

Confidentiality of Patient Records for Alcohol and Other Drug Treatment

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Chapter 1—Overview of Federal Alcohol and Other Drug Confidentiality Law and Regulations

The regulations that protect the identities of persons in alcohol or drug abuse treatment have their genesis in two statutes of the early 1970's: the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 and the Drug Abuse Prevention, Treatment and Rehabilitation Act of 1972. These statutes were implemented by regulations issued by the then Department of Health, Education and Welfare (HEW) in 1975. Revised in 1987 by one of HEW's successors, the Department of Health and Human Services, the regulations are set out at title 42, part 2, of the Code of Federal Regulations. Recently, Congress reaffirmed and reorganized the original confidentiality statutes by merging them into one act, the Public Health Service Act, now title 42, section 290dd-3, of the United States Code. The merger had no effect on the confidentiality regulations. Throughout this document, references to the confidentiality law or regulations will mean the regulations at title 42, part 2, of the Code of Federal Regulations.

Purpose of the Law

The Federal drug and alcohol confidentiality laws are predicated on the public health view that people with substance abuse problems are likelier to seek (and succeed at) treatment if they are assured that their need for treatment will not be disclosed unnecessarily to others. The congressional committee that put the original drug confidentiality statute into final form noted in its report: "The conferees wish to stress their conviction that the strictest adherence to . . . [confidentiality] is absolutely essential to the success of all drug abuse prevention programs. Every patient and former patient must be assured that his right to privacy will be protected. Without that assurance, fear of public disclosure of drug abuse or of records that will attach for life will discourage thousands from seeking the treatment they must have if this tragic national problem is to be overcome."¹ In keeping with this view, the drug and alcohol confidentiality regulations restrict both the disclosure and the use of information about individuals in federally assisted drug or alcohol abuse treatment programs.²

Scope of the Law

The Federal alcohol and drug confidentiality regulations restrict the disclosure and use of "patient identifying" information about individuals in substance abuse treatment. Patient-identifying information is information that reveals that a person is receiving, has received, or has applied for substance abuse treatment.³ What the regulations protect is not the individual's identity per se, but rather his or her identity as a participant in or applicant for substance abuse treatment.

To Whom Does the Law Apply?

The regulations apply to holders, recipients, and seekers of patient-identifying information. An individual or program in possession of such information—for example, a federally assisted substance abuse program—may not release it except as authorized by the patient concerned or as otherwise permitted by the regulations. Anyone who receives such information from a substance abuse program may not redisclose it without patient consent or as otherwise authorized by the regulations and may not use it except for certain purposes discussed below under "Exceptions to the Rule for Holders of Patient-Identifying Information." Finally, anyone seeking such information may not compel its disclosure except as permitted by the regulations.⁴

The Strictness of the Federal Regulations

The Federal drug and alcohol confidentiality regulations are stricter than most other confidentiality rules. In general, they apply whether the person seeking the information already has it, is seeking it for a judicial or administrative proceeding, is a law enforcement or other government official,⁵ has a subpoena or a search warrant, or is the spouse, parent, relative, employer, or friend of the patient.

What Are the Consequences of Violating or Disregarding the Law?

Violators of the regulations are subject to a criminal penalty in the form of a fine of up to \$500 for the first offense and up to \$5,000 for each subsequent offense.⁶ Violators that are licensed or State certified (which would include virtually all programs and their professional employees) jeopardize their license or certification. The patients concerned may also sue violators for unauthorized disclosure.⁷

Conflicts With State Laws

State confidentiality law may be more restrictive than but may not override the Federal regulations. Where State law is not stricter and conflicts with the Federal regulations, State law must yield. Even where State law conflicts with the regulations, however, the State law can usually be complied with through one of the many exceptions to the regulations.

General Rule for Holders of Patient-Identifying Information

The general rule is that a federally assisted drug or alcohol abuse program may not disclose, directly or indirectly, the identity of its former, current, or would-be patients. However, the rule is not absolute, and most requests for patient-identifying information can be accommodated by one or another exception to the rule. This section explores the elements of the rule.

What Is a Program?

The regulations apply to federally assisted organizations and individual practitioners (for example, psychologists, physicians, or even acupuncturists) that specialize in providing, in whole or in part, individualized (that is, one-to-one)⁸ alcohol or drug abuse diagnosis, treatment, or referral for treatment.⁹ The regulations apply to both freestanding programs and programs that are part of larger organizations, for example, a detoxification unit in a general hospital or a substance abuse clinic in a county mental health department. Part- and full-time employees, volunteers, student interns, former staff, and executive, administrative, clinical, and support personnel must comply with the regulations.

What Does It Mean To Be Federally Assisted?

A program is federally assisted if it is directly funded by the Federal Government, is operated by the Federal Government, is certified for medicaid reimbursement, receives Federal block grant funds through a State or local government, is licensed by the Federal Government (for example, to dispense methadone), or is exempt from paying taxes under a provision of the Federal Internal Revenue Code.

What Is a Disclosure of Patient-Identifying Information?

A disclosure of patient-identifying information is any communication that directly or indirectly identifies someone as being in, having been in, or having applied for treatment in a substance abuse program. A program will have made a patient-identifying disclosure where it discloses a patient's record, permits an employee to testify about a patient's treatment, allows a receptionist to confirm that a particular person is a patient of the program, uses stationery that suggests that the addressee may be one of its patients, or discloses anecdotal material from which a patient's identity may be inferred.

Who Is a Patient?

A patient is anyone who has applied for or received a diagnostic examination or interview, treatment, or referral for treatment for drug or alcohol abuse from a drug or alcohol program. Applicants for such services are covered by the regulations even if they fail to show for their initial appointment or evaluation or, having been interviewed or diagnosed, elect not to follow up or enter treatment. The regulations protect current, former, and deceased patients.

Exceptions to the Rule for Holders of Patient-Identifying Information

The Federal confidentiality regulations are strict, but not absolute. They allow patient-identifying disclosures in several situations.

Internal Program Communications

Patient-identifying information may be disclosed within a program, or to an entity having direct administrative control over a program, if the recipient of the disclosure needs the information to provide substance abuse services to the patient. "Within the program" means within the organization or organizational unit that provides substance abuse services. This means, for example, that the staff of a detoxification unit within a hospital may share patient-identifying information with one another—and with hospital administrators with direct supervisory oversight for the program—where such sharing of information is needed to provide substance abuse services to the program's patients. The program may also share information, where necessary, with, for example, the hospital's recordkeeping or billing departments, since those units are integral to the program's functioning. However, the program may not freely share patient-identifying information with other parts or units of the hospital. Anyone within or in direct administrative control of a program who receives patient-identifying information is bound by the confidentiality regulations and may not redisclose the information except as allowed by the regulations.

Consent

Generally, a program may disclose any information about a patient if the patient authorizes it by signing a valid consent form.¹⁰ To be valid, a consent must specify the following:

- The name of the patient
- The name of the program making the disclosure
- The purpose of the disclosure
- Who is to receive the information
- The information to be released (described as exactly and as narrowly as possible in light of the purpose of the release)
- That the patient understands that he or she may revoke the consent at any time, except to the extent that action has been taken in reliance on it¹¹
- That revocation may be oral as well as written
- The date or condition upon which the consent expires, if it has not been revoked earlier
- The date the consent form is signed
- The signature of the patient¹²

A proper consent—that is, a consent that includes the foregoing features—will permit a holder of patient-identifying information to make patient-identifying disclosures to outsiders, such as probation officers, employers, or relatives of the patient. When making a disclosure pursuant to such a consent, a program need not send a copy of the consent to the recipient of the disclosed material. Where, however, the program is asked for a disclosure by someone outside the program, it will have to receive a copy of the consent before it may respond to the request. The

regulations permit a program to make a patient-identifying disclosure pursuant to a copy (as opposed to the original) of a consent.¹³

Whenever a disclosure is made pursuant to a consent, it must be accompanied by a written notice prohibiting redisclosure.¹⁴ The notice prohibiting redisclosure warns the recipient that the information disclosed is protected by Federal law and may not be redisclosed except with the patient's consent or under an exception to the regulations. The prohibition-on-redisclosure notice must be sent to the recipient even where the disclosure was made orally.

Anonymous or Non-Patient-Identifying Information

That programs may not disclose patient-identifying information does not mean that they may not disclose a patient's identity. (Patient-identifying information is information that reveals that the patient is in, has been in, or has applied for substance abuse treatment.) What programs are prohibited from disclosing—except where authorized by the patient or the regulations—is a patient's participation in treatment. Thus, a disclosure may reveal a patient's name, address, or even telephone number without violating the regulations.¹⁵ What a given disclosure may not reveal is the nature of the services received by the patient or provided by the program.¹⁶

Qualified Service Organization Agreement

Programs may disclose information to a "qualified service organization" without the patient's consent.¹⁷ A "service organization" is a person or agency that provides services—such as data processing, dosage preparation, laboratory analyses, vocational counseling, or legal, medical, accounting, or other professional services—to a program that the program does not provide for itself. As the provision of such services may entail patient-identifying disclosures, the outside agency must be "qualified" to communicate freely with the treatment program. To become qualified, the service organization must enter a written agreement with the program in which it acknowledges that it is bound by the Federal confidentiality regulations, promises not to redisclose patient-identifying information to which it becomes privy, and promises to resist unauthorized efforts to gain access to any patient-identifying information that may come into its possession.¹⁸

Once the program and the outside agency have entered an agreement of this kind, the program may freely communicate information from patient records to the qualified service organization, but only that information needed by the organization to provide services to the program. Although programs may enter into qualified service organization agreements with a variety of outside organizations, they are not permitted—according to a legal opinion of the Department of Health and Human Services, which revised the regulations in 1987—to enter them with one another (unless the one offers a service that the other cannot provide) or with law enforcement agencies. A program need not inform its patients of the qualified service organization agreements to which it is a party.

Crimes on Program Premises or Against Program Personnel

The regulations permit a program to release patient-identifying information to the police where a patient commits or threatens to commit a crime on the premises or against program staff. Under these circumstances, the program may give the police the patient's name, address, and last known whereabouts. The exception does not permit the program to report a patient's other crimes.

Medical Emergencies

Even without consent, patient-identifying information may be disclosed to certain persons in a medical emergency.¹⁹ A medical emergency is a situation that poses an immediate threat to the health of an individual (it need not be the patient) and requires immediate medical intervention.²⁰ Under this exception, a program may release patient-identifying information to medical personnel who need the information to treat the medical condition. The medical-emergency exception may not be invoked to disclose patient-identifying information to the patient's family or other nonmedical personnel.

Mandated Reports of Child Abuse or Neglect

All States require people in certain positions or occupations to report cases of suspected child abuse or neglect to the relevant child welfare authorities. In 1986, the Federal regulations were amended to permit substance abuse programs to comply with such laws. Today, the Federal 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."²¹ This means that program staff may make reports to local child abuse hotlines and even confirm the reports in writing. However, the regulations "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." This means that while a program may make State-mandated child abuse reports, it must still protect patient records from subsequent disclosures (even as against local child welfare investigators) and, absent patient consent or a court order, may not permit them to be used in child abuse proceedings against the patient.

Research

Under certain circumstances, a program may allow a researcher to have access to its patients' records.²² In the event, the program director must determine that the researcher is qualified, that the researcher has a protocol under which the security of patient records is assured,²³ and that patient-identifying information will not be redisclosed. Additionally, three or more independent evaluators must have reviewed the research protocol and determined that the rights and welfare of the patients concerned will be adequately protected and that the potential benefits of the research outweigh the risks to patient confidentiality. Researchers are barred from redisclosing patient-identifying information except back to the program itself.

Audit and Evaluation

Certain qualified individuals or organizations may have access to program records for audits or evaluations of the program.²⁴ By definition, an audit or evaluation is a time-limited activity that may not be used to gain access to program records on an ongoing basis. Audits or evaluations may be conducted by regulatory agencies, funders, private third-party payers, and private peer review organizations.²⁵ Information disclosed during an audit or evaluation may not be redisclosed except pursuant to a court order (where a program is being investigated) or to determine compliance by the program with medicaid or medicare regulations. If the auditor or evaluator wishes to copy or remove records, he or she must agree in writing to protect patient-identifying information, destroy all such information on completion of the audit or evaluation, and not use the information except for purposes of the audit or evaluation.

Court Orders

A Federal, State, or local court may authorize a program to make a disclosure of confidential patient-identifying information. A court may issue such an order, however, only after following certain procedures and making certain determinations specified in the regulations.²⁶ A subpoena, search warrant, or arrest warrant, even when it is signed by a judge, is not sufficient, by itself, to require or even permit a program to make a disclosure.²⁷

Procedures and Restrictions

Before a court can issue an order authorizing a disclosure, the program and the patient whose records are sought must be given notice of the application for the order and some opportunity to make an oral or written statement in response. (However, if the information is being sought to investigate or prosecute a patient, the patient is not entitled to notice.²⁸ Similarly, where the program is being investigated, the program is not entitled to notice.²⁹) The application and any court order must use a fictitious name for the patient. All court order proceedings in connection with the application must be confidential unless the patient requests otherwise.³⁰

Before it may order the disclosure of confidential patient information, a court must find that there is "good cause" for the disclosure. A court can find good cause only if it determines that the public interest and the need for disclosure outweigh any adverse effect that the disclosure may have on the patient, the doctor-patient relationship, or the effectiveness of the program's treatment services. If the information is available from another source, the court may not issue the order.³¹ The judge is entitled to examine the records before making a decision.³²

Even where good cause for disclosure exists, there are limits to the scope of the disclosure that the court may authorize. In fact, disclosure must be limited to the information essential to the purpose of the order, and the dissemination of the information must be restricted to those persons who need it to fulfill the purpose of the order. The court should also take steps to protect the patient's confidentiality, for example, by sealing the records of the proceeding.³³

Where the information sought is a "confidential communication," it may not be disclosed unless the disclosure is necessary to protect against a threat to life or of serious bodily injury, is

necessary to investigate or prosecute an extremely serious crime, or is connected with a proceeding in which the patient has already presented evidence concerning the confidential communication.³⁴ In all other situations, not even a court can order disclosure of a confidential communication.

Procedures in Criminal Investigations

Where an investigative, law enforcement, or prosecutorial agency seeks an order authorizing a disclosure for the purpose of investigating or prosecuting a patient,³⁵ it must demonstrate the following:

- The crime involved is extremely serious, that is, one that causes or threatens to cause death or serious injury³⁶
- The records sought are likely to contain information of significance to the investigation or prosecution
- There is no other practical way to obtain the information
- The public interest in disclosure outweighs any actual or potential harm to the patient, the doctor-patient relationship, or the ability of the program to provide services to other patients
- The program has had an opportunity to be represented by independent counsel
- (When the program is a governmental entity, it must be represented by counsel.)³⁷

Where the order is sought to prosecute a patient, the court must follow the same procedures that apply to court-ordered disclosures generally (except that the patient need not be given notice). In addition, a court order authorizing a disclosure for the purpose of investigating or prosecuting a patient must limit the disclosure to those parts of the patient's record that are essential to the purpose of the order. Further, only those law enforcement and prosecutorial officials responsible for conducting the investigation or prosecution may have access to the information. As with other applications, the court may not order the disclosure of "confidential communications" except in narrowly defined circumstances (see "Procedures and Restrictions" above). Under no circumstances may a court authorize a program to turn over a patient's entire record to a law enforcement, investigative, or prosecutorial agency.³⁸

Restrictions on Redislosure

That patient-identifying information may be disclosed pursuant to one of the many exceptions to the general rule does not mean that the disclosed information is no longer protected. Indeed, as noted above, information released pursuant to a consent must be accompanied by a written notice informing the recipient that the information he or she has received is protected by Federal law and may not be redisclosed except as provided for in the regulations. No one who receives patient-identifying information under the regulations—including third-party payers, government employees, program staff, administrators, criminal investigators and law enforcement personnel, court personnel, researchers, auditors, evaluators, and employees of qualified service organizations—may redisclose it unless authorized to do so by the patient, a court order, or another exception to the regulations.

Restrictions on Use

Except pursuant to a court order, information subject to the regulations may not be used to initiate, investigate, or substantiate criminal charges against a patient. In addition, patient-identifying information obtained in violation of the regulations can be excluded from evidence in both civil and criminal proceedings.

Footnotes

¹H.R. Rep. No. 92_920, 92d Cong., 2d Sess., p. 33 (in U.S. Code Cong. & Admin. News, 1972, p. 2072).

²42 CFR § 2.3(a).

³42 CFR § 2.11.

442 CFR § 2.13(b).

⁵42 CFR §§ 2.13(b), 2.20. This includes public health officials. However, holders of patient-identifying information can invoke exceptions to the regulations to comply with their public health obligations, such as the reporting of cases of tuberculosis as mandated by State law.

⁶42 CFR § 2.4. Violations may be reported to the local U.S. attorney. Violations by methadone programs may be reported to the regional offices of the Food and Drug Administration (42 CFR § 2.5).

⁷Evidence used or obtained in violation of the regulations may be excluded in both civil and criminal cases. See *United States v. Eide*, 875 F. 2d 1429 (9th Cir. 1989) (excluding illegally seized records in criminal prosecution), and *Jeanette "A" v. Condon*, 728 F. Supp. 204 (S.D.N.Y. 1990) (prohibiting an employer from terminating an employee on the basis of an improperly disclosed urinalysis result).

⁸Programs that provide generalized services are not covered by the regulations. Thus, a classroom education program aimed at all the students in a class or a grade is not covered. However, should an employee of such a program engage a student in one-to-one or even group counseling, the program would become subject to the regulations.

⁹The regulations apply whether a program provides all three or just one of the following services for drug or alcohol abuse: diagnosis, treatment, or referral for treatment.

1042 CFR §§ 2.31, 2.33. It should be noted that consents authorize but do not compel programs to make a disclosure.

¹¹Depending on State law, a consent for a patient referred by the criminal justice system may be made irrevocable for a period of time (42 CFR § 2.35). Some States have statutes that provide for the automatic expiration of such consents after 60 or 90 days.

¹²If the patient has died, the executor or administrator of the estate or, if there is none, the spouse or closest other relative of the deceased patient may sign (42 CFR § 2.15(b)(2)). If the patient dies while in the program, no consent is needed to disclose information relating to the cause of death to such agencies as are empowered to collect vital statistics or inquire into causes of death (42 CFR § 2.15(b)(1)). If the patient is incompetent, a person appointed by a court to oversee his or her affairs may sign (42 CFR § 2.15(a)). If the patient is a minor, the patient must still always sign the consent form. If State law requires parental consent for treating a minor, a parent's signature will be required, in addition to the minor's, for any release (42CFR § 2.14(c)). If the State permits the minor to be treated without parental consent, the minor's signature alone may authorize a disclosure (42CFR § 2.14(b)).

¹³Disclosures to a central methadone registry must be made with patient consent (42 CFR § 2.34). A central registry collects information about patients applying for methadone maintenance or detoxification. (The registry is intended to prevent dual enrollments.) A program may disclose records to any central registry not more than 200 miles away. Such disclosures may be made only when a patient is accepted for treatment, changes type or dosage of drug, or ends, interrupts, or resumes treatment. Patient consent is required in writing, but programs may refuse to enroll patients who will not consent. Disclosed information must be limited to the patient's name and identifying information, dosage of drug, and relevant dates. The registry may disclose to its member programs the names, addresses, and telephone numbers of any other programs in which the patient is enrolled. Those programs may then communicate with one another without patient consent, but only to the extent necessary to verify that no error has been made or to prevent or eliminate any multiple enrollment.

¹⁴42 CFR § 2.32.

¹⁵Thus, if a patient threatened to harm his or her spouse, the program might make an anonymous telephone call to the spouse or even the police. To be effective, of course, such a call would require the program to disclose the patient's name. It would not, however, require the program to disclose its name or the fact that the patient is in substance abuse treatment.

¹⁶Where a program is part of a larger organization, such as a general hospital, and is required to make reports of communicable diseases, such as tuberculosis or human immunodeficiency virus, it can discharge its reporting obligation by using the larger organization's name and address. Thus, the detoxification unit of a general hospital would make the necessary report under the name of the hospital. It should be noted that some courts have found a duty to warn where there is an identifiable victim. In such cases, a program may very well have to notify both the relevant authorities and the potential victim, and, in the process, may even have to disclose patient-identifying information.

¹⁷42 CFR § 2.12(c)(4).

¹⁸42 CFR § 2.11.

¹⁹42 CFR § 2.51.

²⁰A typical example of a medical emergency is a suicide threat or a drug overdose.

²¹42 CFR § 2.12(c)(6).

²²42 CFR § 2.52.

²³42 CFR § 2.16.

²⁴42 CFR § 2.53.

²⁵Accounting audits do not usually fall under the audit-and-evaluation exception to the regulations. These are usually conducted pursuant to a qualified service organization agreement.

²⁶42 CFR §§ 2.63–2.67.

²⁷42 CFR § 2.61.

²⁸42 CFR § 2.65.

²⁹42 CFR § 2.66.

³⁰42 CFR §§ 2.64–2.66.

³¹42 CFR § 2.64(d).

³²42 CFR § 2.64(c).

³³42 CFR § 2.64(e).

³⁴42 CFR § 2.63.

³⁵42 CFR § 2.65.

³⁶42 CFR § 2.63 sets forth a list of serious crimes for which a court may order disclosure of patient records. The list does not include the possession or sale of illegal drugs.

³⁷Note that the regulations do not permit courts to order those "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." 42 CFR § 2.62.

³⁸ The regulations also contain special provisions regarding court orders authorizing disclosures for purposes of investigating or prosecuting a program or its employees and court orders authorizing a government agency to place an undercover agent or informant in a program to gather evidence of serious criminal conduct by the program or its employees (42 CFR §§ 2.66–2.67). The regulations set strict prerequisites for obtaining such orders and prohibit the use of information obtained through these means to initiate or substantiate criminal prosecutions against patients.

Chapter 2 —Confidentiality of Alcohol and Other Drug Treatment Records and Communicable Disease: Options for Successful Communication and Collaboration

In an effort to prevent, treat, and control the spread of communicable diseases, all States require health care providers and sometimes others to report cases of communicable disease to local public health authorities. These reports enable public health officials to locate, examine, counsel, treat, and monitor anyone presenting with a communicable disease. These mandated reporting requirements may appear to conflict with the Federal confidentiality regulations for drug and alcohol records, which, as discussed in Chapter 1, restrict patient-identifying disclosures about individuals in alcohol or drug treatment. Yet the Federal confidentiality regulations contain exceptions that allow substance abuse programs to discharge their State-mandated responsibilities with respect to the reporting of communicable diseases. In fact, the exceptions to the regulations not only permit programs to make the necessary communicable disease reports but also make it possible for them to cooperate on an ongoing basis with public health officials (and other health care providers) in efforts to treat and monitor those alcohol and other drug (AOD) patients who present with communicable disease.

Public Health Activities With Respect to Communicable Disease

For AOD programs to decide which exception or exceptions should be invoked (or are most apt) for purposes of meeting their State-mandated disease reporting and followup responsibilities, they need to understand what it is that public health officials (and other health care providers) may want or need to do in response to a communicable disease case report. At the least, public health officials want or need to—

- Identify an actual or suspected case of communicable disease
- Verify the case by examination
- Counsel the infected patient with an eye toward preventing further transmission
- Prescribe appropriate treatment
- Locate contacts or trace partners for purposes of identifying other cases and preventing further transmission
- Monitor treatment for efficacy and compliance
- Identify the nonadherent or noncooperative patient for purposes of invoking either civil or criminal sanctions

An appreciation of these activities will enable programs to ascertain exactly what information is needed for which public health purpose or activity and which of the available exceptions to the confidentiality regulations best fits the situation.¹

How Programs Can Comply With Communicable Disease Reporting Requirements

Reporting With Patient Consent

The easiest way for an AOD program to comply with State-mandated communicable disease reporting and followup requirements is for the program to secure the patient's consent to both the mandated report and followup activities. Such a consent can be put in place at intake or screening, with periodic renewals as necessary. Depending on State law, the consent can be made to last for as long as the patient is in the program.²

Given a proper consent, a program may report nearly anything the patient authorizes it to report, including the patient's state of health and whereabouts. The ability to report the patient's whereabouts (something that is almost always problematic for patients in residential treatment, since, by definition, a disclosure of a residential treatment patient's address is patient identifying) is especially important in the case of patients who must be examined without delay, for example, patients with suspected tuberculosis (TB). Easy location of the patient also facilitates followup activities, including counseling and education, interviewing for the purpose of identifying contacts and partners, treatment, and monitoring for compliance.

Moreover, a consent, unlike some other exceptions, can allow for the redisclosure of patient-identifying information. This is particularly important where different public health officials need to communicate with one another or other health care providers for purposes of tracking and controlling disease. Indeed, the only drawbacks to the consent option, at least from the point of view of public health (and leaving aside the question of having to explain a consent to a patient, which some programs find troublesome, depending on the populations they serve), are that a consent may be withdrawn at will by the patient and that a consent may not be the basis for imposing criminal sanctions on a noncompliant patient or a patient who engages in risky behavior. Only a court order may authorize the imposition of such sanctions against a noncompliant or risk-taking patient.

Reporting "Anonymously"

A program could conceivably discharge its State-mandated disease reporting obligations by making anonymous or non-patient-identifying disclosures. Under this exception, a program is allowed, for example, to disclose a patient's name and state of health and even his or her whereabouts as long as in doing so it does not also disclose that the patient is in substance abuse treatment. Notwithstanding its apparent attractions, there are problems with a program's electing to rely on this exception to discharge its disease reporting or followup obligations. The most obvious of these has to do with the fact that most States require reporters to identify themselves. Obviously, a freestanding or residential treatment program would not be able to comply with an identification requirement without giving itself and the patient away. (A program that is part of a

larger organization, such as a hospital, can simply report under the larger organization's name, assuming, of course, that the larger organization is not itself an identifiable substance abuse treatment provider.) A second problem arises where the recipient of the disclosure—here, a public health agency—wishes to establish ongoing communication with the program for the purpose of identifying and locating individuals who may have come in contact with, say, an AOD patient who is suspected of having TB. Under the circumstances, a program would not be able to cooperate with public health officials in locating, examining, counseling, educating, treating, or monitoring such contacts, since, in all likelihood, such cooperation would result in impermissible disclosures.³

Reporting by Use of a Qualified Service Organization Agreement

Programs required to make communicable disease case reports to local public health officials may comply with their reporting obligations—and put in place a mechanism authorizing ongoing communications between the program and an outside agency involved in treating or monitoring a patient's care—by entering a qualified service organization agreement (QSOA) with an outside agency or individual (the qualified service organization).

Thus, a treatment program can enter a QSOA with an outside medical care provider who would agree to provide screening and treatment to the program's patients and make mandated communicable disease reports to the State or local public health authorities. Such an arrangement would enable the AOD program and the outside service organization to share information (including AOD-patient-identifying information) without first obtaining individual patient consents.⁴ However, in making mandated reports to public health officials, the outside service provider would be forbidden from disclosing any AOD-patient-identifying information, unless the redisclosure was authorized by consent or by one of the other exceptions under the regulations. Such a QSOA arrangement would permit the program to discharge its State-mandated communicable disease case reporting obligations. However, depending on the nature of the qualified service organization, this arrangement probably would not permit the program to cooperate with local public health officials in following up on a given communicable disease report.

The program could overcome this problem by entering a QSOA directly with the State or local public health officials responsible for conducting communicable disease prevention, treatment, and control activities. A QSOA between an AOD program and a public health agency would open a channel of communication between the two that would permit the former to make mandated reports and allow the latter to follow up on any such reports to the degree necessary.

Because qualified service organizations may not redisclose AOD-patient-identifying information except with the patient's consent or as otherwise authorized by the AOD confidentiality rules, a question arises as to whether a program can meet all its State-mandated communicable disease reporting obligations through a QSOA where those obligations require the redisclosure of patient-identifying information throughout the public health bureaucracy involved in controlling communicable disease. In some States, the State and local public health units are separate governmental entities. In those States, an AOD program could enter a QSOA with each of the units (assuming that each agreed to provide services to the program) and could communicate

AOD-patient-identifying information back and forth with each public health unit. However, the State and local units could not share such information with each other—unless the patient consented or another exception to the Federal rules authorized such disclosures. This is because the QSOA between the AOD program and each of the public health units could not authorize either of the latter to redisclose AOD-patient-identifying information to any other entity, including other public health units. And since QSOA's may only be entered into between an AOD program and an outside service organization, the respective State and local health departments or units—neither of which would qualify as an AOD program—could not enter a QSOA with each other.

Thus, if the local public health agency and the State public health agency are separate entities, a QSOA with the local public health authorities will not permit the local public health agency to redisclose AOD-patient-identifying information to the State public health agency. In that event—for example, where the qualified service organization is a private physician or other agency—the local public health office has three options: (1) delete patient-identifying information from its reports to the State, (2) get patient consent to the disclosure, or (3) contact the patient for followup and rely on the patient's self-disclosing that he or she is in substance abuse treatment. (The regulations do not prevent patients from disclosing their own treatment status. Self-disclosures are not protected information and may be redisclosed without violating the regulations.)

However, where the qualified service organization is the local public health unit and the local public health unit is part of the same governmental entity as the State public health agency—that is, where the local public health unit is a subdivision of the State public health agency—a single QSOA can solve this problem. In such cases, the QSOA can specify that the qualified service organization that is to provide services to the program consists of both the local and State public health agencies.

Reporting and Followup Under the Research Exception

Under the research exception to the regulations, a program may permit a researcher to gather data for research purposes. Presumably, the exception would allow the program to give public health agencies access to patient records for purposes of gathering data on the presence of communicable disease within the program. The exception might even allow public health agencies to engage in examination, counseling, education, contact identification, treatment, and monitoring. It would not permit public health agencies to share patient-identifying information with other health care providers or patient contacts or partners. Indeed, inasmuch as it is predicated on the idea that the researcher is conducting research (as opposed to public health followup), requires the researcher to be possessed of a research protocol, and turns on an independent panel's evaluation of the benefits of the proposed research, this exception seems to be of only limited use for purposes of public health reporting and followup. A broader interpretation would distort the language and spirit of the regulations.

Audit and Evaluation

The audit-and-evaluation exception is plainly intended to permit regulatory agencies, funders, third-party payers, and peer review organizations to keep an eye on AOD programs to make sure that such programs are doing what they are supposed to be doing: providing effective substance abuse treatment. Accordingly, information disclosed during an audit or evaluation may not be used except for purposes of the audit or evaluation, and, in any case, may not be redisclosed except to medicaid or medicare officials or to law enforcement officials investigating a program pursuant to a court order. Under the circumstances, it would be inappropriate to rely on this exception for purposes of public health reporting or followup. Nonetheless, according to an opinion letter issued by the Department of Health and Human Services, this exception may be used for purposes of public health reporting and some followup—namely, patient counseling and interviewing—in cases of human immunodeficiency virus and acquired immunodeficiency syndrome (HIV/AIDS).⁵ The Department has never opined formally as to whether the exception may also be used for purposes of reporting and following up sexually transmitted diseases, TB, or other communicable diseases.

Reporting and Followup Under the Medical-Emergency Exception

Under the medical-emergency exception, a program may make a patient-identifying disclosure to medical personnel in a medical emergency that requires immediate medical intervention. Under this rather narrow exception (which requires a case-by-case decision as to whether a threat exists or immediate medical intervention is required), a program could report a communicable disease to public health officials only if the following conditions are met:

- The presence of an infected or allegedly infected individual in the program could be said to constitute a medical emergency
- Public health officials are medical personnel

Assuming that public health officials are medical personnel (a safe enough assumption), the real question is whether the presence in a treatment program of an individual who is infected with a communicable disease can be said to constitute a medical emergency for either the individual or others. (Under the regulations, a medical emergency is a situation that requires immediate medical intervention.) The answer to the question turns on the nature of the disease itself and how it is transmitted. Generally, sexually transmitted diseases—such as syphilis and gonorrhea, and even hepatitis—are not considered emergencies of the sort that require immediate medical intervention;⁶ this is also the case with HIV/AIDS. These diseases, though communicable, are not emergencies because they do not pose immediate threats to life and because the threat posed by HIV/AIDS cannot be prevented or relieved by resort to immediate medical intervention. Accordingly, they may not be reported to public health officials under the medical-emergency exception to the regulations.

The situation is different with TB or suspected TB. Because TB is transmitted by casual contact, is difficult to confirm, and is potentially deadly, the presence of a suspected case of TB in a treatment program may very well constitute the sort of emergency that can be reported to public health officials under the medical-emergency exception to the regulations. For the same reasons,

it may also be that a suspected or confirmed case of TB will permit a program not only to make the required report to public health officials but also to cooperate with them in their followup activities.

Court Orders

A program that is required to report communicable diseases to local public health officials may always resort to a court order to make the necessary report. This is true whether the program is seeking to report sexually transmitted diseases, HIV/AIDS, or TB. A proper court order may authorize a program both to make mandated reports and to cooperate with public health followup activities.

Nonetheless, there are serious drawbacks to the use of a court order in such a situation. In the first place, the procedure for obtaining a court order is complicated and time-consuming. Second, there is no guarantee that a court will grant the requested order, since the court must find that the information in question is not otherwise available and that the public interest outweighs the private interest at stake. Third, the benefit of a court order might be outweighed by its negative impact on client-program relations. (A program that readily resorts to court orders to meet public health reporting requirements is probably undermining itself, though this is not to deny the place of court orders in certain situations.)⁷

Options for Communicating and Collaborating in the Provision of Communicable Disease Treatment, Monitoring, and Followup: What Is Possible?

It is up to each program to decide what is the best or most apt exception for purposes of meeting State public health reporting requirements. Perhaps in an ideal world programs and patients would both agree to put in place appropriate consents that would allow programs to comply with all their public health obligations. Yet consents are not without their drawbacks. The most important of these drawbacks is that consents can be withdrawn at will.

To be sure, a program might counter the revocation of a consent by making treatment contingent on a new consent (whether a program can do this depends on State law), but such a move—smacking as it does of coercion—would not be without costs and could damage the therapeutic relationship.

Another option would be to put in place a QSOA with the local public health agency. This would permit the program to comply with both reporting and followup obligations. Since a program is not obligated to inform a client of the existence of a QSOA, this option may also be considered to have the added advantage of making the QSOA appear to be something of a *fait accompli*. (This is not to suggest that a program should be casual about its patients' concerns about confidentiality; it is actually to suggest something else: that programs are under obligations that they may not avoid, that these obligations sometimes involve the rights of their patients, and that programs should be open and matter-of-fact about meeting those obligations.)

Though they have less to recommend them, the other exceptions to the regulations have their uses. Thus, a program that cannot persuade a patient to consent to a disclosure and that does not have an appropriate QSOA in place may wish to report a communicable disease anonymously. (The limits of anonymous reports are discussed in "Reporting 'Anonymously'" above.) Programs wishing to report a case of HIV could invoke the unpersuasive but useful route recommended by the Department of Health and Human Services, namely, using the audit-and-evaluation exception for that purpose. With regard to TB or suspected TB, a program can probably rely on the medical-emergency exception to make a report. Finally, a program can always seek to discharge its reporting and followup obligations by going to court.

Footnotes

¹It goes without saying that collaboration and cooperation in this important area redound to everyone's benefit. This is particularly true with respect to cases of tuberculosis, which, unlike some other communicable diseases, can be spread by casual contact.

²Some States have laws that limit the validity of releases and consents to no more than 60 or 90 days. In such States, a consent would have to be renewed at the appropriate juncture.

³Of course, there is nothing to prevent the program from urging those of its staff and clients who may have been exposed to a communicable disease to call the appropriate officials or other providers for examination and followup.

⁴AOD programs are not required to obtain patient consent prior to entering a QSOA, nor need they inform patients of the QSOA's to which they are a party. Naturally, to the extent that a patient (who, after all, proceeds with the assurance that his or her records are confidential) is surprised by a given QSOA, his or her confidence in the program or his or her therapist may be undermined. It is probably in a program's interest to inform its patients of existing or proposed QSOA's.

⁵The Legal Action Center disagrees with the Department of Health and Human Services on this matter (see letter from Margaret K. Brooks, President/Director, Legal Action Center, to Richard Riseberg, Esq., General Counsel, Office of the General Counsel, September 25, 1990, in Appendix B).

⁶This is the opinion of the Department of Health and Human Services (see letter from Susan K. Zagame, Acting General Counsel, Health and Human Services, to Peter J. Millock, General Counsel, Department of Health, State of New York, May 17, 1989, in Appendix B).

⁷Court orders are not a panacea. They do not permit redisclosure and are not readily available for the purpose of imposing criminal sanctions on a patient.

Appendix A—Sample Forms

Sample Form #1

CONSENT FOR THE RELEASE OF CONFIDENTIAL ALCOHOL OR DRUG TREATMENT INFORMATION

I, _____, authorize

(Name of patient)

(Name or general designation of program making disclosure)

to disclose to _____ the

(Name of person or organization to which disclosure is to be made)

following information: _____

(Nature of the information, as limited as possible)

The purpose of the disclosure authorized herein is to: _____

(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

PROHIBITION ON REDISCLOSURE
OF INFORMATION CONCERNING CLIENT
IN ALCOHOL OR DRUG ABUSE TREATMENT

This notice accompanies a disclosure of information concerning a client in alcohol/drug abuse treatment, made to you with the consent of such client. 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 #3

CONSENT FOR THE RELEASE OF CONFIDENTIAL ALCOHOL OR DRUG TREATMENT
AND [TB] [STD] [HIV/AIDS] INFORMATION TO COMPLY WITH DISEASE REPORTING
REQUIREMENTS

I, _____ authorize

(Name of Patient)

The ABC Substance Abuse Program

(Name or general designation of program making disclosure)

to disclose to the [State and/or local] Department of Health officials authorized to require and

(Name of person or organization to which disclosure is to be made)

receive mandated [HIV/AIDS/STD/TB] reports

the following information: (Nature of the information as limited as possible)

(1) information that State law requires to be reported about my diagnosis and treatment for—

[initial any which apply]

___ HIV infection

___ AIDS

___ STD (sexually transmitted disease)

___ TB (tuberculosis).

(2) my name and other personal identifying information, if required to be reported by State law; and

(3) information about my status as a patient in alcohol or drug treatment, if required to be reported by State law.

The purpose of the disclosure authorized herein is to: allow my alcohol or drug treatment program

(Purpose of disclosure as specific as possible)

(named above) to comply with State law(s) requiring the reporting of cases of [HIV/AIDS/STD/TB]

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 HIV-related information about me, STD-related information about me, and TB-related information about me is protected by State law and cannot be disclosed unless the disclosure is authorized by State law. 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 patient

Sample Form #4

CONSENT FOR THE RELEASE OF CONFIDENTIAL INFORMATION ABOUT ALCOHOL OR DRUG TREATMENT AND [TB] [STD] [AND/OR] [HIV/AIDS] CARE

I [name and address of patient], authorize—

(1) the following alcohol or drug treatment program(s): [name and address of each treatment program authorized to make and receive disclosures],

AND

(2) the following health care provider(s): [name and addresses of each [TB] [STD] [and/or] [HIV/AIDS] care provider authorized to make and receive disclosures],

AND

(3) [designate staff of the State/local Department of Health responsible for [TB] [STD] [and/or] [HIV/AIDS] prevention, control and care; specify appropriate name and address]—

to communicate with and disclose to one another the following information:

[initial each category that applies]*

* ____ (1) Alcohol or drug treatment: information about my participation and attendance in the alcohol or drug treatment program(s) named above that is needed to enable the persons and agencies listed above to provide, coordinate and monitor my treatment for [TB] [STD] [and/or] [HIV/AIDS].

* ____ (2) Tuberculosis (TB): information about my diagnosis and treatment for TB that is needed to enable the persons and agencies listed above to provide, coordinate and monitor my treatment for {TB} [STD] [and/or] [HIV/AIDS].

* ____ (3) Sexually transmitted disease(s) (STD): information about my diagnosis and treatment for any STD that is needed in order to enable the persons named above to provide, coordinate and monitor my treatment for the [TB] [STD] [and/or] [HIV/AIDS].

* ____ (4) HIV/AIDS: information about my HIV status (including HIV test results and information about my diagnosis and treatment for HIV-related conditions, including AIDS) that is needed to enable the persons and agencies listed above to provide, coordinate and monitor my treatment for [TB] [STD] [and/or] [HIV/AIDS].

The purpose of these disclosures is to (1) enable the persons and agencies listed above to provide, coordinate and monitor the treatment I receive for [TB] [STD] [and/or] [HIV/AIDS]; and (2) discuss with me any [sexual/needle sharing] partners or contacts and/or family members who might be infected [with [TB] [STD] [HIV] and need treatment.

I understand that my alcohol and drug treatment records are protected under the federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that HIV-related information about me, STD-related information about me, and TB-related information about me is protected by State law, and cannot be disclosed except as authorized by State law.

I understand that I may revoke this consent at any time except to the extent that action has already been taken in reliance on it, and that in any event this consent expires automatically as follows:

[Specify the date, event or condition upon which this consent expires. This could be one of the following:

(1) The date on which my treatment for [TB] [the STD] is completed.

(2) A specific date (such as six months or one year) after the consent form is signed.]

Dated: _____

Signature of patient

Sample Form #5

QUALIFIED SERVICE ORGANIZATION AGREEMENT ON COORDINATION OF [HIV/STD/TB] CARE (AOD TREATMENT PROGRAM & [HIV/STD/TB] HEALTH CARE PROVIDER)

[Name of health care facility providing [HIV/AIDS/STD/TB] care to Program patients] ("the [HIV/AIDS/STD/TB] Care Provider") and the [name of alcohol or drug treatment program] ("the Program") hereby enter into a qualified service organization agreement, whereby the [HIV/AIDS/STD/TB] Care Provider agrees to [provide, coordinate and/or monitor] the treatment and/or related services for [HIV/AIDS/STD/TB] being provided to patients of the Program who are diagnosed, treated and/or provided related services for [HIV/AIDS/STD/TB] by the [HIV/AIDS/STD/TB] Care Provider.

Furthermore, the [HIV/AIDS/STD/TB] Care Provider:

(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 C.F.R. 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 C.F.R. Part 2.

Executed this _____ day of _____, 199__.

President

AOD Program Director

[Name of [HIV/AIDS/STD/TB] Care Provider] [Name of Program]

[address]

[address]

Sample Form #6

QUALIFIED SERVICE ORGANIZATION AGREEMENT ON REPORTING OF [HIV/AIDS/STD/TB] AND COORDINATION OF [HIV/AIDS/STD/TB] CARE (AOD TREATMENT PROGRAM & HEALTH DEPARTMENT [HIV/STD/TB] STAFF)

[Name of relevant Health Department [HIV/AIDS/STD/TB] unit and staff] ("the Health Department [HIV/AIDS/STD/TB] Unit") and the [name of alcohol or drug treatment program] ("the Program") hereby enter into a qualified service organization agreement, whereby the Health Department [HIV/AIDS/STD/TB] Unit agrees to [provide, coordinate and/or monitor] the treatment and/or related services for [HIV/AIDS/STD/TB] being provided to patients of the Program who are diagnosed and reported as having [HIV/AIDS/STD/TB] and are provided [HIV/AIDS/STD/TB]-related services by the Health Department [HIV/AIDS/STD/TB] Unit.

Furthermore, the Health Department [HIV/AIDS/STD/TB] Unit:

(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 C.F.R. 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 C.F.R. Part 2.

Executed this _____ day of _____, 199__.

Director

AOD Program Director

[Name of Health Department] [Name of Program]

HIVAIDS/STD/TB Unit] [address]

[address]

Appendix B—Opinion Letters

September 25, 1990

Richard Riseberg, Esq.
General Counsel
Office of the General Counsel
Alcohol, Drug Abuse, and Mental Health Administration
Room 4A_53 Parklawn
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Riseberg:

We are writing to offer our comments on two opinion letters issued in the past two years about disclosure of HIV-related information to state health departments under 42 C.F.R., Part 2. (Opinion letter by the Legal Advisor to the Alcohol, Drug Abuse, and Mental Health Administration to the Oklahoma State Department of Health (September 2, 1988) and Opinion letter by Acting General Counsel to the Department of Health and Human Services (Office of the Secretary) to the New York State Department of Health (May 17, 1989).)

These two letters suggest a variety of ways in which HIV-related information contained in alcohol or drug abuse patient records protected by 42 U.S.C. § 290 dd-3 and § 290 ee-3 and 42 C.F.R. Part 2 can be disclosed to state health departments pursuant to mandatory reporting requirements. We think that some of the advice offered in the letters is excellent. For example, we agree that obtaining patient consent is the best way to report such information while abiding by the federal law and regulations; and we agree that reports can be made by some programs by deleting alcohol or drug abuse information from the report. However, a number of suggestions the letters make disturb us profoundly.

1. *Use of the "audit or evaluation" exception of 42 C.F.R. § 2.53*

Both letters suggest that reports of HIV information may be made by a drug or alcohol program to the state health department pursuant to 42 C.F.R. § 2.53, the "audit or evaluation" exception of the regulations. The letters approve the use of § 2.53 whether the purpose of the state's reporting law is research or whether it also includes measures to control the spread of infection, such as contact tracing. The letters state that HIV reports made for the purposes of audit or evaluation could be used for contact tracing purposes if the identity of the infected individual remains anonymous. The letters also state that the health department can contact the patient to discuss his or her HIV status, and presumably, sexual and needle contacts. In other words, the public health authority can use the information disclosed by the programs to contact the HIV-infected patient directly to offer counseling and contact notification services and then approach those contacts, provided that the patient's name is not revealed to the contacts.

We believe that using § 2.53 to report HIV data to public health authorities distorts the meaning and purpose of that section.¹

Section 2.53 is designed to permit financial and programmatic evaluation of programs' functioning. The section contemplates an outside agency such as an accounting firm or a state regulatory agency entering the program's premises and examining and/or copying its books and records for the purposes of determining how the program is functioning financially or otherwise. Reporting the HIV status of patients to public health authorities pursuant to a mandatory reporting law serves no audit or evaluation function. The purpose of reporting patients' HIV status is clearly not to determine how the program is functioning but to permit the public health authorities to use patient-identifying information gained by the program for other purposes.

Moreover, the public health department's use of patient-identifying information to perform contact tracing would likely violate subsection (d) of § 2.53, which states that "patient identifying information disclosed under [§ 2.53] may be disclosed only back to the program from which it was obtained and *used only to carry out an audit or evaluation purpose*" (emphasis

added). Since contact tracing is not an audit or evaluation and does not serve such a purpose, § 2.53(d) appears to prohibit the use of information about a patient to perform contact tracing functions, even when the name of the patient is not disclosed to his or her contact.

2. Use of patient consent when the reporting may lead to civil or criminal sanctions

The May 17, 1989 letter from the Acting General Counsel to the New York State Health Department notes that it would clearly be improper to use either § 2.52 or § 2.53 to make reports to public health officials "if the purpose of the initial report ... is to investigate an alcohol or drug abuse patient for purposes of civil or criminal sanctions...." However, the letter then suggests that a program making an initial report to investigate a patient in order to punish that patient might make the report with patient consent under § 2.31. In fact, 42 U.S.C. §§ 290 dd-3(c) and ee-3(c) make clear that *only* a court order—not written consent—can authorize use of records for criminal investigations. That prohibition is carried over into the regulations at 42 C.F.R. § 2.12(d)(1).

We thought we would share with you another solution to the problem of complying with a mandatory reporting law that has occurred to us: using a "qualified service organization agreement" to make such mandated reports. This might be especially useful for programs that are not part of a general medical or mental health facility and are therefore barred in a practical sense from making a report by deleting alcohol or drug information. Such a "free-standing" program could enter into a QSOA with a laboratory or medical care provider that conducts HIV testing or other diagnostic services for the program. As part of its service the QSO could report the HIV information to the public health department and delete the alcohol and drug information from the report. We recognize that this solution would not be available in some states (New York is among them) that have strict laws restricting disclosure of HIV-related information.

We would be pleased to discuss the issues this letter raises with you, at your convenience.

Sincerely,

Margaret K. Brooks
President/Director
Legal Action Center
153 Waverly Place
New York, NY 10014

1However, we believe that if the purpose of the state's reporting law is solely to collect research data about the existence, incidence and impact of HIV/AIDS, alcohol and drug programs can comply if the procedural requirements of § 2.52 are met, *i.e.*, (1) if the public health authority is qualified to conduct the research (which it probably is), (2) if it has a research protocol to protect patient-identifying information and if a group of three or more individuals independent of the research project has reviewed the protocol and found it adequate, and (3) if the public health authority agrees not to disclose patient-identifying information except back to the program and

not to identify any individual patient in any report or otherwise disclose patient identities.

Opinion Letters

May 17, 1989

Peter J. Millock
General Counsel
Department of Health
State of New York
Corning Tower, Empire State Plaza
Albany, New York 12237

Dear Mr. Millock:

We are responding to your letter of April 21 seeking our advice on how the Federal confidentiality regulations on alcohol and drug abuse patient records, 42 C.F.R. Part 2, affect the reporting of communicable diseases under New York law. In our opinion, such disclosures may be made by deletion of all alcohol or drug abuse information from the report consistent with 42 C.F.R. § 2.13(c)(1), with written patient consent under 42 C.F.R. § 2.31–2.33, or as disclosure for purposes of research, audit, or evaluation under 42 C.F.R. § 2.52–2.53. In addition, in selected cases, reports may be made for purposes of treating a bona fide medical emergency under section 2.51. Finally, where a civil or criminal investigation of a particular individual is envisioned, it may be necessary to obtain an appropriate court order under section 2.64 or 2.65 of the regulations.

As we understand it, New York law requires that physicians and institutions report cases of communicable disease to the local health officer, who in turn is required to report the information to the State Department of Health. Your letter states that the purpose of such reporting is to enable State and local health officials to "investigate cases of communicable disease and take whatever action is necessary and appropriate to deter the spread of a communicable disease." In this regard, you indicate that in at least two cases alcohol abuse facilities have refused to cooperate with "communicable disease investigations" based on the Federal confidentiality regulations. Because of your concern that the Federal law impedes the implementation of State reporting requirements, you have sought our advice on the matter.

We have recently responded to a similar inquiry from the State of Oklahoma on HIV reporting and are enclosing a copy of our reply for your review. We advised in that situation that HIV reports may be made to Oklahoma public health officials as audit or evaluation disclosures under 42 C.F.R. § 2.53 if the purpose of such reports was to increase the knowledge of the incidence and prevalence of HIV and for health planning purposes. We also suggested, and now conclude,

that under appropriate circumstances such reports could also be made for purposes of research under section 2.52. Finally, we advised that such reports could be made with the patient's written consent under sections 2.31 and 2.33 of the regulations. In this regard, we enclosed an opinion to Beth Israel Medical Center in New York City which discusses making venereal disease reports under State law either with written patient consent or by deletion of alcohol or drug abuse identifying information from the report. *See* 42 C.F.R. § 2.12(a)(1)(I) and (e)(3) and 2.13(c)(1).

In the Oklahoma opinion, we concluded that HIV reports made for purposes of audit or evaluation could be redisclosed back to the alcohol or drug abuse program from which the information was obtained and could otherwise be used for contact tracing purposes if the identity of the infected individual remained anonymous. However, we should emphasize that both the authorizing legislation and the regulations would otherwise generally prohibit the redisclosure of alcohol or drug abuse patient identities where the original disclosure was made for purposes of research, audit, or evaluation. 42 U.S.C. § 290dd-3; 42 U.S.C. § 290ee-3; 42 C.F.R. §§ 2.52(a)(2)(ii) and (b) and 2.53(d).

Thus, it is unclear to us whether the type of "communicable disease investigations" to which you refer in your letter could be carried out under section 2.52 or 2.53 of the regulations. In particular, it is our view that if the purpose of the initial report to public health officials is to investigate an alcohol or drug abuse patient for purposes of civil or criminal sanctions the report could not be made as a disclosure for purposes of research, audit, or evaluation. In those circumstances, the report would need to be authorized with written patient consent or a court order under 42 C.F.R. § 2.64 or 2.65. With respect to section 2.65, we note, however, that it only authorizes disclosures for purposes of criminally investigating or prosecuting an alcohol or drug abuse patient in cases of "extremely serious" crimes. 42 C.F.R. § 2.65(d)(1).

In your letter, you have particularly sought our advice on whether the authority in section 2.51 for disclosing alcohol or drug abuse patient records in cases of a bona fide medical emergency would permit communicable disease reports. We have advised under prior regulations that a positive venereal disease test did not constitute a bona fide medical emergency under the authorizing legislation and regulations because the need for medical treatment of the infected individual was not sufficiently immediate to consider it an emergency and, thereby, to justify bypassing the normal procedures for obtaining a written consent or a court order. However, as the revised regulations provide that the medical emergency which justifies the disclosure could be a threat to the health of "any individual" and not just the patient (42 C.F.R. § 2.51(a); 48 Fed. Reg. 38767, August 25, 1983) and in recognition of the varying seriousness of different diseases, we now conclude that the incidence of venereal and other communicable diseases should be assessed on an individual basis to determine whether they constitute a bona fide medical emergency for which a disclosure could be made under section 2.51.

To justify such a disclosure, it is necessary to determine that the information would be disclosed to "medical personnel" for the purpose of treating a condition which poses an "immediate threat" to the health of any individual and which requires "immediate medical intervention." 42 C.F.R. § 2.51(a). Furthermore, the alcohol or drug abuse program making the disclosure is required to document the circumstances surrounding the disclosure, including the medical personnel to

whom the disclosure was made and the nature of the emergency. 42 C.F.R. § 2.51(c).

Because of the nature of these determinations and the documentation required, we believe that a medical emergency disclosure would normally have to be made on a case-by-case basis. Thus, we do not find that it constitutes a general authority for making communicable disease reports. In addition, while the authorizing legislation and regulations do not contain a prohibition on redisclosure as is done for research, audit, and evaluation disclosures (42 U.S.C. § 290dd-3(b)(2)(A); 42 U.S.C. § 290ee-3(b)(2)(A); 42 C.F.R. § 2.51), they do prohibit use of the information to criminally investigate or prosecute the alcohol or drug abuse patient absent the appropriate court order. 42 U.S.C. § 290dd-3(c); 42 U.S.C. § 290ee-3(c); 42 C.F.R. § 2.12(d)(1). Thus, once again we are unsure whether this authority would permit the type of "communicable disease investigations" you envision.

In summary, subject to the constraints discussed above, we conclude that communicable disease reports may be made by alcohol and drug abuse treatment programs under New York law by deletion of alcohol or drug abuse information from the report, with written patient consent, for purposes of research, audit, or evaluation, to medical personnel in cases of a bona fide medical emergency, or pursuant to an authorizing court order. If you have any further questions, you may wish to discuss them directly with Chris Pascal of my staff who advises the Department on the Federal confidentiality laws. If you wish to contact him, he may be reached at 301-443-1212.

Sincerely,

Susan K. Zagame
Acting General Counsel
Office of the Secretary
Department of Health and Human Services
Washington, D.C. 20201

Enclosures

bcc: Dr. Pickens
Sandy Garcia
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Dr. Jones, CDC
Aaron Handler, IHS
Robert Allen, Ph.D., VA

National Institute on Drug Abuse, Opinion 78_3, February 1, 1978 (Legal Opinions on the Confidentiality of Alcohol and Drug Abuse Patient Records (1975_1978), at p. 13 (1980))

REPORTING OF POSITIVE FINDINGS OF VENEREAL DISEASE IN HOSPITAL PATIENTS WITHOUT IDENTIFYING THEM AS RECIPIENTS OF METHADONE MAINTENANCE TREATMENT (2.11(p)(3); 2.11(j))

To Mr. Karten, Beth Israel Medical Center, New York, NY

You request an opinion on whether, consistent with the "Confidentiality of Alcohol and Drug Abuse Patient Records" regulations, 42 CFR Part 2, Beth Israel Medical Center may report to local health authorities positive venereal disease results of hospital patients enrolled in a Methadone Maintenance Treatment Program (MMTP), if those patients are not identified in any way as MMTP patients.

It is our opinion that the confidentiality regulations permit Beth Israel Medical Center (BIMC) to report, without patient consent, to local health authorities positive venereal disease results of BIMC patients who are enrolled in a Methadone Maintenance Treatment Program, if the patients are not identified in any way to the health authorities as MMTP patients.

BIMC is a voluntary hospital which operates a Methadone Maintenance Treatment Program. Under section 11.03 of New York City's Health Code, the hospital is required to report all patients with positive findings of venereal disease to local health authorities. Due to the possible conflict between the confidentiality regulations which restrict disclosure of drug abuse patient records and local health laws which require disclosure to health authorities of the identity of all patients with positive venereal disease results, the Division of Methadone Monitoring, Food and Drug Administration, has recommended that as part of their intake procedure drug abuse treatment programs, including MMTP, routinely obtain patient consent to release identifying information in cases of positive findings of venereal disease.

You have indicated dissatisfaction with this method of releasing positive venereal disease results of MMTP patients, expressing concern that seeking consent at intake for disclosure of patient identifying information under such circumstances will be perceived as coercive by prospective patients, and thus render the consent involuntary. As an alternative, Beth Israel Medical Center has proposed to report the positive venereal disease results of its MMTP patients by identifying them as BIMC patients without indicating that they are MMTP patients. In your inquiry, you have asked us whether this proposed method of reporting is allowed under the confidentiality regulations.

It is our opinion that BIMC's proposed method of reporting positive venereal disease results is consistent with the confidentiality regulations.¹ 42 CFR § 2.13(a) states that "[r]ecords to which this part applies shall be confidential and may be disclosed only as authorized by this part" 42 CFR § 2.11(p) states:

"The following types of communications do not constitute disclosures of records:

"(3) Communications of information which includes neither patient identifying information nor identifying numbers assigned by the program to patients."²

Read together, these two provisions of the regulations provide that communications of information which include neither patient identifying information nor identifying numbers assigned by the program to patients are not disclosures of records subject to the restrictions of 42 CFR Part 2. Thus, BIMC may report the positive venereal disease results of its MMTP patients without patient consent, if the reports do not disclose "patient identifying information" or "identifying numbers assigned by the program to patients."

Section 2.11(j) of the regulations defines "patient identifying information", in pertinent part, as "... 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." Furthermore, "patient" is defined, in pertinent part, by §2.11(i) as "any individual ... who has applied for or been given diagnosis or treatment for *drug abuse* or *alcohol abuse*" (Emphasis added.) Thus, we conclude that "patient identifying information" as used in 42CFR§2.11(p)(3) refers to information which can be used to identify a patient, with reasonable accuracy and speed, as an "individual ... who has applied for or been given diagnosis or treatment for drug abuse or alcohol abuse." Accordingly, when reporting its patients' positive venereal disease results, if BIMC does not identify a patient as having applied for or been given diagnosis or treatment for drug or alcohol abuse nor provide his or her program identifying number, it is not making a disclosure of a record for purposes of the regulations.

This conclusion is consistent with 42 CFR § 2.13(f) which provides that:

"The presence of any in-patient in a medical facility for the treatment of drug or alcohol abuse may be acknowledged to callers and visitors with his written consent. *Without such consent, the presence of any in-patient or resident in a facility for the treatment of a variety of conditions may be acknowledged if done in such a way as not to indicate that the patient is being treated for drug or alcohol abuse.*" (Emphasis added.)

Since Beth Israel Medical Center is a "voluntary hospital" which, we presume, treats a variety of conditions, it qualifies under section 2.13(f) as a facility that may report the presence of a drug or alcohol abuse patient in its facility without the patient's consent if this reporting is done "in such a way as not to indicate that the patient is being treated for drug or alcohol abuse."

In summary, we conclude that BIMC may report, without patient consent, the positive venereal disease results of its MMTP patients to local health authorities, if these patients are not identified as MMTP patients in accord with the provisions of 42 CFR §§ 2.11(p)(3) and 2.13(f).

¹We note that we do not find anything legally incorrect in the Division of Methadone Monitoring's recommendation that patient consent to disclosure of positive venereal disease

results be routinely obtained at intake. This recommendation is consistent with our prior advice. Letter, GH (Greene) to Young, July 18, 1977 (DF #25B).

²For a general discussion of 42 CFR § 2.11(p)(3), see, letter, GH (Edelman) to Ichord, May 17, 1977 (DF #25B).

Opinion Letters

September 2, 1988

John Harkess, M.D.
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Re: Disclosure of HIV Records to State Health Department Under 42 C.F.R. Part 2—GH Ref. #88-1776 (DF#92, #25B)

Dear Dr. Harkess:

We are responding to your letter of July 12, 1988, and our subsequent phone conversation in which you requested legal advice on the disclosure of HIV information from drug abuse treatment records subject to 42C.F.R. Part 2 to the Oklahoma State Department of Health. This disclosure is now required in Oklahoma under a change in State law which makes HIV infection a reportable disease. Okla. Stat. tit. 63, § 1-503 (1981) (an emergency rule was adopted Jan. 20, 1988, by the Oklahoma State Board of Health adding HIV to the list of reportable diseases).

As we understand it, the procedure for reporting HIV infections to the health department is as follows. The infected person's name and birthdate is reported, although no address is included. The health department uses this information to increase its knowledge of the incidence and prevalence of the disease and for health planning purposes. It also will use this information internally to eliminate double-counting of HIV cases (where reports on the same person are received from more than one source) and to contact the infected person to offer services, such as HIV counseling and assistance with contact notification. Although HIV reports may be made in other instances as well, most reports involving drug abusers are expected as a result of a State health department initiative which offers drug abuse patients HIV testing with informed consent and pre- and post-test counseling. Your legal questions concern how the Federal confidentiality regulations for drug abuse treatment programs, 42C.F.R. Part 2, affect compliance with Oklahoma's HIV reporting requirement and the health department's use of this information once received.

We have previously advised that identifiable HIV records may be disclosed from drug abuse treatment programs to public health authorities without patient consent to the extent that the information is needed to research the causation of AIDS, to conduct epidemiological studies or health program planning, or to evaluate the incidence and treatment of the disease.¹ Although the regulatory provisions on which this prior advice was based have changed, we believe that HIV reports may be made by drug abuse treatment programs to the Oklahoma health department without patient consent under 42 C.F.R. 2.53 as a disclosure for the purposes of audit or evaluation.² Although section 2.52 which authorizes disclosures for research activities could also be used for making HIV reports to the health department, it requires the researcher to obtain an independent review of the research protocol for purposes of protecting the research subjects before any drug abuse records may be disclosed. 42 C.F.R. 2.52(a)(3) (as amended by 52 F.R. 41997, Nov. 2, 1987).³ Thus, it might be unsuitable for the type of mandatory HIV reporting envisioned here.⁴ In any event, reliance on section 2.52 does not appear necessary as disclosures to the health department could be made under section 2.53. Although 2.53 authorizes the initial disclosure of HIV information to the health department, the health department may not identify any individual patient in any report of its audit or evaluation activities or otherwise redisclose information except back to the program from which it was obtained. 42 C.F.R. 2.53(d); 42 U.S.C. § 290ee-3(b)(2)(B).⁵

This limited authority to make redisclosures would permit the State health authority to contact the drug abuse treatment program that made the HIV report to offer counseling and contact notification services to the HIV infected individual. It would also permit the public health authority to notify the sexual and needle contacts of the HIV individual because, as we understand it, such notification keeps the name of the infected person anonymous, thus exempting this communication of information from the meaning of disclosure under the regulations. 42 C.F.R. 2.11 ("disclosure"); 42 C.F.R. 2.12(a)(1)(I).⁶ However, there is no explicit authorization in the regulations for contacting the HIV infected individual directly if the individual is no longer at the drug abuse program. We previously advised under the prior regulations that we did not believe the confidentiality protections were intended to restrict disclosures to the patient of information in his or her records of which the patient was already aware.⁷ We find that this position continues to be sound under the revised regulations and, accordingly, conclude that the State health authority may contact the HIV infected individual directly to offer counseling and contact notification services. However, in doing so, the authority must ensure that it does not disclose information that would identify the individual as a drug abuse patient to others.

In addition to the nonconsensual disclosures which may be made for purposes of research, audit, or evaluation, HIV reports may be made to public health authorities with written patient consent. The use of written patient consent has a number of advantages, including placing the patient on notice of the existence of the State HIV reporting law and ensuring that the State health department may make all disclosures necessary to fulfill their contact notification responsibilities.

In obtaining the patient's consent, the confidentiality regulations require that a special consent form must be used and that any needed redisclosures must be expressly permitted. 42 C.F.R. 2.31 and 2.32. Because HIV testing on drug abusers in Oklahoma will largely be performed with

patient consent at drug abuse treatment programs, it may be convenient to obtain the patient's written consent to disclosure at the same time consent to the HIV test is obtained. Since the confidentiality regulations themselves and Oklahoma law provide for confidentiality of the HIV report, those individuals who wish to be tested would presumably be willing to consent to disclosure of the HIV information to the State health authority. Nevertheless, in those cases where consent was not obtained, the HIV information could be reported for purposes of research, audit, or evaluation as previously discussed.

In summary, we believe that the reports of HIV infection required under Oklahoma law may be made in compliance with the Federal confidentiality laws for drug abuse treatment records, 42 U.S.C. § 290ee-3 and 42C.F.R. Part 2, either with written patient consent or, without such consent, as a disclosure for purposes of research, audit, or evaluation.

We hope this information has been helpful. Please let me know if you have any further questions.

Sincerely,

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¹Memorandum, GH (Pascal) to NIDA (Gardner), Nov. 3, 1983 (DF #25B); *See also*, C. Pascal, "Selected Legal Issues About AIDS for Drug Abuse Treatment Programs," *Journal of Psychoactive Drugs*, Vol. 19, P. 2, Jan.-Mar. 1987.

²Although revised section 2.53 refers to an evaluation or audit activity encompassing a "review of records on program premises" (which is not envisioned here since the program will transmit the information to the State), we do not believe this is intended as a limitation on the type of audit and evaluation activities which could be conducted but rather as a description of perhaps its most common form. In this regard, we do not find that there was any intention during the revision of the regulations to restrict disclosures for audit or evaluation activities to an on-site review of records and note that the definition of "program evaluation" in the prior regulations was much broader in scope than the evaluation of an individual alcohol or drug abuse program. *See* 52F.R. 21800, 21801, June 9, 1987; 42 C.F.R. 2.11(f)(2) and (g)(2) (1986) (prior

regulations). Accordingly, we conclude that an HIV report to the Oklahoma State Health Department may be made as a nonconsensual disclosure for purposes of audit or evaluation under 42 C.F.R. 2.53 and 42 U.S.C. § 290ee-3(b)(2)(B).

It is interesting to note that the authority of the Veterans Administration for protection of alcohol and drug abuse patient records (which is modeled after the Department of Health and Human Services authority discussed here) was recently amended to add HIV records to the confidentiality protections and to give explicit authority for disclosing the HIV records to State or local public health authorities without consent. 38 U.S.C. 4132(b)(2)(C), as amended by section 121 of Pub. L. 100-322, the "Veterans' Benefits and Services Act of 1988," enacted May 20, 1988.

³We have doubts that the provisions of section 2.52 requiring a research protocol and its independent review are intended to apply to the type of non-experimental research contemplated here, i.e., tracking the causation and incidence of disease. In this regard, the prior regulations did not restrict the meaning of "scientific research" in any way and there is no indication that the Department intended to change this position in the revised regulations. 42 C.F.R. 2.52(a), 2.52-1(n), and 2.53(c)(1986); 48F.R.38765,38766, Aug. 25, 1983; 52 F.R. 21800, 21801, June 9, 1987. This suggests that the conduct of research which does not include a formal research protocol would not be barred by section 2.52 nor would it be subject to the protocol review requirements. However, we need not formally resolve this issue because we believe that the type of reporting required by the State health department falls within the scope of disclosures for purposes of audit or evaluation as discussed above.

⁴We note, however, that, even assuming the research protocol provisions of section 2.52 apply, certain Federally sponsored HIV testing, such as that performed under the national seroprevalence survey, has received Institutional Review Board approval and, thus, would comply with these provisions.

⁵Section 2.53(a) requires the person performing the audit or evaluation activity to agree in writing to abide by the prohibitions on redisclosure. We believe the State health department may comply with this provision by simply adopting a written policy to this effect and notifying the pertinent drug abuse providers of its existence.

⁶We note that the Veterans Administration statute discussed in Note 2 also provides for nonconsensual notification of a positive finding of HIV to the infected person's spouse or sexual partner. 38 U.S.C. 4132(f). This is consistent with recommendation 9-36 of the *Report of the Presidential Commission on the Human Immuno-deficiency Virus*, p. 129 (June 1988).

⁷In Opinion 77-14, we advised that "neither the confidentiality statutes, 21 U.S.C. § 1175 and 42 U.S.C. 4582, nor the regulations, are intended to restrict the communication to a patient of limited information, necessary for purposes of bill collection, which he knows by reason of his participation in the program...." We believe this same analysis would apply to a disclosure to the patient of his HIV status by the State health department in those cases in which the patient has already received the information from the program.

