USE AND DISCLOSURE OF PHI: SUBSTANCE ABUSE

I. INTRODUCTION

Medical records and information pertaining to the identity of a patient and his or her diagnosis of, or treatment for, an alcohol and/or drug abuse-related disorder or condition are particularly sensitive. Unjustified release of such records may expose the hospital to substantial fines and/or liability to the patient.

Records containing information pertaining to alcohol and drug abuse patients are subject to special protection under federal statute [42 U.S.C. Section 290dd-2] and under federal regulations found in "Confidentiality of Alcohol and Drug Abuse Patient Records," 42 C.F.R. part 2 ("substance abuse regulations").

In addition, individually-identifiable health information and records pertaining to alcohol and drug abuse patients are also subject to the federal privacy regulations promulgated pursuant to the Health Insurance Portability and Accountability Act (HIPAA). The Substance Abuse and Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services (DHHS) has prepared an analysis of the confidentiality provided under the substance abuse regulations and the HIPAA privacy regulations. The document, *The Confidentiality of Alcohol and Drug Abuse Patient Records Regulations and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs*, is posted on the SAMHSA website and can be found at www.samhsa.gov/HealthPrivacy/docs/SAMHSAPart2-HIPAAComparison2004.pdf.

The preamble to the HIPAA Privacy Rule states that in most cases, no conflict exists between the two sets of regulations. This view is confirmed in the SAMHSA document, which states, "Programs subject to both sets of rules must comply with both, unless there is a conflict between them. Generally, this will mean that substance abuse treatment programs should continue to follow the Part 2 (substance abuse) regulations." SAMHSA invites programs to contact it for assistance in the event a program identifies a conflict between the substance abuse regulations and the HIPAA Privacy Rule.

The HIPAA Privacy Rule permits a health care provider to disclose information in a number of situations that are not permitted under the substance abuse regulations. For example, disclosures allowed, without patient authorization, under the Privacy Rule for law enforcement, judicial and administrative proceedings, public health, health oversight, directory assistance, and as required by other laws, would generally be prohibited under the substance abuse statute and regulation without patient authorization. However, because these disclosures are permissive and not mandatory, there is no conflict. A health care provider would not be in violation of the Privacy Rules for failing to make these disclosures. [65 Fed. Reg. 82482-82483 (Dec. 28, 2000)]

Health and Safety Code Section 11845.5 also gives special protections to records of certain substance abuse programs. According to the California Department of Alcohol and Drug Programs, which oversees the implementation of the state statute, the special protections are intended to apply to facilities which are regulated by that department, such as outpatient methadone treatment programs and outpatient counseling programs, and not to general acute care hospitals or chemical dependency recovery hospitals. *(See VIII. "Other Restrictions on Substance Abuse Records," page 10.11.)*

The Confidentiality of Medical Information Act (CMIA) [Civil Code Section 56 *et seq.*] does not apply to information governed by the federal substance abuse regulations or the Health and Safety Code provisions regarding narcotic and drug abuse information [Civil Code Section 56.30(i)] *(see chapter 8 for information about the CMIA)*. However, the CMIA may apply to information concerning physical conditions other than alcohol or drug abuse for which the patient receives health care services, and such information may be released in accordance with the CMIA provided that all patient information concerning substance abuse, including the fact of the patient's presence in an alcohol or drug abuse treatment program, is withheld or released only as otherwise permitted under federal and state law.

Restrictions of the Lanterman-Petris-Short Act will apply if the patient receives services to which that act applies, including involuntary evaluation and treatment because the patient is gravely disabled or dangerous to self or others as a result of abuse of alcohol, narcotics or other dangerous drugs *(see chapter 9)*. Some state laws regulating the disclosure of medical information in particular circumstances may also apply. *(See, for example, VI. "Release of Information Without Patient Authorization," page 10.6.)*

II. FACILITIES COVERED BY THE FEDERAL REGULATIONS

The substance abuse regulations apply to any federally assisted program that is specialized to the extent that it holds

itself out as providing, and does provide, alcohol or drug abuse diagnosis, treatment, or referral for treatment.

A. "PROGRAM" DEFINED

"Program" means an individual or entity, other than a general medical care facility, that holds itself out as providing, and does provide, alcohol or drug abuse diagnosis, treatment or referral for treatment. Outside of hospitals, this may include employee assistance programs, rehabilitation programs or private practitioners.

For a general medical care facility, or any part thereof, to be a program under the regulations, the facility must have:

1. An identified unit that holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment; or
2. Medical personnel or other staff whose primary function is the provision of alcohol or drug abuse diagnosis, treatment, or referral for treatment and who are identified as such providers.

[42 C.F.R. Section 2.11]

The substance abuse regulations were amended in 1995 for the express purpose of clarifying that a general medical care facility (e.g., general acute care hospital) is not considered a program unless it meets one of the above specific requirements. This amendment was intended to nullify the impact of the decision in *United States v. Eide*, 875 F.2d 1429 (9th Cir. 1989), where the court had ruled that a hospital emergency room was a program under the federal statute and regulations.

NOTE: The substance abuse regulations were revised effective Aug. 10, 1987, with the effect of narrowing their application. As a result, some alcohol or drug abuse treatment that was covered under the previous regulations may no longer be covered after this date. DHHS takes the position that records and information reflecting drug or alcohol treatment provided prior to Aug. 10, 1987, are still confidential (even if they would not be covered by the current law) and access to them is governed by the current federal law and regulations.

The HIPAA Privacy Rule applies to **"covered entities"** (health plans, health care clearinghouses and health care providers that transmit health information in electronic form) in connection with HIPAA standard transactions *(see 45 C.F.R. Section 160.103)*. According to SAMHSA, HIPAA transactions in which a substance abuse treatment program might engage include:

1. Submission of claims to health plans;
2. Coordination of benefits with health plans;
3. Inquiries to health plans regarding eligibility, coverage or benefits or status of health care claims;
4. Transmission of enrollment and other information related to payment to health plans; and
5. Referral certification and authorization (i.e., requests for review of health care to obtain an authorization for providing health care or requests to obtain authorization for referring an individual to another health care provider).

If a federally-assisted substance abuse treatment program *(see below)* transmits health information electronically in connection with one or more of these transactions, then it must comply with the HIPAA Privacy Rule as well as with the substance abuse regulations.

B. "FEDERAL ASSISTANCE" DEFINED

The substance abuse regulations apply only to alcohol and drug abuse programs that receive federal assistance. A program is **"federally assisted"** if any of the following applies:

1. The program is conducted in whole or in part, directly or by contract or otherwise, by any federal department or agency.
2. The program is carried out under a license, certification, registration, or other authorization granted by any federal department or agency including, but not limited to, Medicare certification, certification to conduct opioid treatment *(see 42 C.F.R. part 8)*, or registration to dispense a controlled substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse.
3. The program is supported by funds provided by any federal department or agency by being a recipient of federal financial assistance in any form or by being conducted by a state or local government unit which receives federal funds which could be (but are not necessarily) spent for alcohol or drug abuse programs.
4. The program is assisted by the Internal Revenue Service through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program (e.g., hospital exempt from federal taxation under Internal Revenue Code Section 501(c)(3)).

[42 C.F.R. Section 2.12(b)(1) to (4)]

III. PATIENT'S RIGHTS

Federally assisted programs must comply with the patient's rights provisions of HIPAA, discussed in chapter 6. This section discusses additional patient's rights conferred by the federal substance abuse regulations.

A. NOTICE TO PATIENTS

The substance abuse regulations require that each patient be advised of these confidentiality provisions and furnished a

written summary thereof at the time of admission or as soon thereafter as the patient is capable of rational communication [42 C.F.R. Section 2.22]. This notice must be given in addition to the Notice of Privacy Practices required by the HIPAA Privacy Rule *(see II. "Right to Notice of Privacy Practices," page 6.1)*. A facility that serves primarily substance abuse patients may wish to combine the information into one document.

REQUIRED ELEMENTS OF WRITTEN SUMMARY

The written summary required by the substance abuse 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 the 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.

(See A. "Contents of the Notice of Privacy Practices," page 6.1, for information concerning the required elements of the HIPAA Notice of Privacy Practices.)

PROGRAM OPTIONS

To comply with the notice requirements of the substance abuse regulations, a program may devise its own notice or may use the sample notice found in CHA Appendix 18-B, "Notice to Patient: Confidentiality of Substance Abuse Patient Records." The program may also include in the written summary, if desired, information concerning state law and any program policy consistent with state and federal law on the subject of confidentiality of substance abuse patient records.

B. PATIENT ACCESS AND RESTRICTIONS ON USE

PATIENT ACCESS NOT PROHIBITED

The substance abuse regulations do not prohibit a program from giving a patient access to his or her own records. The program is not required to obtain a patient's written consent or other authorization to provide such access to the patient. [42 C.F.R. Section 2.23] Under HIPAA, a patient has the right to access his or her health information. *(See III. "Right to Access PHI," page 6.4.)*

RESTRICTIONS ON USE OF INFORMATION

The substance abuse regulations state that information obtained by patient access to his or her record may not be used to initiate or substantiate criminal charges against the patient or to conduct a criminal investigation of the patient [42 C.F.R. Section 2.23]. There is no similar provision in HIPAA.

IV. USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Under the substance abuse regulations, programs may not use or disclose any patient information unless the patient has consented in writing or unless a very limited exception specified in the regulations applies. The HIPAA Privacy Rule permits uses and disclosures for "treatment, payment and health care operations" as well as certain other disclosures without the individual's prior written authorization. Except in certain limited situations, both the substance abuse regulations and the HIPAA Privacy Rule permit rather than require the disclosure of information (the HIPAA Privacy Rule requires disclosure only to DHHS for purposes of investigation and enforcement and to the patient him/herself).

Since the substance abuse regulations are generally more restrictive, treatment programs may continue to follow the substance abuse regulations and not disclose information unless they can obtain consent or point to an exception to that rule that specifically permits the disclosure. Programs must then make sure that the disclosure is also permissible under the HIPAA Privacy Rule.

The substance abuse regulations also include restrictions on the use of drug and alcohol abuse information to initiate or substantiate criminal charges against a patient or to conduct a criminal investigation of a patient [42 C.F.R. Section 2.12(a)(2)].

A. INFORMATION COVERED

The substance abuse regulations apply to any information, whether or not recorded, which:

1. Would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such identification by another person; and
2. 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 any ongoing treatment episode which extends past the date), for the purpose of treating alcohol or drug abuse, or for making a diagnosis or referral for such treatment.

[42 C.F.R. Section 2.12(a)(1)]

The 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, whether or not the diagnosis is actually so used. However, a diagnosis is not covered by these regulations when it is made solely for the purpose of providing evidence for law enforcement authorities or when it clearly shows that the individual involved is not an alcohol or drug abuser (e.g., a diagnosis of drug overdose or alcohol intoxication in cases of involuntary ingestion of drugs or alcohol or reaction to a prescribed dosage of one or more drugs) [42 C.F.R. Section 2.12(e)(4)].

The HIPAA Privacy Rule applies to individually-identifiable health information held or transmitted by a covered entity or by the covered entity's "business associate." Such information is called protected health information or PHI.

The information covered by the two regulations is essentially the same, but there are some differences. For instance, the HIPAA Privacy Rule treats medical record numbers as PHI, while the substance abuse regulations would permit a program to disclose a medical record number because the regulation does not apply to "a number assigned to a patient by a program, if that number does not consist of, or contain numbers ... which could be used to identify a patient with reasonable accuracy and speed from sources external to the program." [42 C.F.R. Section 2.11] Programs subject to both rules must follow the HIPAA rule's protection of a medical record number.

Neither rule applies to information that has been de-identified. *(See 45 C.F.R. Section 164.514(a) (de-identification of PHI) and 42 C.F.R. Section 2.11 (definition of "patient-identifying information"). These terms are defined in CHA's* California Health Information Privacy Manual.*)* The HIPAA Privacy Rule includes numerous elements that make information identifiable, including, but not limited to, information regarding employers, relatives and household members that are not necessarily considered identifiable information under the substance abuse regulations. Such information should be protected consistent with the HIPAA requirements.

Former patients and deceased patients are protected under both the substance abuse regulations and the HIPAA Privacy Rule. *(See 42 C.F.R. Sections 2.11 and 2.15; 45 C.F.R. Sections 164.501 and 164.502(f).)* Note that if PHI is received by a treatment program prior to a patient applying to the program, under the HIPAA rule, such information is protected even though it may not be protected under the substance abuse regulations (because the individual has not received services from the program).

B. EXTENT OF DISCLOSURE: MINIMUM NECESSARY

The substance abuse regulations specify that any disclosure must be limited to the information necessary to carry out the purpose of the disclosure [42 C.F.R. Section 2.13(a)]. Similarly, with certain exceptions, the HIPAA Privacy Rule generally requires that uses and disclosures of PHI be limited to the minimum necessary for the intended purpose of the use or disclosure. *(See VI. "'Minimum Necessary' Use and Disclosure," page 7.9.)*

C. VERIFICATION

Federally assisted programs must comply with the verification procedures required by HIPAA prior to disclosing any information or records. Specifically, providers must verify the identity of any person requesting information as well as the authority of the person to have access to the information, if the identity or authority is not already known to the provider. *(See V. "Verification Procedures," page 7.8.)*

D. RESPONSE TO UNAUTHORIZED REQUEST

Under the substance abuse regulations, an answer to a request for a disclosure of patient records that is not permitted under the regulations must not affirmatively reveal that an identified individual has been or is an alcohol or drug abuse patient. The regulations state that an inquiring party may be given a copy of the confidentiality regulations along with general advice that the regulations restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations pertain to the records of an identified patient. However, the regulations permit a provider to say that an identified individual is not and never has been a patient. [42 C.F.R. Section 2.13(c)(2)]

The patient's presence in a facility may be acknowledged 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 [42 C.F.R. Section 2.13(c)(1)]. *(See chapters 8 and 9 regarding the disclosure of information about a patient. Additional protections apply to mental health patients covered by LPS.)*

V. RELEASE OF INFORMATION WITH PATIENT AUTHORIZATION

A. WRITTEN AUTHORIZATION

Disclosure of a patient's substance abuse records to an individual or organization is permitted if the patient consents

in writing, except that when disclosure is made to central registries, to a detoxification or treatment program not more than 200 miles away for the purpose of preventing multiple enrollment of the patient, or in connection with criminal justice referrals, special requirements must be met [42 C.F.R. Section 2.33] *(see below)*.

State and federal law contain strict requirements regarding the use and disclosure of psychotherapy notes *(see A. "Psychotherapy Notes," page 7.5)* and HIV test results *(see B. "HIV Test Results," page 7.6)*. In addition, HIPAA restricts the use and disclosure of PHI for marketing purposes, and in the near future, will prohibit the exchange of PHI for remuneration (with limited exceptions) *(see C. "Marketing," page 7.8, and D. "Prohibition on Sale of PHI," page 7.8)*. Health care providers should be thoroughly familiar with these requirements and incorporate them into their policies and procedures.

B. AUTHORIZATION FORM TO BE USED

Both the substance abuse regulations and HIPAA establish required elements that an authorization for the use or disclosure of patient-identifiable health information must meet. The HIPAA requirements are described in III. "Requirements for a Valid Authorization," page 7.2. The "Authorization for Use or Disclosure of Health Information" form (CHA Form 16-1), found in chapter 7, complies with these regulatory requirements and with other state and federal requirements. However, this form does not meet necessary requirements for disclosure of information to a central registry, a detoxification or treatment program not more than 200 miles away, or to the criminal justice system *(see below)* [42 C.F.R. Section 2.31].

Disclosure must not be made on the basis of a consent that has expired, is known to be revoked, is known or should be known to be materially false, or that on its face substantially fails to contain the required elements [42 C.F.R. Section 2.31(c)].

C. DISCLOSURE TO CENTRAL REGISTRIES AND IN CONNECTION WITH CRIMINAL JUSTICE REFERRALS

Under the substance abuse regulations, special requirements apply to the disclosure of substance abuse records, even with patient consent, when disclosure is made:

1. To a central registry or to a detoxification or treatment program not more than 200 miles away for the purpose of preventing multiple enrollment of the patient [42 C.F.R. Section 2.34].
2. To those persons within the criminal justice system who have made the patient's participation in the drug or alcohol abuse program a condition of the disposition of criminal proceedings against the patient or of the patient's parole or other release from custody [42 C.F.R. Section 2.35].

The special requirements limit the persons or organizations to whom disclosure may be made, the purposes for which disclosure may be made, the use that may be made of the information disclosed (including redisclosure), and the duration of each use. The patient's consent form must also meet special requirements. The hospital should consult its legal counsel when disclosure to those entities listed above is requested.

D. PROHIBITION OF REDISCLOSURE

The substance abuse regulations require that any information disclosed with the patient's (or legal representative's) consent be accompanied by a statement that further disclosure is prohibited unless the consent expressly permits further disclosure or the disclosure is otherwise permitted by the federal regulations. The "Substance Abuse Program Notice of Prohibition of Redisclosure" form (CHA Form 18-1) has been prepared to comply with this requirement [42 C.F.R. Section 2.32].

E. AUTHORIZATION FOR MINOR

GENERAL RULE

If under state law a minor patient can legally apply for and obtain substance abuse treatment, then where treatment is provided by a "federally assisted program," only the minor may authorize disclosure of information and records that are maintained in connection with those services [42 C.F.R. Section 2.14(b)]. (This restriction includes disclosure of information to the parent for purposes of obtaining reimbursement. However, a program may refuse to provide treatment unless the minor consents to the disclosure necessary to obtain reimbursement [42 C.F.R. Section 2.14(b)].) California law permits minors 12 years of age or older to consent to medical care and counseling relating to the treatment of alcohol- or drug-related problems [Family Code Section 6929(b)]. Therefore, this provision would apply and only the minor being treated may authorize disclosure. *(See chapter 2 regarding the ability of minors to consent to medical treatment.)*

Family Code Section 6929(g) provides that a parent or guardian who sought substance abuse treatment for a minor is able to receive information concerning the care from the minor's physician even where the minor objects. Because of the clear conflict with federal law that requires that only the minor may authorize disclosure, this state law may only apply to federally-assisted programs if the patient is less than 12 years old. Legal counsel should be consulted when a minor's parent attempts to obtain access to, or authorize disclosure of, substance abuse records from a federally-assisted program.

The HIPAA Privacy Rule defers to requirements in other applicable laws regarding the use or disclosure of health information regarding minors and, therefore, does not change the rules in the substance abuse regulations regarding minors and consent. [45 C.F.R. Section 164.502(g)]

EXCEPTION: METHADONE OR REPLACEMENT NARCOTIC ABUSE TREATMENT

California law does not authorize minors to receive methadone treatment or replacement narcotic abuse treatment using methadone, levoalphacetylmethadol (LAAM), buprenorphine products, combination products or any other federally approved controlled substances used for narcotic replacement treatment without the consent of a parent or guardian [Family Code Section 6929(e)]. Therefore, the following provisions of the federal regulations apply:

1. Written consent for disclosure of information and records must be given by both the minor and his or her parent, guardian, or other person authorized by law to act on his or her behalf [42 C.F.R. Section 2.14(c)(1)].
2. The fact of a minor's application for treatment may be communicated to the parent or guardian only if the minor has given written consent to disclosure or lacks capacity to make a rational choice regarding such consent as judged by the program director [42 C.F.R. Section 2.14(c)(2)].

EXCEPTION: THREAT TO LIFE OR PHYSICAL WELL-BEING OF APPLICANT OR OTHER PERSON

Facts relevant to reducing a threat to the life or physical well-being of the minor or any other individual may be disclosed to the parent, guardian, or other person legally authorized to act on behalf of the minor if:

1. The program director judges that the minor lacks capacity (because of extreme youth or mental or physical condition) to make a rational decision on whether to consent to the disclosure, 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 parent or guardian or other person legally authorized to act on behalf of the minor.

[42 C.F.R. Section 2.14(d)]

F. AUTHORIZATION FOR INCOMPETENT PATIENT

If a patient has been adjudicated incompetent to manage his or her own affairs, the substance abuse regulations permit consent to disclosure of the patient's substance abuse records to be given by the patient's conservator or other person authorized by law [42 C.F.R. Section 2.15(a)]. Similarly, the HIPAA Privacy Rule permits the use or disclosure of PHI upon the written authorization of a person legally authorized to make health care decisions for the individual.

In addition, for any period for which the program director determines that a patient, other than a minor or a patient 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 for the sole purpose of obtaining payment for services from a third party payer [42 C.F.R. Section 2.15(a)(2)].

G. AUTHORIZATION FOR DECEASED PATIENT

Under the substance abuse regulations, consent to disclosure of substance abuse records of a deceased patient may be given by:

1. An executor, administrator, or other personal representative;
2. The spouse if no representative has been appointed; or
3. Any responsible family member if there is neither spouse nor representative.

[42 C.F.R. Section 2.15(b)(2)]

Under the HIPAA Privacy Rule, where applicable law gives an executor, administrator or other person authority to act on behalf of a deceased individual or the individual's estate, then such person may be treated as the personal representative of the patient and as such has authority to authorize the use or disclosure of health information.

H. REVOCATION OF AUTHORIZATION

The federal substance abuse regulations permit a patient to revoke authorization for use or disclosure of PHI orally [42 C.F.R. Section 2.31(a)(8)]. HIPAA requires a written revocation of an authorization [45 C.F.R. Section 164.508(b)(5)]. According to *The Confidentiality of Alcohol and Drug Abuse Patient Records Regulations and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs* prepared by SAMHSA *(see I. "Introduction," page 10.1, for more information)*, substance abuse treatment programs must honor verbal revocations but may want to obtain written revocation when possible, or at a minimum, document the revocation in the medical record.

VI. RELEASE OF INFORMATION WITHOUT PATIENT AUTHORIZATION

Under the federal substance abuse regulations, disclosures are permitted without patient authorization in the following situations.

A. PROGRAM PERSONNEL

Communication of information between or among personnel who need such information to diagnose, treat, or refer for treatment of alcohol or drug abuse are permitted without patient authorization, if the communications are within a program or between a program and an entity that has direct administrative control over the program [42 C.F.R. Section 2.12(c)(3)]. Under HIPAA, these uses of health information are permitted without authorization as they fall within the definition of "treatment, payment or health care operations."

B. QUALIFIED SERVICE ORGANIZATIONS

Communications between a program and a qualified service organization of information needed by the organization to provide services to the program are permitted without patient authorization [42 C.F.R. Section 2.12(c)(4)]. A **"qualified service organization"** is a person or entity that provides services to a program (e.g., data processing, laboratory analysis, services to prevent or treat child abuse or neglect) under a written agreement in which the organization acknowledges that it is bound by the regulations in dealing with patient records and will resist efforts to obtain access to such records except as permitted by the regulations [42 C.F.R. Section 2.11]. Under HIPAA, third parties that handle patient information for, or on behalf of, the covered entity are business associates and must sign a business associate agreement with the covered entity. Thus, the written agreement between the program and the qualified service organization must meet the requirements of both regulations.

(See CHA's California Health Information Privacy Manual *for a detailed discussion of business associate requirements and a model business associate agreement.)*

C. CRIMES ON PROGRAM PREMISES OR AGAINST PROGRAM PERSONNEL

Communications from program personnel to law enforcement officers are permitted without patient authorization if they are directly related to a patient's commission of a crime on the program premises or against program personnel, or to a threat to commit such a crime, and are limited to the circumstances of the incidents, 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 [42 C.F.R. Section 2.12(c)(5)]. The HIPAA Privacy Rule has a similar provision permitting disclosure for this purpose [45 C.F.R. Section 164.512(f)(5)].

D. CHILD ABUSE REPORTS

Reports of suspected child abuse and neglect under state law may be made to the appropriate authorities. However, the legal restrictions on disclosure continue to apply to the original alcohol or drug abuse patient records maintained by the program, including any requested disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect [42 C.F.R. Section 2.12(c)(6)]. The HIPAA Privacy Rule permits disclosure of PHI to public health and other government authorities authorized to receive reports of child abuse or neglect [45 C.F.R. Section 164.512(b)(1)(ii)].

E. VETERANS' ADMINISTRATION AND ARMED FORCES

Records and information maintained by the Veterans' Administration and the Armed Forces [42 C.F.R Section 2.12(c)(1) and (2)] may be disclosed in limited circumstances. Facilities operated by these branches of the federal government should consult their legal counsel regarding the disclosure of substance abuse information. HIPAA has a somewhat related provision at 45 C.F.R. Section 164.512(k).

F. MEDICAL EMERGENCIES

Information may be disclosed to medical personnel who need the information to treat a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention [42 C.F.R. Section 2.51(a)]. HIPAA also permits the use or disclosure of health information for treatment purposes.

Information may also be disclosed to medical personnel of the Food and Drug Administration (FDA) who believe that the patient may be threatened by an error in manufacturing, 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 [42 C.F.R. Section 2.51(b)]. The HIPAA Privacy Rule also permits the disclosure of patient information to the FDA for such purposes [45 C.F.R. Section 164.512(b)(1)(iii)].

Immediately following disclosure in the above situations, the program must document the disclosure in the patient's medical record, noting in writing the following:

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

[42 C.F.R. Section 2.51(c)]

The HIPAA Privacy Rule requires covered entities to document disclosure of PHI, with certain significant exceptions. *(See V. "Right to Accounting of Disclosures of PHI," page 6.12, regarding required accounting of disclosures of PHI*

and F. "Documentation and Copies," page 7.4, regarding documentation of disclosures pursuant to a patient authorization.)

G. RESEARCH ACTIVITIES

Under the substance abuse regulations, information may be disclosed for the purpose of conducting scientific research if the program director determines that the recipient of the patient-identifiable information is qualified to conduct the research and has a research protocol under which the patient-identifiable information will be maintained in accordance with specified security requirements under the regulations *(see 42 C.F.R. Section 2.16 for security requirements)*, or more stringent requirements, and such information will not be redisclosed except back to the program from which that information was obtained [42 C.F.R. Section 2.52]. The program director must also determine that the recipient of the patient-identifiable information 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 the rights and welfare of patients will be adequately protected, and the risks in disclosing patient-identifiable information are outweighed by the potential benefits of the research [42 C.F.R. Section 2.52(a)(3)]. The HIPAA Privacy Rule includes strict limitations and standards for the use of patient health information in research in the absence of patient authorization. Treatment programs would have to meet the criteria of both sets of regulations in order to use or disclose patient health information for research. *(See chapter 8 of CHA's* California Health Information Privacy Manual *for a full discussion of additional requirements related to the confidentiality of research records.)*

H. AUDIT AND EVALUATION ACTIVITIES

The substance abuse regulations contain specific provisions for the use or disclosure of patient information for audit or evaluation activities. These are also permissible under the HIPAA Privacy Rule, which permits use or disclosure of PHI to a health oversight agency [45 C.F.R. Section 164.512(d)], or for payment and health care operations. The more restrictive provisions of the substance abuse regulations should be followed with respect to such uses or disclosures. In some cases, however, disclosure to these bodies (e.g., disclosure to The Joint Commission for accreditation purposes) will require the body to enter into a business associate agreement with the program meeting the requirements of the HIPAA Privacy Rule.

GENERAL PRINCIPLE

Information may be disclosed for audit by:

1. An appropriate federal, state, or local governmental agency that provides financial assistance to the program or is authorized by law to regulate its activities;
2. A third party payer covering patients in the program;
3. A private person or entity that provides financial assistance to the program;
4. A quality improvement organization performing utilization or quality control review; or
5. An entity authorized to conduct a Medicare or Medicaid audit or evaluation.

[42 C.F.R. Section 2.53(a) and (c)]

Records Not Copied or Removed

Where patient-identifiable information is disclosed to a person or entity listed in the preceding paragraph for review on the premises, but not copied or removed, the person to whom the information is disclosed must agree in writing to disclose the identifying information only back to the program from which it was obtained, and to use it only for audit or evaluation purposes or to investigate or prosecute criminal activities as authorized by an appropriate court order [42 C.F.R. Section 2.53(a) and (d)].

Copying or Removal of Record

Where patient-identifiable information is disclosed to a person or entity listed in "General Principle," above for copying or removal from program premises, the person to whom the disclosure is made must agree in writing:

1. To maintain the patient-identifiable information in accordance with the security requirements provided under these regulations *(see 42 C.F.R. Section 2.16 for security requirements)*, or more stringent requirements;
2. To destroy all the patient-identifiable information upon completion of the audit or evaluation; and
3. To disclose the identifying information only back to the program from which it was obtained and to use it only for audit or evaluation purposes or to investigate or prosecute criminal activities as authorized by an appropriate court order [42 C.F.R. Section 2.53(b) and (d)].

ADDITIONAL REQUIREMENTS

In summary, both the substance abuse regulations and the HIPAA Privacy Rule permit programs to disclose patient-identifying information to qualified persons who are conducting an audit or evaluation of the program, without patient consent, provided that certain safeguards are met. The HIPAA Privacy Rule requires that uses and disclosures be limited to the minimum necessary to accomplish the audit or evaluation. *(See VI. "'Minimum Necessary' Use and Disclosure," page 7.9.)*

Each rule has its own additional requirements. Substance abuse treatment programs subject to both regulations must combine those requirements. Three options result:

1. If the audit or evaluation is conducted by a program or its employees, it is permissible under both sets of regulations; no patient consent or authorization is required. [42 C.F.R. Section 2.12(c)(3) and 45 C.F.R. Section 64.502(a)(1)(ii)]

2. If the audit or evaluation is conducted by a **"health oversight agency"** (an agency acting under authority of the federal or state or local government, that is authorized by law to oversee the health care system or government programs in which health information is necessary to determine eligibility or compliance or to enforce civil rights laws for which health information is relevant [45 C.F.R. Section 164.501]), the program may disclose patient-identifying information so long as the health oversight agency makes the written commitments required by the substance abuse regulations [42 C.F.R. Section 2.53(d)] and the disclosure meets the requirements in the HIPAA Privacy Rule [45 C.F.R. Section 164.512(d)].

   If the health oversight agency copies or removes patient records from the program, it must agree in writing to abide by the requirements of the substance abuse regulations [42 C.F.R. Section 2.53(b)].

   Disclosures to health oversight agencies when the patient is the subject of the investigation are prohibited under certain circumstances [45 C.F.R. Section 164.512(d)(2)].

3. If an audit or evaluation is conducted by an outside entity on behalf of the program as opposed to a health oversight agency (e.g., by The Joint Commission) the program must have signed a business associate agreement with the entity that satisfies the requirements of both the HIPAA Privacy Rule and the substance abuse regulations.

I. VITAL STATISTICS AND CORONER'S CASES

Disclosure of deceased patients' records are permitted without patient authorization under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death [42 C.F.R. Section 2.15(b)(1)]. HIPAA allows such disclosures [45 C.F.R. Section 164.512(b)(l)(i) and (g)].

VII. RELEASE OF INFORMATION IN RESPONSE TO A SUBPOENA OR OTHER LEGAL PROCESS

A. COURT AUTHORIZATION REQUIRED

Information protected by the substance abuse regulations may not be released in response to a subpoena or any other discovery mechanism, or even in response to a court order for discovery, unless the release has been specifically authorized by a separate court order that meets the requirements specified in the federal regulations [42 C.F.R. Sections 2.13(a) and 2.61-2.67]. The HIPAA Privacy Rule generally permits the release of records pursuant to subpoena, so long as certain notice requirements have been met [45 C.F.R. Section 164.512(e)]. The more restrictive requirements of the substance abuse regulations must be followed.

LEGAL EFFECT OF A COURT ORDER

A court order entered under these regulations is a unique kind of court order. Its only purpose is to authorize a disclosure of patient information that would otherwise be prohibited by federal law and regulations. Such an order authorizes, but does not compel, disclosure. A subpoena or a similar legal mandate must also be issued to compel disclosure. This mandate may be entered at the same time as, and accompany, an authorizing court order entered under these regulations [42 C.F.R. Section 2.61]. Some examples follow:

1. A hospital holding records subject to these regulations receives a subpoena for those records. The hospital may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under these regulations [42 C.F.R. Section 2.61(b)(1)].

2. An authorizing court order is entered under these regulations, but the hospital does not want to make the disclosure. If there is no subpoena or other compulsory process, or the subpoena for the records has expired or been quashed, the hospital may refuse to make the disclosure. However, upon the entry of a valid subpoena or other compulsory process the hospital must disclose the records, unless there is a valid legal defense to the process other than the confidentiality restrictions of these regulations [42 C.F.R. Section 2.61(b)(2)].

SPECIAL APPLICATIONS

Information Supplied for Research, Audit or Evaluation

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 may authorize disclosure and use of records to investigate or prosecute the personnel holding the records [42 C.F.R. Section 2.62].

Confidential Communications by the Patient

A court order may authorize the 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; or
2. The disclosure is necessary in connection with the investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or
3. The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the context of the confidential communication.

[42 C.F.R. Section 2.63]

B. PROCEDURES AND CRITERIA FOR COURT ORDERS

The regulations establish procedures and criteria for obtaining court orders in four different situations:

1. For noncriminal purposes,
2. To criminally investigate or prosecute patients,
3. To investigate or prosecute a program or the person holding the records, and
4. To criminally investigate employees or agents of a program.

[42 C.F.R. Sections 2.64-2.67]

The criteria and procedures are somewhat different in each instance, and custodians of alcohol and drug abuse records are therefore advised to contact legal counsel whenever they receive a subpoena or court order requesting access to them. Noncompliance with a valid court order may constitute contempt of court and subject the record holder to civil or criminal penalties.

For purposes of illustration and because requests for records made in the context of a noncriminal, or civil, lawsuit are most common, the following describes the procedures and criteria used in such situations.

PROCEDURES AND CRITERIA FOR ORDERS AUTHORIZING DISCLOSURE FOR NONCRIMINAL PURPOSES

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 that 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 a patient and may not contain or otherwise disclose any patient-identifiable 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.

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-identifiable 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.

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-identifiable 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 the federal regulations. The proceeding may include an examination by the judge of the patient's records referred to in the application.

Criteria for Entry of Order

An order 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.

Content of Order

An order authorizing a disclosure must:

1. Limit disclosure to those parts of the patient's record that are essential to fulfill the objective of the order;
2. Limit disclosure to those persons whose need for the 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 physi-

cian 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.

CHA has prepared a model order, "Order for Production of Substance Abuse Records" (CHA Appendix 18-A), that may be offered to the judge for use in issuing the order.

[42 C.F.R. Section 2.64]

IF THE PATIENT CONSENTS

No court order is required for disclosure if the patient has given written authorization that complies with all applicable laws, including HIPAA and California law.

OTHER LAWS APPLICABLE

The requirement for court authorization also does not apply if the information requested by the subpoena does not indicate in any manner that the patient was diagnosed or treated for alcohol or drug abuse; in such case, however, to the extent that PHI is being sought, the subpoena would have to meet the general requirements for subpoenas. *(See VII. "Disclosure of PHI Pursuant to Subpoena," page 8.25.)*

If the information and records are also subject to the restrictions in Welfare and Institutions Code Section 5328 *et seq.* of the Lanterman-Petris-Short Act *(see F. "Response to a Subpoena That Requests LPS Records," page 9.14)*, the hospital should release the records or information only to the court, and not to a notary, hearing officer, referee, administrative agency, or other quasi-judicial body. In such cases, the hospital should follow the procedure for evaluation of, and compliance with, a subpoena for information and records governed by the provisions in the Lanterman-Petris-Short Act (which are discussed in F. "Response to a Subpoena That Requests LPS Records," page 9.14) in addition to the specific requirement for an authorizing court order pursuant to the federal regulations. Other state or federal laws may also limit disclosure of the information requested because it is privileged information or is otherwise protected by law *(see "Privileged and Confidential Information," page 8.25, regarding privileged information and B. "HIV Test Results," page 7.6, regarding HIV test results)*.

ADVICE OF LEGAL COUNSEL

As noted above, it is recommended that a hospital not respond to a subpoena or other legal process for records it believes to be covered by federal substance abuse regulations without the advice of legal counsel.

C. RESPONSE TO IMPROPER SUBPOENA OR OTHER LEGAL PROCESS

If a person holding confidential records receives a subpoena for those records, disclosing the records is not permitted unless an authorizing court order is entered.

If there is no subpoena or other compulsory process or a subpoena for the records has expired or has been quashed, a person holding confidential records may refuse to make the disclosure. *(See D. "Response to Unauthorized Request," page 10.4, regarding the response permitted.)* (A subpoena is "quashed" when someone — usually the patient whose records are sought or the health care provider holding the requested records — challenges the subpoena in court, and the judge rules that the records should not be disclosed. The judge invalidates or "quashes" the subpoena.)

VIII. OTHER RESTRICTIONS ON SUBSTANCE ABUSE RECORDS

A. STATE LAW RESTRICTIONS ON NARCOTIC AND DRUG ABUSE RECORDS

State law establishes that records maintained in connection with the performance of certain substance abuse programs are confidential and can be disclosed only for the purposes and under the circumstances described below [Health and Safety Code Section 11845.5]. The content of these records may also be disclosed with the prior written authorization of the patient. The statutory restrictions apply to "any alcohol and other drug abuse treatment or prevention effort or function conducted, regulated, or directly or indirectly assisted by the [California Department of Alcohol and Drug Programs]" [Health and Safety Code Sedtion 11845.5(a)]. Such programs must be registered with the county, and thus it can be easily determined whether a program falls within this category. According to the California Department of Alcohol and Drug Programs, Health and Safety Code Section 11845.5 does not apply to general acute care hospitals or chemical dependency recovery hospitals.

Without patient consent, the content of such records may be disclosed only in the following circumstances:

1. In communications between qualified professional persons employed by the treatment or prevention program in the provision of service.
2. To qualified medical persons not employed by the treatment program to the extent necessary to meet a bona fide medical emergency.
3. To qualified personnel for the purpose of conducting scientific research, management audits, financial and compliance audits, or program evaluation. Such personnel are not to identify, directly or indirectly, any

individual patient in any report of the research, audit, or evaluation, or otherwise disclose patient identities in any manner.

"Qualified personnel" is defined as persons whose training and experience are appropriate to the nature and level of work in which they are engaged, and who, when working as part of an organization, are performing that work with adequate administrative safeguards against unauthorized disclosures.

4. If the recipient of services is a minor, ward, or conservatee, and his or her parent, guardian, or conservator designates, in writing, persons to whom his or her identity in records or information may be disclosed. However, a physician, psychologist, social worker, nurse, attorney, or other professional person is not required to reveal information that has been given to him or her in confidence by members of the patient's family. This state law conflicts with federal law with respect to patients 12 years of age or older obtaining services from a federally-assisted program; thus, it is recommended that legal counsel be consulted when a minor's parent attempts to obtain access to, or authorize disclosure of, the minor's information *(see E. "Authorization for Minor," page 10.5).*
5. If authorized by a court, granted after showing probable cause therefor, as provided in Penal Code Section 1524(c). This statute governs disclosures to law enforcement agencies pursuant to a search warrant. Except as authorized by such a court order, no record may be used to initiate or substantiate criminal charges against a patient or to conduct an investigation of a patient.

In the absence of a court order, the records may not be released in response to a subpoena or other request for disclosure that is issued in connection with a legal proceeding or governmental investigation.

It is recommended that the facility obtain the advice of legal counsel before releasing any records or information pursuant to a subpoena or any other type of request for disclosure.

The prohibitions against disclosure will continue to apply to records concerning an individual who has been a patient, irrespective of whether he or she ceases to be a patient.

B. STATE LAW RESTRICTIONS ON ALCOHOL ABUSE RECORDS

State law provides that all personal information and records obtained by the county, a program which has a contract with the county, or the California Department of Alcohol and Drug Programs pursuant to the provision of alcohol services are confidential and may be disclosed only in those instances designated in Welfare and Institutions Code Section 5328. [Health and Safety Code Section 11812] *(See chapter 9.)*

SUBSTANCE ABUSE PROGRAM NOTICE OF PROHIBITION OF REDISCLOSURE

Date: _____

Re: _____
(name of patient)

Date of birth: _____

Dr. _____
(physician name)

This information has been disclosed to you from records protected by federal confidentiality rules (42 C.F.R. part 2).

The federal rules prohibit you from making any further disclosure of the information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains, or as otherwise permitted by 42 C.F.R. 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.

Date: _____ Time: _____ AM / PM

Signature: _____
(medical records staff)

Print name: _____
(medical records staff)

ORDER FOR PRODUCTION OF SUBSTANCE ABUSE RECORDS

Noncriminal Cases Only

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF _____

In the Matter of the Petition of

_____ *
_____

No. _____

ORDER RE: PRODUCTION OF SUBSTANCE ABUSE RECORDS OF

It appearing to the court that:

1. A valid subpoena duces tecum has been served on the custodian of records of (name of hospital): _____ _____("custodian of records"); and
2. Said subpoena seeks records relating to treatment for alcohol and/or drug abuse of the following patient*: _____; and
3. The custodian of records has produced said records for the court's preliminary review in camera; and
4. Said records contain information subject to the confidentiality requirements of 42 U.S.C. Section 290dd-2 and 42 C.F.R. part 2; and
5. Disclosure of the information contained in said records as described below is necessary in the interests of justice, and other ways of obtaining this information are not available or would not be effective; and
6. The public interest and need for disclosure outweigh the potential injury to the patient, the physician-patient and/or the psychotherapist-patient relationship, and the treatment services; and
7. The public interest will best be served by disclosure of said information; and

Said records contain no information that would be prohibited from disclosure by the physician-patient privilege, psychotherapist-patient privilege or any other privilege.

NOW, GOOD CAUSE APPEARING THEREFOR, IT IS ORDERED THAT:

1. The custodian of records is to deliver to this court the drug/alcohol abuse records of * _____ _____ for use only in these proceedings.
2. The following portions of said records contain information essential to fulfill the objectives of this order: _____.
3. Disclosure of the records identified in paragraph 2 (may/shall) be made to the following persons whose need for the information is the basis for this order: _____ _____.
4. The clerk of the court shall seal from public access such of the said records as may become part of this court's records, whether as evidence or otherwise
5. Any person who obtains copies of the records disclosed pursuant to this order shall maintain their confidentiality and shall make no further disclosure except as provided by law or by order of this court.

Upon termination of these proceedings, including any appeal, the parties and their counsel shall destroy all copies of records and information pursuant to this order. Any original records shall be returned to the hospital.

Date: _____ Time: _____ AM / PM

Signature: _____
(judge)

Print name: _____
(judge)

**Unless the records of this proceeding are ordered by the court to be sealed from the public scrutiny, references to the patient must use a fictitious name (e.g., John Doe or Jane Doe) and may not otherwise contain any patient-identifying information. [42 C.F.R.Section 2.64(a)]*

NOTICE TO PATIENT: CONFIDENTIALITY OF SUBSTANCE 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:

- ***The patient consents in writing,***
- ***The disclosure is allowed by a court order, or***
- ***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 law 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.

Ref. 42 U.S.C. Section 290dd-2 for federal statutes and 42 C.F.R. part 2 for federal regulations.