterans Administration furnishing health care to veterans.

(3) *Communication within a program or between a program and an entity having direct administrative control over that program*. The restrictions on disclosure in these regulations do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are

- (i) Within a program or
- (ii) Between a program and an entity that has direct administrative control over the program.

(4) *Qualified Service Organizations*. The restrictions on disclosure in these regulations do not apply to communications between a program and a qualified service organization of information needed by the organization to provide services to the program.

(5) *Crimes on program premises or against program personnel*. The restrictions on disclosure and use in these regulations do not apply to communications from program personnel to law enforcement officers which—

- (i) Are directly related to a patient's commission of a crime on the premises of the program or against program personnel or to a threat to commit such a crime; and
- (ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts.

(6) *Reports of suspected child abuse and neglect*. The restrictions on disclosure and use in these regulations do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities. However, the restrictions continue to apply to the original alcohol or drug abuse patient records maintained by the program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

(d) *Applicability to recipients of information*—(1) *Restriction on use of information.* The restriction on the use of any information subject to these regulations to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from a federally assisted alcohol or drug abuse program, regardless of the status of the person obtaining the information or of whether the information was obtained in accordance with these regulations. This restriction on use bars, among other things, the introduction of that information as evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants (see § 2.17) or through patient access (see § 2.23) is subject to the restriction on use.

(2) *Restrictions on disclosures—Third party payers, administrative entities, and others.* The restrictions on disclosure in these regulations apply to:

- (i) Third party payers with regard to records disclosed to them by federally assisted alcohol or drug abuse programs;
- (ii) Entities having direct administrative control over programs with regard to information communicated to them by the program under § 2.12(c)(3); and
- (iii) Persons who receive patient records directly from a federally assisted alcohol or drug abuse program and who are notified of the restrictions on redisclosure of the records in accordance with § 2.32 of these regulations.

(e) *Explanation of applicability*—(1) *Coverage.* These regulations cover any information (including information on referral and intake) about alcohol and drug abuse patients obtained by a program (as the terms “patient” and “program” are defined in § 2.11) if the program is federally assisted in any manner described in § 2.12(b). Coverage includes, but is not limited to, those treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, based programs, and private practitioners who hold themselves out as providing, and provide alcohol or drug abuse diagnosis, treatment, or referral for treatment. However, these regulations would not apply, for example, to emergency room personnel

who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of alcohol or drug abuse diagnosis, treatment or referral and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.

(2) *Federal assistance to program required.* If a patient’s alcohol or drug abuse diagnosis, treatment, or referral for treatment is not provided by a program which is federally conducted, regulated or supported in a manner which constitutes Federal assistance under § 2.12(b), that patient’s record is not covered by these regulations. Thus, it is possible for an individual patient to benefit from Federal support and not be covered by the confidentiality regulations because the program in which the patient is enrolled is not federally assisted as defined in § 2.12(b). For example, if a Federal court placed an individual in a private for-profit program and made a payment to the program on behalf of that individual, that patient’s record would not be covered by these regulations unless the program itself received Federal assistance as defined by § 2.12(b).

(3) *Information to which restrictions are applicable.* Whether a restriction is on use or disclosure affects the type of information which may be available. The restrictions on disclosure apply to any information which would identify a patient as an alcohol or drug abuser. The restriction on use of information to bring criminal charges against a patient for a crime applies to any information obtained by the program for the purpose of diagnosis, treatment, or referral for treatment of alcohol or drug abuse. (Note that restrictions on use and disclosure apply to recipients of information under § 2.12(d).)

(4) *How type of diagnosis affects coverage.* These regulations cover any record of a diagnosis identifying a patient as an alcohol or drug abuser which is prepared in connection with the treatment or referral for treatment of alcohol or drug abuse. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by these regulations. The following are not covered by these regulations:

- (i) Diagnosis which is made solely for the purpose of providing evidence for use by law enforcement authorities; or

(ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alcohol or drug abuser (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987, as amended at 60 FR 22297, May 5, 1995]

§ 2.13 Confidentiality restrictions.

(a) *General.* The patient records to which these regulations apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

(b) *Unconditional compliance required.* 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.

(c) *Acknowledging the presence of patients: Responding to requests.* (1) The presence of an identified patient in a facility or component of a facility which is publicly identified as a place where only alcohol or drug abuse diagnosis, treatment, or referral is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of these regulations or if an authorizing court order is entered in accordance with subpart E of these regulations. The regulations permit acknowledgment of the presence of an identified patient in a facility or part of a facility if the facility is not publicly identified as only an alcohol or drug abuse diagnosis, treatment or referral facility, and if the acknowledgment does not reveal that the patient is an alcohol or drug abuser.

(2) Any answer to a request for a disclosure of patient records which is not permissible under these regulations must be made in a way that will not

affirmatively reveal that an identified individual has been, or is being diagnosed or treated for alcohol or drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

§ 2.14 Minor patients.

(a) *Definition of minor.* As used in these regulations the term "minor" means a person who has not attained the age of majority specified in the applicable State law, or if no age of majority is specified in the applicable State law, the age of eighteen years.

(b) *State law not requiring parental consent to treatment.* If a minor patient acting alone has the legal capacity under the applicable State law to apply for and obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations may be given only by the minor patient. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. These regulations do not prohibit a program from refusing to provide treatment until the minor patient consents to the disclosure necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a State or local law requiring the program to furnish the service irrespective of ability to pay.

(c) *State law requiring parental consent to treatment.* (1) Where State law requires consent of a parent, guardian, or other person for a minor to obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations must be given by both the minor and his or her parent, guardian, or other person authorized under State law to act in the minor's behalf.

(2) Where State law requires parental consent to treatment the fact of a minor's application for treatment may be communicated to the minor's

parent, guardian, or other person authorized under State law to act in the minor's behalf only if:

- (i) The minor has given written consent to the disclosure in accordance with subpart C of these regulations or
- (ii) The minor lacks the capacity to make a rational choice regarding such consent as judged by the program director under paragraph (d) of this section.

(d) *Minor applicant for services lacks capacity for rational choice.* Facts relevant to reducing a threat to the life or physical well being of the applicant or any other individual may be disclosed to the parent, guardian, or other person authorized under State law to act in the minor's behalf if the program director judges that:

- (1) A minor applicant for services lacks capacity because of extreme youth or mental or physical condition to make a rational decision on whether to consent to a disclosure under subpart C of these regulations to his or her parent, guardian, or other person authorized under State law to act in the minor's behalf, and
- (2) The applicant's situation poses a substantial threat to the life or physical well being of the applicant or any other individual which may be reduced by communicating relevant facts to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf.

§ 2.15 Incompetent and deceased patients.

(a) *Incompetent patients other than minors—(1) Adjudication of incompetence.* In the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs, any consent which is required under these regulations may be given by the guardian or other person authorized under State law to act in the patient's behalf.

(2) *No adjudication of incompetency.* For any period for which the program director determines that a patient, other than a minor or one who has been adjudicated incompetent, suffers from a medical condition that prevents knowing or effective action on his or her own behalf, the program director may exercise the right of the patient to consent to a disclosure under subpart C of these regulations for the sole purpose of

obtaining payment for services from a third party payer.

(b) *Deceased patients—(1) Vital statistics.* These regulations do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.

(2) *Consent by personal representative.* Any other disclosure of information identifying a deceased patient as an alcohol or drug abuser is subject to these regulations. If a written consent to the disclosure is required, that consent may be given by an 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.

§ 2.16 Security for written records.

(a) Written records which are subject to these regulations must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use; and

(b) Each program shall adopt in writing procedures which regulate and control access to and use of written records which are subject to these regulations.

§ 2.17 Undercover agents and informants.

(a) *Restrictions on placement.* Except as specifically authorized by a court order granted under § 2.67 of these regulations, no program may knowingly employ, or enroll as a patient, any undercover agent or informant.

(b) *Restriction on use of information.* No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.18 Restrictions on the use of identification cards.

No person may require any patient to carry on his or her person while away from the program premises any card or other object which would identify the patient as an alcohol or drug abuser. This section does not prohibit a person from requiring patients to use or carry cards or other identification objects on the premises of a program.

§ 2.19 Disposition of records by discontinued programs.

(a) *General.* If a program discontinues operations or is taken over or acquired by another program, it must purge patient identifying information from its records or destroy the records unless—

(1) The patient who is the subject of the records gives written consent (meeting the requirements of § 2.31) to a transfer of the records to the acquiring program or to any other program designated in the consent (the manner of obtaining this consent must minimize the likelihood of a disclosure of patient identifying information to a third party); or

(2) There is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the program.

(b) *Procedure where retention period required by law.* If paragraph (a)(2) of this section applies, the records must be:

(1) Sealed in envelopes or other containers labeled as follows: “Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]”; and
(2) Held under the restrictions of these regulations by a responsible person who must, as soon as practicable after the end of the retention period specified on the label, destroy the records.

§ 2.20 Relationship to State laws.

The statutes authorizing these regulations (42 U.S.C. 290ee-3 and 42 U.S.C. 290dd-3) do not preempt the field of law which they cover to the exclusion of all State laws in that field. If a disclosure permitted under these regulations is prohibited under State law, neither these regulations nor the authorizing statutes may be construed to authorize any violation of that State law. However, no State law may either authorize or compel any disclosure prohibited by these regulations.

§ 2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

(a) *Research privilege description.* There may be concurrent coverage of patient identifying information by these regulations and by administrative action taken under: Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a) and the implementing regulations at 42 CFR part 2a); or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These “research privilege” statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* These regulations restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person

engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under subpart E of these regulations of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes. However, the research privilege granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any information which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with subpart E of these regulations authorizes a methadone maintenance treatment program to disclose certain information about its patients, that program may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

§ 2.22 Notice to patients of Federal confidentiality requirements.

(a) *Notice required.* At the time of admission or as soon thereafter as the patient is capable of rational communication, each program shall:

- (1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and
- (2) Give to the patient a summary in writing of the Federal law and regulations.

(b) *Required elements of written summary.* The written summary of the Federal law and regulations must include:

- (1) A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.
- (2) A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.
- (3) A statement that information related to a patient's commission of a crime on the premises of the program or against personnel of the program is not protected.
- (4) A statement that reports of suspected child abuse and neglect made under State law to

appropriate State or local authorities are not protected.

- (5) A citation to the Federal law and regulations.

(c) *Program options.* The program may devise its own notice or may use the sample notice in paragraph (d) to comply with the requirement to provide the patient with a summary in writing of the Federal law and regulations. In addition, the program may include in the written summary information concerning State law and any program policy not inconsistent with State and Federal law on the subject of confidentiality of alcohol and drug abuse patient records.

(d) *Sample notice.*

CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by Federal law and regulations. Generally, the program may not say to a person outside the program that a patient attends the program, or disclose any information identifying a patient as an alcohol or drug abuser Unless:

- (1) The patient consents in writing;
- (2) The disclosure is allowed by a court order; or
- (3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation. Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations. Federal law and regulations do not protect any information about a crime committed by a patient either at the program or against any person who works for the program or about any threat to commit such a crime. Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.

(See 42 U.S.C. 290dd-3 and 42 U.S.C. 290ee-3 for Federal laws and 42 CFR part 2 for Federal regulations.) (Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.23 Patient access and restrictions on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The program is not required to obtain a patient’s written consent or other authorization under these regulations in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient record is subject to the restriction on use of his information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 2.12(d)(1).

Subpart C—Disclosures With Patient’s Consent

§ 2.31 Form of written consent.

(a) *Required elements.* A written consent to a disclosure under these regulations must include:

- (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 insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Sample consent form.* The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (*name of patient*)

Q Request Q Authorize:

2. (*name or general designation of program which is to make the disclosure*)

3. To disclose: (*kind and amount of information to be disclosed*)

4. To: (*name or title of the person or organization to which disclosure is to be made*)

5. For: (*purpose of the disclosure*)

6. Date: (*on which this consent is signed*)

7. Signature of patient

8. Signature of parent or guardian (*where required*)

9. Signature of person authorized to sign in lieu of the patient (*where required*)

10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (*specific date, event, or condition*)

(c) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

- (1) Has expired;
- (2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;
- (3) Is known to have been revoked; or
- (4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

(Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.32 Prohibition on redisclosure.

Notice to accompany disclosure. Each disclosure made with the patient’s written consent must be accompanied by 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 this 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. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

[52 FR 21809, June 9, 1987; 52 FR 41997, Nov. 2, 1987]

§ 2.33 Disclosures permitted with written consent.

If a patient consents to a disclosure of his or her records under § 2.31, a program may disclose those records in accordance with that consent to any individual or organization named 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.

§ 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.

(a) *Definitions.* For purposes of this section:

Central registry means an organization which obtains from two or more member programs patient identifying information about individuals applying for maintenance treatment or detoxification treatment for

the purpose of avoiding an individual’s concurrent enrollment in more than one program.

Detoxification treatment means the dispensing of a narcotic drug in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to withdrawal from the sustained use of a narcotic drug.

Maintenance treatment means the dispensing of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

Member program means a detoxification treatment or maintenance treatment program which reports patient identifying information to a central registry and which is in the same State as that central registry or is not more than 125 miles from any border of the State in which the central registry is located.

(b) *Restrictions on disclosure.* A program may disclose patient records to a central registry or to any detoxification or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:

- (1) The disclosure is made when:
 - (i) The patient is accepted for treatment;
 - (ii) The type or dosage of the drug is changed; or
 - (iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

- (i) Patient identifying information;
 - (ii) Type and dosage of the drug; and
 - (iii) Relevant dates.
- (3) The disclosure is made with the patient’s written consent meeting the requirements of §2.31, except that:
- (i) The consent must list the name and address of each central registry and each known detoxification or maintenance treatment program to which a disclosure will be made; and
 - (ii) The consent may authorize a disclosure to any detoxification or maintenance treatment program established within 200 miles of the program after the consent is given without naming any such program.

(c) *Use of information limited to prevention of multiple enrollments.* A central registry and any detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not redisclose or use patient

identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order under subpart E of these regulations.

(d) *Permitted disclosure by a central registry to prevent a multiple enrollment.* When a member program asks a central registry if an identified patient is enrolled in another member program and the registry determines that the patient is so enrolled, the registry may disclose—

- (1) The name, address, and telephone number of the member program(s) in which the patient is already enrolled to the inquiring member program; and
- (2) The name, address, and telephone number of the inquiring member program to the member program(s) in which the patient is already enrolled. The member programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.

(e) *Permitted disclosure by a detoxification or maintenance treatment program to prevent a multiple enrollment.* A detoxification or maintenance treatment program which has received a disclosure under this section and has determined that the patient is already enrolled may communicate as necessary with the program making the disclosure to verify that no error has been made and to prevent or eliminate any multiple enrollment.

§ 2.35 Disclosures to elements of the criminal justice system which have referred patients.

(a) A program may disclose information about a patient to those persons within the criminal justice system which have made participation in the program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

- (1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or posttrial release, probation or parole officers responsible for supervision of the patient); and
- (2) The patient has signed a written consent meeting the requirements of § 2.31 (except paragraph (a)(8) which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this

section.

(b) *Duration of consent.* The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:

- (1) The anticipated length of the treatment;
- (2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and
- (3) Such other factors as the program, the patient, and the person(s) who will receive the disclosure consider pertinent.

(c) *Revocation of consent.* The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified, ascertainable event. The time or occurrence upon which consent becomes revocable may be no later than the final disposition of the conditional release or other action in connection with which consent was given.

(d) *Restrictions on redisclosure and use.* A person who receives patient information under this section may redisclose and use it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given.

Subpart D—Disclosures Without Patient Consent

§ 2.51 Medical emergencies.

(a) *General Rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.

(b) *Special Rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose of notifying patients or

their physicians of potential dangers.

(c) *Procedures.* Immediately following disclosure, the program shall document the disclosure in the patient's records, setting forth in writing:

- (1) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;
- (2) The name of the individual making the disclosure;
- (3) The date and time of the disclosure; and
- (4) The nature of the emergency (or error, if the report was to FDA).

(Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.52 Research activities.

(a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

- (1) Is qualified to conduct the research;
- (2) Has a research protocol under which the patient identifying information:
 - (i) Will be maintained in accordance with the security requirements of § 2.16 of these regulations (or more stringent requirements); and
 - (ii) Will not be redisclosed except as permitted under paragraph (b) of this section; and
- (3) Has provided a satisfactory written statement that a group of three or more individuals who are independent of the research project has reviewed the protocol and determined that:
 - (i) The rights and welfare of patients will be adequately protected; and
 - (ii) The risks in disclosing patient identifying information are outweighed by the potential benefits of the research.

(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

[52 FR 21809, June 9, 1987, as amended at 52 FR 41997, Nov. 2, 1987]

§ 2.53 Audit and evaluation activities.

(a) *Records not copied or removed.* If patient records are not copied or removed, patient identifying information may be disclosed in the course of a review of records on program premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (d) of this section and who:

- (1) Performs the audit or evaluation activity on behalf of:
 - (i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or
 - (ii) Any private person which provides financial assistance to the program, which is a third party payer covering patients in the program, or which is a peer review organization performing a utilization or quality control review; or

(2) Is determined by the program director to be qualified to conduct the audit or evaluation activities.

(b) *Copying or removal of records.* Records containing patient identifying information may be copied or removed from program premises by any person who:

(1) Agrees in writing to:

(i) Maintain the patient identifying information in accordance with the security requirements provided in § 2.16 of these regulations (or more stringent requirements);

(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and

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

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

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third part payer covering patients in the program, or which is a peer review organization performing a utilization or quality control review.

(c) *Medicare or Medicaid audit or evaluation.* (1) For purposes of Medicare or Medicaid audit or evaluation under this section, audit or evaluation includes a civil or administrative investigation of the program by any Federal, State, or local agency responsible for oversight of the Medicare or Medicaid program and includes administrative enforcement, against the program by the agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

(2) Consistent with the definition of program in § 2.11, program 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)(1) of this section.

(3) If a disclosure to a person is authorized under this section for a Medicare or Medicaid audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section, then a peer review organization which obtains the information under paragraph (a) or (b) may disclose the information to that person but only for purposes of Medicare or Medicaid audit or evaluation.

(4) The provisions of this paragraph do not authorize the agency, the program, or any other person to disclose or use patient identifying information obtained

during the audit or evaluation for any purposes other than those necessary to complete the Medicare or Medicaid audit or evaluation activity as specified in this paragraph.

(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 of these regulations.

Subpart E—Court Orders Authorizing Disclosure and Use

§ 2.61 Legal effect of order.

(a) *Effect.* An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a disclosure or use of patient information which would otherwise be prohibited by 42 U.S.C. 290ee-3, 42 U.S.C. 290dd-3 and these regulations. Such an order does not compel disclosure. A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under these regulations.

(b) *Examples.* (1) A person holding records subject to these regulations receives a subpoena for those records: a response to the subpoena is not permitted under the regulations unless an authorizing court order is entered. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under these regulations.

(2) An authorizing court order is entered under these regulations, but the person authorized does not want to make the disclosure. If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed, that person may refuse to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person authorized to disclose must disclose, unless there is a valid legal defense to the process other than the confi-

dentiality restrictions of these regulations.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.

A court order under these regulations may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under § 2.66 may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records.

§ 2.63 Confidential communications.

(a) A court order under these regulations may authorize disclosure of confidential communications made by a patient to a program in the course of diagnosis, treatment, or referral for treatment 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 which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnaping, 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.

(b) [Reserved]

§ 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.

(a) *Application.* An order authorizing the disclosure of patient records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the disclosure which is sought. The application may be filed separately or as part of a pending civil action in which it appears that the patient records are needed to provide evidence. An application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or has given a written consent (meeting the requirements of these regulations) to disclosure or the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice.* The patient and the person holding the records from whom disclosure is sought must be given:

(1) Adequate notice in a manner which will not disclose patient identifying information to other persons; and

(2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Review of evidence: Conduct of hearing.* Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or the person holding the record, unless the patient requests an open hearing in a manner which meets the written consent requirements of these regulations. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria for entry of order.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that:

- (1) **Other ways of obtaining the information are not available or would not be effective; and**
- (2) **The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.**

(e) *Content of order.* An order authorizing a disclosure must:

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

§ 2.65 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.

(a) *Application.* An order authorizing the disclosure or use of patient records to criminally investigate or prosecute a patient may be applied for by the person holding the records or by any person conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending

criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may not contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under § 2.66 is sought with an order under this section, the person holding the records must be given:

- (1) **Adequate notice (in a manner which will not disclose patient identifying information to third parties) of an application by a person performing a law enforcement function;**
- (2) **An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order; and**
- (3) **An opportunity to be represented by counsel independent of counsel for an applicant who is a person performing a law enforcement function.**

(c) *Review of evidence: Conduct of hearings.* Any oral argument, review of evidence, or hearing on the application shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or the person holding the records. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria.* A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

- (1) **The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnaping, armed robbery, assault with a deadly weapon, and child abuse and neglect.**
- (2) **There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.**
- (3) **Other ways of obtaining the information are not available or would not be effective.**

(4) 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.

(5) If the applicant is a person performing a law enforcement function that:

(i) The person holding the records has been afforded the opportunity to be represented by independent counsel; and

(ii) Any person holding the records which is an entity within Federal, State, or local government has in fact been represented by counsel independent of the applicant.

(e) Content of order. Any order authorizing a disclosure or use of patient records under this section must:

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

(2) Limit 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; and

(3) Include 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.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.

(a) Application. (1) An order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute a program or the person holding the records (or employees or agents of that program or person) may be applied for by any administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the program's or person's activities.

(2) The application may be filed separately or as

part of a pending civil or criminal action against a program or the person holding the records (or agents or employees of the program or person) in which it appears that the patient records are needed to provide material evidence. The application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written consent (meeting the requirements of § 2.31 of these regulations) to that disclosure.

(b) Notice not required. An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to the program, to the person holding the records, or to any patient whose records are to be disclosed, upon implementation of an order so granted any of the above persons must be afforded an opportunity to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) Requirements for order. An order under this section must be entered in accordance with, and comply with the requirements of, paragraphs (d) and (e) of § 2.64 of these regulations.

(d) Limitations on disclosure and use of patient identifying information:

(1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

(2) No information obtained under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under § 2.65 of these regulations.

§ 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.

(a) Application. A court order authorizing the placement of an undercover agent or informant in a program as an employee or patient may be applied

for by any law enforcement or prosecutorial agency which has reason to believe that employees or agents of the program are engaged in criminal misconduct.

(b) *Notice.* The program director must be given adequate notice of the application and an opportunity to appear and be heard (for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order), unless the application asserts a belief that:

- (1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or**
- (2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.**

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find:

- (1) There is reason to believe that an employee or agent of the program is engaged in criminal activity;**
- (2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and**
- (3) The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the program, physician-patient relationships and the treatment services.**

(d) *Content of order.* An order authorizing the placement of an undercover agent or informant in a program must:

- (1) Specifically authorize the placement of an undercover agent or an informant;**
- (2) Limit the total period of the placement to six months;**
- (3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the program; and**

(4) Include any other measures which are appropriate to limit any potential disruption of the program by the placement and any potential for a real or apparent breach of patient confidentiality; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

(e) *Limitation on use of information.* No information obtained by an undercover agent or informant placed under this section may be used to criminally investigate or prosecute any patient or as the basis for an application for an order under § 2.65 of these regulations.

Appendix A—The Federal Confidentiality Law and Regulations

SUBCHAPTER A—GENERAL PROVISIONS

PART 1 [RESERVED]

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

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- 2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.
- 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.

AUTHORITY: Sec. 408 of Pub. L. 92–255, 86 Stat. 79, as amended by sec. 303 (a), (b) of Pub. L. 93–282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94–237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94–581, 90 Stat. 2852; sec. 509 of Pub. L. 96–88, 93 Stat. 695; sec. 973(d) of Pub. L. 97– 35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98–24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290ee–3) and sec. 333 of Pub. L. 91–616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93–282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94–581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98–24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290dd–3), as amended by sec. 131 of Pub. L. 102–321, 106 Stat. 368, (42 U.S.C. 290dd–2).

SOURCE: 52 FR 21809, June 9, 1987, unless otherwise noted.

Subpart A—Introduction

§ 2.1 Statutory authority for confidentiality of drug abuse patient records.

The restrictions of these regulations upon the disclosure and use of drug abuse patient records were initially authorized by section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175). That section as amended was transferred by Pub. L. 98–24 to section 527 of the Public Health Service Act which is codified at 42 CFR Ch. I (10-1-97 Edition § 2.2 at 42 U.S.C. 290ee–3. The amended statutory authority is set forth below:

§ 290ee–3. CONFIDENTIALITY OF PATIENT RECORDS.

(a) Disclosure authorization

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit,

or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Prohibition against use of record in making criminal charges or investigation of patient

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a p a t i e n t o r t o conduct any investigation of a patient.

(d) Continuing prohibition against disclosure irrespective of status as patient

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) Armed Forces and Veterans' Administration; interchange of records; report of suspected child abuse and neglect to State or local authorities

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces. The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) Penalty for first and subsequent offenses

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

(g) Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders

Except as provided in subsection (h) of this section, the Secretary, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby,

shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(3) of Pub. L. 94–581. The responsibility of the Administrator of Veterans’ Affairs to write regulations to provide for confidentiality of drug abuse patient records under Title 38 was moved from 21 U.S.C. 1175 to 38 U.S.C. 4134.)

§ 2.2 Statutory authority for confidentiality of alcohol abuse patient records.

The restrictions of these regulations upon the disclosure and use of alcohol abuse patient records were initially authorized by section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582). The section as amended was transferred by Pub. L. 98–24 to section 523 of the Public Health Service Act which is codified at 42 U.S.C. 290dd–3. The amended statutory authority is set forth below:

§ 290dd–3. CONFIDENTIALITY OF PATIENT RECORDS

(a) Disclosure authorization

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be

allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Prohibition against use of record in making criminal charges or investigation of patient

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) Continuing prohibition against disclosure irrespective of status as patient

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) Armed Forces and Veterans’ Administration; interchange of record of suspected child abuse and neglect to State or local authorities

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans’ Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces. The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) Penalty for first and subsequent offenses

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

(g) Regulations of Secretary; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders

Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection(b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(4) of Pub. L. 94–581. The responsibility of the Administrator of Veterans’ Affairs to write regulations to provide for confidentiality of alcohol abuse patient records under Title 38 was moved from 42 U.S.C. 4582 to 38 U.S.C. 4134.)

§ 2.3 Purpose and effect.

(a) Purpose. Under the statutory provisions quoted in §§ 2.1 and 2.2, these regulations impose restrictions upon the disclosure and use of alcohol and drug abuse patient records which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program. The regulations specify:

- (1) Definitions, applicability, and general restrictions in subpart B (definitions applicable to § 2.34 only appear in that section);
- (2) Disclosures which may be made with written patient consent and the form of the written consent in subpart C;
- (3) Disclosures which may be made without written patient consent or an authorizing court order in subpart D; and
- (4) Disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders in subpart E.

(b) Effect. (1) These regulations prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstances exists under which disclosure is permitted, that circumstance acts

to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

(2) These regulations are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.

(3) Because there is a criminal penalty (a fine—see 42 U.S.C. 290ee–3(f), 42 U.S.C. 290dd–3(f) and 42 CFR 2.4) for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute (see *M. Kraus & Brothers v. United States*, 327 U.S. 614, 621–22, 66 S. Ct. 705, 707–08 (1946)).

§ 2.4 Criminal penalty for violation.

Under 42 U.S.C. 290ee–3(f) and 42 U.S.C. 290dd–3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

§ 2.5 Reports of violations.

(a) The report of any violation of these regulations may be directed to the United States Attorney for the judicial district in which the violation occurs.

(b) The report of any violation of these regulations by a methadone program may be directed to the Regional Offices of the Food and Drug Administration.

Subpart B—General Provisions

§ 2.11 Definitions.

For purposes of these regulations:

Alcohol abuse means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

Drug abuse means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user.

Diagnosis means any reference to an individual’s alcohol or drug abuse or to a condition which is

identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment.

Disclose or disclosure means a communication of patient identifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

Informant means an individual:

- (a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the request of a law enforcement agency or official: and
- (b) Who at the request of a law enforcement agency or official observes one or more patients or employees of the program for the purpose of reporting the information obtained to the law enforcement agency or official.

Patient means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

Patient identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.

Person means an individual, partnership, corporation, Federal, State or local government agency, or any other legal entity.

Program means:

- (a) An individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or
- (b) An identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or
- (c) Medical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or drug abuse diagnosis,

treatment or referral for treatment and who are identified as such providers. (See § 2.12(e)(1) for examples.)

Program director means:

(a) In the case of a program which is an individual, that individual:

(b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to act as chief executive of the organization.

Qualified Service Organization means a person which:

(a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(b) Has entered into a written agreement with a program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the programs, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

Records means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

Third party payer means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

Treatment means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient.

Undercover agent means an officer of any Federal, State, or local law enforcement agency who enrolls in or becomes an employee of a program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

[52 FR 21809, June 9, 1987, as amended by 60 FR 22297, May 5, 1995]

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:

§ 2.12 Applicability.

(a) *General*—(1) *Restrictions on disclosure*. The restrictions on disclosure in these regulations apply to any information, whether or not recorded, which:

(i) 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; and

(ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date) for the purpose of treating alcohol or drug abuse, making a diagnosis for that treatment, or making a referral for that treatment.

(2) *Restriction on use*. The restriction on use of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290ee-3(c), 42 U.S.C. 290dd-3(c)) applies to any information, whether or not recorded which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date), for the purpose of treating alcohol or drug abuse, making a diagnosis for the treatment, or making a referral for the treatment.

(b) *Federal assistance*. An alcohol abuse or drug abuse program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (c)(2) of this section relating to the Veterans' Administration and the Armed Forces);

(i) Certification of provider status under the Medicare program;

(ii) Authorization to conduct methadone maintenance treatment (see 21 CFR 291.505); or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of Federal financial assistance in any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities; or

(ii) Conducted by a State or local government unit which, through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) *Exceptions—(1) Veterans' Administration.*

These regulations do not apply to information on alcohol and drug abuse patients maintained in connection with the Veterans' Administration provisions of hospital care, nursing home care, domiciliary care, and medical services under title 38, United States Code. Those records are governed by 38 U.S.C. 4132 and regulations issued under that authority by the Administrator of Veterans' Affairs.

(2) *Armed Forces.* These regulations apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

(i) Any interchange of that information within the Armed Forces; and

(ii) Any interchange of that information between the Armed Forces and those components of the Veterans Administration furnishing health care to veterans.

(3) *Communication within a program or between a program and an entity having direct administrative control over that program.* The restrictions on disclosure in these regulations do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are

(i) Within a program or

(ii) Between a program and an entity that has direct administrative control over the program.

(4) *Qualified Service Organizations.* The restrictions on disclosure in these regulations do not apply to communications between a program and a qualified service organization of information needed by the organization to provide services to the program.

(5) *Crimes on program premises or against program personnel.* The restrictions on disclosure and use in these regulations do not apply to communications from program personnel to law enforcement officers which—

(i) Are directly related to a patient's commission of a crime on the premises of the program or against program personnel or to a threat to commit such a crime; and

(ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts.

(6) *Reports of suspected child abuse and neglect.*

The restrictions on disclosure and use in these regulations do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities. However, the restrictions continue to apply to the original alcohol or drug abuse patient records maintained by the program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

(d) *Applicability to recipients of information*—(1) *Restriction on use of information.* The restriction on the use of any information subject to these regulations to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from a federally assisted alcohol or drug abuse program, regardless of the status of the person obtaining the information or of whether the information was obtained in accordance with these regulations. This restriction on use bars, among other things, the introduction of that information as evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants (see § 2.17) or through patient access (see § 2.23) is subject to the restriction on use.

(2) *Restrictions on disclosures—Third party payers, administrative entities, and others.* The restrictions on disclosure in these regulations apply to:

- (i) Third party payers with regard to records disclosed to them by federally assisted alcohol or drug abuse programs;
- (ii) Entities having direct administrative control over programs with regard to information communicated to them by the program under § 2.12(c)(3); and
- (iii) Persons who receive patient records directly from a federally assisted alcohol or drug abuse program and who are notified of the restrictions on redisclosure of the records in accordance with § 2.32 of these regulations.

(e) *Explanation of applicability*—(1) *Coverage.* These regulations cover any information (including information on referral and intake) about alcohol and drug abuse patients obtained by a program (as the terms “patient” and “program” are defined in § 2.11) if the program is federally assisted in any manner described in § 2.12(b). Coverage includes, but is not limited to, those treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, based programs, and private practitioners who hold themselves out as providing, and provide alcohol or drug abuse diagnosis, treatment, or referral for treatment. However, these regulations would not apply, for example, to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of alcohol or drug

abuse diagnosis, treatment or referral and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.

(2) *Federal assistance to program required.* If a patient’s alcohol or drug abuse diagnosis, treatment, or referral for treatment is not provided by a program which is federally conducted, regulated or supported in a manner which constitutes Federal assistance under § 2.12(b), that patient’s record is not covered by these regulations. Thus, it is possible for an individual patient to benefit from Federal support and not be covered by the confidentiality regulations because the program in which the patient is enrolled is not federally assisted as defined in § 2.12(b). For example, if a Federal court placed an individual in a private for-profit program and made a payment to the program on behalf of that individual, that patient’s record would not be covered by these regulations unless the program itself received Federal assistance as defined by § 2.12(b).

(3) *Information to which restrictions are applicable.* Whether a restriction is on use or disclosure affects the type of information which may be available. The restrictions on disclosure apply to any information which would identify a patient as an alcohol or drug abuser. The restriction on use of information to bring criminal charges against a patient for a crime applies to any information obtained by the program for the purpose of diagnosis, treatment, or referral for treatment of alcohol or drug abuse. (Note that restrictions on use and disclosure apply to recipients of information under § 2.12(d).)

(4) *How type of diagnosis affects coverage.* These regulations cover any record of a diagnosis identifying a patient as an alcohol or drug abuser which is prepared in connection with the treatment or referral for treatment of alcohol or drug abuse. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by these regulations. The following are not covered by these regulations:

- (i) Diagnosis which is made solely for the purpose of providing evidence for use by law enforcement authorities; or
- (ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alcohol or drug abuser (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987, as amended at 60 FR 22297, May 5, 1995]

§ 2.13 Confidentiality restrictions.

(a) *General.* The patient records to which these regulations apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

(b) *Unconditional compliance required.* 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.

(c) *Acknowledging the presence of patients: Responding to requests.* (1) The presence of an identified patient in a facility or component of a facility which is publicly identified as a place where only alcohol or drug abuse diagnosis, treatment, or referral is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of these regulations or if an authorizing court order is entered in accordance with subpart E of these regulations. The regulations permit acknowledgment of the presence of an identified patient in a facility or part of a facility if the facility is not publicly identified as only an alcohol or drug abuse diagnosis, treatment or referral facility, and if the acknowledgment does not reveal that the patient is an alcohol or drug abuser.

(2) Any answer to a request for a disclosure of patient records which is not permissible under these regulations must be made in a way that will not affirmatively reveal that an identified individual has been, or is being diagnosed or treated for alcohol or drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do

not restrict a disclosure that an identified individual is not and never has been a patient.

§ 2.14 Minor patients.

(a) *Definition of minor.* As used in these regulations the term "minor" means a person who has not attained the age of majority specified in the applicable State law, or if no age of majority is specified in the applicable State law, the age of eighteen years.

(b) *State law not requiring parental consent to treatment.* If a minor patient acting alone has the legal capacity under the applicable State law to apply for and obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations may be given only by the minor patient. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. These regulations do not prohibit a program from refusing to provide treatment until the minor patient consents to the disclosure necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a State or local law requiring the program to furnish the service irrespective of ability to pay.

(c) *State law requiring parental consent to treatment.* (1) Where State law requires consent of a parent, guardian, or other person for a minor to obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations must be given by both the minor and his or her parent, guardian, or other person authorized under State law to act in the minor's behalf.

(2) Where State law requires parental consent to treatment the fact of a minor's application for treatment may be communicated to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf only if:

(i) The minor has given written consent to the disclosure in accordance with subpart C of these regulations or

(ii) The minor lacks the capacity to make a rational choice regarding such consent as judged by the program director under paragraph (d) of this section.

(d) *Minor applicant for services lacks capacity for rational choice.* Facts relevant to reducing a threat to the life or physical well being of the applicant or any other individual may be disclosed to the parent, guardian, or other person authorized under State law to act in the minor's behalf if the program director judges that:

(1) A minor applicant for services lacks capacity because of extreme youth or mental or physical condition to make a rational decision on whether to consent to a disclosure under subpart C of these regulations to his or her parent, guardian, or other person authorized under State law to act in the minor's behalf, and

(2) The applicant's situation poses a substantial threat to the life or physical well being of the applicant or any other individual which may be reduced by communicating relevant facts to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf.

§ 2.15 Incompetent and deceased patients.

(a) *Incompetent patients other than minors—(1) Adjudication of incompetence.* In the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs, any consent which is required under these regulations may be given by the guardian or other person authorized under State law to act in the patient's behalf.

(2) *No adjudication of incompetency.* For any period for which the program director determines that a patient, other than a minor or one who has been adjudicated incompetent, suffers from a medical condition that prevents knowing or effective action on his or her own behalf, the program director may exercise the right of the patient to consent to a disclosure under subpart C of these regulations for the sole purpose of obtaining payment for services from a third party payer.

(b) *Deceased patients—(1) Vital statistics.* These regulations do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.

(2) *Consent by personal representative.* Any other disclosure of information identifying a deceased patient as an alcohol or drug abuser is subject to these regulations. If a written consent to the

disclosure is required, that consent may be given by an 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.

§ 2.16 Security for written records.

(a) Written records which are subject to these regulations must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use; and

(b) Each program shall adopt in writing procedures which regulate and control access to and use of written records which are subject to these regulations.

§ 2.17 Undercover agents and informants.

(a) *Restrictions on placement.* Except as specifically authorized by a court order granted under § 2.67 of these regulations, no program may knowingly employ, or enroll as a patient, any undercover agent or informant.

(b) *Restriction on use of information.* No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.18 Restrictions on the use of identification cards.

No person may require any patient to carry on his or her person while away from the program premises any card or other object which would identify the patient as an alcohol or drug abuser. This section does not prohibit a person from requiring patients to use or carry cards or other identification objects on the premises of a program.

§ 2.19 Disposition of records by discontinued programs.

(a) *General.* If a program discontinues operations or is taken over or acquired by another program, it must purge patient identifying information from its records or destroy the records unless—

(1) The patient who is the subject of the records gives written consent (meeting the requirements of § 2.31) to a transfer of the records to the acquiring program or to any other program designated in the consent (the manner of obtaining this consent must minimize the likelihood of a disclosure of patient identifying information to a third party); or

(2) There is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the program.

(b) *Procedure where retention period required by law.* If paragraph (a)(2) of this section applies, the records must be:

(1) Sealed in envelopes or other containers labeled as follows: “Records of [insert name of program] required to be maintained under [insert citation to

statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]”; and
(2) Held under the restrictions of these regulations by a responsible person who must, as soon as practicable after the end of the retention period specified on the label, destroy the records.

§ 2.20 Relationship to State laws.

The statutes authorizing these regulations (42 U.S.C. 290ee–3 and 42 U.S.C. 290dd–3) do not preempt the field of law which they cover to the exclusion of all State laws in that field. If a disclosure permitted under these regulations is prohibited under State law, neither these regulations nor the authorizing statutes may be construed to authorize any violation of that State law. However, no State law may either authorize or compel any disclosure prohibited by these regulations.

§ 2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

(a) *Research privilege description.* There may be concurrent coverage of patient identifying information by these regulations and by administrative action taken under: Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a) and the implementing regulations at 42 CFR part 2a); or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These “research privilege” statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* These regulations restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under subpart E of these regulations of a court order authorizing a disclosure of information about a patient does not affect an

exercise of authority under these research privilege statutes. However, the research privilege granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any information which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with subpart E of these regulations authorizes a methadone maintenance treatment program to disclose certain information about its patients, that program may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

§ 2.22 Notice to patients of Federal confidentiality requirements.

(a) *Notice required.* At the time of admission or as soon thereafter as the patient is capable of rational communication, each program shall:

- (1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and
- (2) Give to the patient a summary in writing of the Federal law and regulations.

(b) *Required elements of written summary.* The written summary of the Federal law and regulations must include:

- (1) A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.
- (2) A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.
- (3) A statement that information related to a patient's commission of a crime on the premises of the program or against personnel of the program is not protected.
- (4) A statement that reports of suspected child abuse and neglect made under State law to appropriate State or local authorities are not protected.
- (5) A citation to the Federal law and regulations.

(c) *Program options.* The program may devise its own notice or may use the sample notice in paragraph (d) to comply with the requirement to provide the patient with a summary in writing of the Federal law and regulations. In addition, the program may include in the written summary

information concerning State law and any program policy not inconsistent with State and Federal law on the subject of confidentiality of alcohol and drug abuse patient records.

(d) *Sample notice.*

CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by Federal law and regulations. Generally, the program may not say to a person outside the program that a patient attends the program, or disclose any information identifying a patient as an alcohol or drug abuser Unless:

- (1) The patient consents in writing;
- (2) The disclosure is allowed by a court order; or
- (3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation. Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations. Federal law and regulations do not protect any information about a crime committed by a patient either at the program or against any person who works for the program or about any threat to commit such a crime. Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.

(See 42 U.S.C. 290dd-3 and 42 U.S.C. 290ee-3 for Federal laws and 42 CFR part 2 for Federal regulations.) (Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.23 Patient access and restrictions on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The program is not required to obtain a patient's written consent or other authorization under these regulations in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient record is subject to the restriction on use of his information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 2.12(d)(1).

Subpart C—Disclosures With Patient’s Consent

§ 2.31 Form of written consent.

(a) *Required elements.* A written consent to a disclosure under these regulations must include:

- (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 insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Sample consent form.* The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (*name of patient*)

 Q Request Q Authorize:

2. (*name or general designation of program which is to make the disclosure*)

 3. To disclose: (*kind and amount of information to be disclosed*)

 4. To: (*name or title of the person or organization to which disclosure is to be made*)

 5. For: (*purpose of the disclosure*)

 6. Date: (*on which this consent is signed*)

 7. Signature of patient

 8. Signature of parent or guardian (*where required*)

 9. Signature of person authorized to sign in lieu of the patient (*where required*)

 10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (*specific date, event, or condition*)

 (c) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

- (1) Has expired;
- (2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;
- (3) Is known to have been revoked; or
- (4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

(Approved by the Office of Management and Budget under control number 0930–0099)

§ 2.32 Prohibition on redisclosure.

Notice to accompany disclosure. Each disclosure made with the patient’s written consent must be accompanied by 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 this 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. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

[52 FR 21809, June 9, 1987; 52 FR 41997, Nov. 2, 1987]

§ 2.33 Disclosures permitted with written consent.

If a patient consents to a disclosure of his or her records under § 2.31, a program may disclose those records in accordance with that consent to any individual or organization named 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.

§ 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.

(a) *Definitions.* For purposes of this section:

Central registry means an organization which obtains from two or more member programs patient identifying information about individuals applying for maintenance treatment or detoxification treatment for the purpose of avoiding an individual's concurrent enrollment in more than one program.

Detoxification treatment means the dispensing of a narcotic drug in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to withdrawal from the sustained use of a narcotic drug.

Maintenance treatment means the dispensing of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

Member program means a detoxification treatment or maintenance treatment program which reports patient identifying information to a central registry and which is in the same State as that central registry or is not more than 125 miles from any border of the State in which the central registry is located.

(b) *Restrictions on disclosure.* A program may disclose patient records to a central registry or to any detoxification or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:

(1) The disclosure is made when:

- (i) The patient is accepted for treatment;
- (ii) The type or dosage of the drug is changed; or
- (iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

- (i) Patient identifying information;
- (ii) Type and dosage of the drug; and
- (iii) Relevant dates.

(3) The disclosure is made with the patient's written consent meeting the requirements of § 2.31, except that:

- (i) The consent must list the name and address of each central registry and each known detoxification or maintenance treatment program to which a disclosure will be made; and
- (ii) The consent may authorize a disclosure to any detoxification or maintenance treatment program established within 200 miles of the program after the consent is given without naming any such program.

(c) *Use of information limited to prevention of multiple enrollments.* A central registry and any detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not redisclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order under subpart E of these regulations.

(d) *Permitted disclosure by a central registry to prevent a multiple enrollment.* When a member program asks a central registry if an identified patient is enrolled in another member program and the registry determines that the patient is so enrolled, the registry may disclose—

- (1) The name, address, and telephone number of the member program(s) in which the patient is already enrolled to the inquiring member program; and
- (2) The name, address, and telephone number of the inquiring member program to the member program(s) in which the patient is already enrolled. The member programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.

(e) *Permitted disclosure by a detoxification or maintenance treatment program to prevent a multiple enrollment.* A detoxification or maintenance treatment program which has received a disclosure under this section and has determined that the patient is already enrolled may communicate as necessary with the program making the disclosure to verify that no error has been made and to prevent or eliminate any multiple enrollment.

§ 2.35 Disclosures to elements of the criminal justice system which have referred patients.

(a) A program may disclose information about a patient to those persons within the criminal justice system which have made participation in the program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or posttrial release, probation or parole officers responsible for supervision of the patient); and (2) The patient has signed a written consent meeting the requirements of § 2.31 (except paragraph (a)(8) which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.

(b) *Duration of consent.* The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:

(1) The anticipated length of the treatment;

(2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and

(3) Such other factors as the program, the patient, and the person(s) who will receive the disclosure consider pertinent.

(c) *Revocation of consent.* The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified, ascertainable event. The time or occurrence upon which consent becomes revocable may be no later than the final disposition of the conditional release or other action in connection with which consent was given.

(d) *Restrictions on redisclosure and use.* A person

who receives patient information under this section may redisclose and use it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given.

Subpart D—Disclosures Without Patient Consent

§ 2.51 Medical emergencies.

(a) *General Rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.

(b) *Special Rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose of notifying patients or their physicians of potential dangers.

(c) *Procedures.* Immediately following disclosure, the program shall document the disclosure in the patient's records, setting forth in writing:
(1) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;
(2) The name of the individual making the disclosure;
(3) The date and time of the disclosure; and
(4) The nature of the emergency (or error, if the report was to FDA).

(Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.52 Research activities.

(a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

- (1) Is qualified to conduct the research;
- (2) Has a research protocol under which the patient identifying information:
 - (i) Will be maintained in accordance with the security requirements of § 2.16 of these regulations (or more stringent requirements); and
 - (ii) Will not be redisclosed except as permitted under paragraph (b) of this section; and
- (3) Has provided a satisfactory written statement that a group of three or more individuals who are independent of the research project has reviewed the protocol and determined that:
 - (i) The rights and welfare of patients will be adequately protected; and
 - (ii) The risks in disclosing patient identifying information are outweighed by the potential benefits of the research.

(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

[52 FR 21809, June 9, 1987, as amended at 52 FR 41997, Nov. 2, 1987]

§ 2.53 Audit and evaluation activities.

(a) *Records not copied or removed.* If patient records are not copied or removed, patient identifying information may be disclosed in the course of a review of records on program premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (d) of this section and who:

- (1) Performs the audit or evaluation activity on behalf of:
 - (i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or
 - (ii) Any private person which provides financial assistance to the program, which is a third party payer covering patients in the program, or which is a peer review organization performing a utilization or quality control review; or
- (2) Is determined by the program director to be qualified to conduct the audit or evaluation activities.

(b) *Copying or removal of records.* Records containing patient identifying information may be copied or removed from program premises by any person who:

- (1) Agrees in writing to:
 - (i) Maintain the patient identifying information in accordance with the security requirements provided in § 2.16 of these regulations (or more stringent requirements);
 - (ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and
 - (iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and
- (2) Performs the audit or evaluation activity on behalf of:
 - (i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or
 - (ii) Any private person which provides financial assistance to the program, which is a third part payer covering patients in the program, or which is a peer review organization performing a utilization or quality control review.

(c) *Medicare or Medicaid audit or evaluation.* (1) For purposes of Medicare or Medicaid audit or evaluation under this section, audit or evaluation includes a civil or administrative investigation of the program by any Federal, State, or local agency responsible for oversight of the Medicare or Medicaid program and includes administrative enforcement, against the program by the agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

(2) Consistent with the definition of program in § 2.11, program 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)(1) of this section.

(3) If a disclosure to a person is authorized under this section for a Medicare or Medicaid audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section, then a peer review organization which obtains the information under paragraph (a) or (b) may disclose the information to that person but only for purposes of Medicare or Medicaid audit or evaluation.

(4) The provisions of this paragraph do not authorize the agency, the program, or any other person to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the Medicare or Medicaid audit or evaluation activity as specified in this paragraph.

(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 of these regulations.

Subpart E—Court Orders Authorizing Disclosure and Use

§ 2.61 Legal effect of order.

(a) *Effect.* An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a disclosure or use of patient information which would otherwise be prohibited by 42 U.S.C. 290ee–3, 42 U.S.C. 290dd–3 and these regulations. Such an order does not compel disclosure. A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under these regulations.

(b) *Examples.* (1) A person holding records subject to these regulations receives a subpoena for those records: a response to the subpoena is not permitted under the regulations unless an authorizing court order is entered. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under these regulations.

(2) An authorizing court order is entered under these regulations, but the person authorized does not want to make the disclosure. If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed, that person may refuse to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person authorized to disclose must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of these regulations.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.

A court order under these regulations may not

authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under § 2.66 may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records.

§ 2.63 Confidential communications.

(a) A court order under these regulations may authorize disclosure of confidential communications made by a patient to a program in the course of diagnosis, treatment, or referral for treatment 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 which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnaping, 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.

(b) [Reserved]

§ 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.

(a) *Application.* An order authorizing the disclosure of patient records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the disclosure which is sought. The application may be filed separately or as part of a pending civil action in which it appears that the patient records are needed to provide evidence. An application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or

has given a written consent (meeting the requirements of these regulations) to disclosure or the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice.* The patient and the person holding the records from whom disclosure is sought must be given:

(1) Adequate notice in a manner which will not disclose patient identifying information to other persons; and

(2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Review of evidence: Conduct of hearing.* Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or the person holding the record, unless the patient requests an open hearing in a manner which meets the written consent requirements of these regulations. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria for entry of order.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that:

(1) Other ways of obtaining the information are not available or would not be effective; and

(2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

(e) *Content of order.* An order authorizing a disclosure must:

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

(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.

§ 2.65 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.

(a) *Application.* An order authorizing the disclosure or use of patient records to criminally investigate or prosecute a patient may be applied for by the person holding the records or by any person conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may not contain or otherwise disclose patient identifying information

unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under § 2.66 is sought with an order under this section, the person holding the records must be given:

- (1) **Adequate notice (in a manner which will not disclose patient identifying information to third parties) of an application by a person performing a law enforcement function;**
- (2) **An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order; and**
- (3) **An opportunity to be represented by counsel independent of counsel for an applicant who is a person performing a law enforcement function.**

(c) *Review of evidence: Conduct of hearings.* Any oral argument, review of evidence, or hearing on the application shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or the person holding the records. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria.* A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

- (1) **The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnaping, armed robbery, assault with a deadly weapon, and child abuse and neglect.**
- (2) **There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.**
- (3) **Other ways of obtaining the information are not available or would not be effective.**

(4) 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.

(5) **If the applicant is a person performing a law enforcement function that:**

- (i) **The person holding the records has been afforded the opportunity to be represented by independent counsel; and**
- (ii) **Any person holding the records which is an entity within Federal, State, or local government has in fact been represented by counsel independent of the applicant.**

(e) *Content of order.* Any order authorizing a disclosure or use of patient records under this section must:

- (1) **Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;**
- (2) **Limit 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; and**
- (3) **Include 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.**

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.

(a) *Application.* (1) An order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute a program or the person holding the records (or employees or agents of that program or person) may be applied for by any administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the program's or person's activities.

(2) **The application may be filed separately or as part of a pending civil or criminal action against a program or the person holding the records (or**

agents or employees of the program or person) in which it appears that the patient records are needed to provide material evidence. The application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written consent (meeting the requirements of § 2.31 of these regulations) to that disclosure.

(b) *Notice not required.* An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to the program, to the person holding the records, or to any patient whose records are to be disclosed, upon implementation of an order so granted any of the above persons must be afforded an opportunity to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Requirements for order.* An order under this section must be entered in accordance with, and comply with the requirements of, paragraphs (d) and (e) of § 2.64 of these regulations.

(d) *Limitations on disclosure and use of patient identifying information:*

(1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

(2) No information obtained under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under § 2.65 of these regulations.

§ 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.

(a) *Application.* A court order authorizing the placement of an undercover agent or informant in a program as an employee or patient may be applied for by any law enforcement or prosecutorial agency which has reason to believe that employees or agents of the program are engaged in criminal misconduct.

(b) *Notice.* The program director must be given adequate notice of the application and an opportunity to appear and be heard (for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order), unless the application asserts a belief that:

- (1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or**
- (2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.**

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find:

- (1) There is reason to believe that an employee or agent of the program is engaged in criminal activity;**
- (2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and**
- (3) The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the program, physician-patient relationships and the treatment services.**

(d) *Content of order.* An order authorizing the placement of an undercover agent or informant in a program must:

- (1) Specifically authorize the placement of an undercover agent or an informant;**
- (2) Limit the total period of the placement to six months;**
- (3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the program; and**

(4) Include any other measures which are appropriate to limit any potential disruption of the program by the placement and any potential for a real or apparent breach of patient confidentiality; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

(e) Limitation on use of information. No information obtained by an undercover agent or informant placed under this section may be used to criminally investigate or prosecute any patient or as the basis for an application for an order under § 2.65 of these regulations.

**Appendix B—Sample Forms
and Agreements To Facilitate Collaborative
Efforts Between the Substance Abuse
Treatment and Welfare Systems**

Sample Form #1:

Patient Consent for the Release of Confidential Information

Patient Consent for the Release of Confidential Information

I, Jane Doe,
authorize
(NAME OF PATIENT)

ABC Treatment Program
(NAME OR GENERAL DESIGNATION OF PROGRAM MAKING DISCLOSURE)

to disclose to Mary Roe or another TANI FF counselor
(NAME OF PERSON OR ORGANIZATION TO WHICH
DISCLOSURE IS TO BE MADE)

the following information: my attendance and compliance in substance abuse
treatment

(NATURE OF THE INFORMATION, AS LIMITED AS POSSIBLE)

The purpose of the disclosure authorized herein is to: Assist the Hill Co. Dept of
Welfare to determine my eligibility for benefits and/or to evaluate my
readiness/ability to participate in a training program.

(PURPOSE OF DISCLOSURE, AS SPECIFIC AS POSSIBLE)

I understand that my records are protected under the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows:

(SPECIFICATION OF THE DATE, EVENT, OR CONDITION UPON WHICH THIS CONSENT EXPIRES)

Dated: _____

(Signature of Participant)

(Signature of Parent,
Guardian or Authorized
Representative, When
Required)

Sample Form #2:

Multiparty Consent Form

Multiparty Consent Form

I, _____, authorize
(NAME OF PATIENT)

(NAME OR GENERAL DESIGNATION OF PROGRAM MAKING DISCLOSURE)

to disclose to: (the following persons or organizations)

1. _____
2. _____
3. _____

The purpose of the disclosure authorized herein is to: **permit the participants of a case conference concerning my case to exchange information with one another.**

I understand that my records are protected under the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows:

(SPECIFICATION OF THE DATE, EVENT, OR CONDITION UPON WHICH THIS CONSENT EXPIRES)

(DATE)

(SIGNATURE OF PARTICIPANT)

(SIGNATURE OF PARENT, GUARDIAN OR
AUTHORIZED REPRESENTATIVE IF REQUIRED)

Sample Form #3:

Prohibition on Redisclosure of Information Concerning Client in Alcohol or Drug Abuse Treatment

The following notice accompanies a disclosure of information concerning a client in alcohol/drug abuse treatment, made to you with the consent of such client.

Prohibition on Redisclosure of Information Concerning Client in Alcohol or Drug Abuse Treatment

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 this 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. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

Sample Form #4:

Qualified Service Organization Agreement

Qualified Service Organization Agreement

XYZ Service Center ("the Center") and

(NAME OF THE PROGRAM)

("the Program") hereby enter into a qualified service organization agreement, whereby the Center agrees to provide

(NATURE OF SERVICES TO BE PROVIDED)

Furthermore, the Center:

(1) acknowledges that in receiving, storing, processing, or otherwise dealing with any information from the Program about the patients in the Program, it is fully bound by the provisions of the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2; and

(2) undertakes to resist in judicial proceedings any effort to obtain access to information pertaining to patients otherwise than as expressly provided for in the Federal confidentiality regulations, 42 CFR Part 2.

Executed this _____ day of _____, 199 ____.

President
XYZ Service Center
[address]

Program Director
[Name of the Program]
[address]

