HHS Amendments to Waxman

syndrome" by the grantee, regardless whether carried out with Federal funds, will comply with the conditions of sections 2302 (requirements for confidentiality (including all requirements under part B) and informed consent) and 2303 (requirements for counseling). Section 2362(16) defines such testing to include any diagnosis of such infection made by a health care provider.

Where the part A grantee is a State, the combined effect of these provisions will be to subject to the part A requirements for testing activities of, for example, medical personnel in State hospitals and clinics who happen to arrive at a diagnosis of AIDS or HIV infection in the course of providing medical treatment.

Proposed revision:

On page 58, strike lines 20 through 25.

PART B -- CONFIDENTIALITY WITH RESPECT TO COUNSELING AND TESTING

Coverage (sec. 2321)

The bill covers essentially every health practitioner and institution in the United States that tests, counsels, or treats for AIDS or HIV infection, and every individual and entity that receives patient information from those who test, counsel, or treat. In the case of general health care institutions, the bill would require separate treatment of records dealing with testing or treatment for HIV infection or AIDS, which would be administratively burdensome; furthermore, the requirement could threaten the very confidentiality it is intended to protect, as the separate treatment could of itself signal that the individuals whose records are subject to this handling have been tested or treated for these conditions. Thus, it is difficult to evaluate the effect of such a bill and to modify it so the rules work well in practice. A more targeted coverage, limited to counseling and testing facilities receiving funds under part A of the bill, would be easier to manage.

Proposed revisions:

On page 25, strike lines 16 through 25 and insert instead "of providing to the protected individual, under a grant under part A, counseling with respect to acquired immune deficiency syndrome or testing the protected individual for infection with the etiologic agent for such syndrome;".

On page 55, line 11, strike ", testing, or health care" and insert instead "or testing".

On page 56, lines 23 through 25, strike "or in a context" and all that follows and insert instead a period.

On page 57, line 16, insert "or" at the end.

On page 57, line 20, strike "; or" and insert instead a period.

On page 57, strike lines 21 through 23.

On page 58, strike lines 20 through 25.

Disclosure to Patient (sec. 2323(a))

The bill curiously lists the patient (or his guardian, where the patient is legally incompetent) among the persons who can receive information on the patient under the authority for nonconsensual disclosure with respect to counseling and testing (sec. 2323(a)(2)). As the bill is structured, this results in anomalous requirements. The patient himself is apparently bound by restrictions on redisclosure. (Implicit effect of secs. 2321(b)(2) and 2324). When receiving information this way, the patient must be given a written document warning of the confidentiality restrictions, and must be notified by mail that the disclosure has been made. (sec. 2330(a)(1)). It is hard to believe that this is intended. A patient has a natural right to information about himself in the records. We recommend that the bill be amended to make clear that it does not apply to disclosures to the patient or his guardian.

Proposed revision:

On page 25, line 10, insert before the period "(other than to the protected individual or (if the protected individual is legally incompetent under the laws of the State in which the protected individual resides) his or her guardian)".

On page 29, line 6, strike the hyphen and insert instead "to a health care provider for the purpose of providing to the protected individual the counseling or testing described in such section.".

On page 29, strike lines 7 through 15.

Reports to Health Officers (secs. 2323(c), 2327)

The bill permits non-consensual disclosures to State health officers, and provides a procedure for State health officers to compel disclosures. However, local as well as State health

officers are involved in disease tracking and contact notification, and indeed often have the principal responsibility in this regard.

Proposed revisions:

On page 29, line 25, insert "OR LOCAL" after "STATE".

On page 30, line 3, insert "or local" after "State".

On page 33, line 25, insert "or local" after "State".

Disclosure in case of death (sec. 2323)

Legally required reports of death are not always made to health officers. Some are to vital registrars not in health departments, although the health department ultimately gets the information. Use of this information is governed by an existing body of State law. The bill should permit reports to whatever official is charged with receiving reports of death, so that deaths can be reported in accord with State law.

Proposed revision:

On page 30, after line 5, insert the following:

"(d) NONCONSENSUAL DISCLOSURE TO STATE OR LOCAL OFFICIAL IN CASE OF DEATH.--(1) A person described in section 2321(b)(1) may disclose identifying information with respect to a deceased protected individual to officials authorized to receive reports of deaths in accordance with provisions of State law requiring such reports.

"(2) Disclosures by officials described in paragraph (1) of information received pursuant to that paragraph, if made in accordance with State law, shall not be subject to the provisions of this part.".

On page 30, line 6, strike "(d)" and insert instead "(e)".

On page 30, line 19, strike "(e)" and insert instead "(f)".

On page 31, line 1, strike "(f)" and insert instead "(g)".

Disclosure for purposes of audit or evaluation (sec. 2323)

The bill makes no provision for nonconsensual disclosure for audit or investigation of activities supported by Federal and State funds. All other health activities (including drug and alcohol treatment activities subject to their own strict statutory confidentiality rules (PHS Act secs. 544 and 548, 42 U.S.C. secs. 290dd-3 and 290ee-3)) are subject to review of identifiable records for audit purposes.

If auditors cannot review actual records, including patient identifiers, there can be no assurance that governmental funds received by the covered institutions are being spent properly. Likewise, review of research projects for scientific soundness would be impossible without review of actual records including patient names.

The problem can be solved by permitting nonconsensual disclosure for scientific, management, or financial audit or other investigation of projects supported by Federal or other government funds. This access to the records should be solely for review of the program, and no patient identifying information should be disclosed outside of immediate audit personnel, and no information thus developed should ever be used against a patient.

Proposed revision:

On page 31, after line 6, insert the following:

"(h)(1) NONCONSENSUAL DISCLOSURE FOR PURPOSES OF AUDIT OR EVALUATION.--A person described in section 2321(b)(1) may disclose identifying information with respect to a protected individual to qualified and properly identified persons for the purpose of conducting scientific audits, management audits, financial audits, or program investigation or evaluation, but such personnel may not identify, directly or indirectly, any protected individual in any report of such audit or evaluation, or otherwise disclose the identity of a protected individual.

"(2) No information referred to in paragraph (1) may be used to initiate or substantiate any criminal charges against a protected individual or to conduct any investigation of a protected individual.

Disclosure to sexual and needle-sharing contacts (sec. 2329)

In order to help ensure that the authority for physicians or counselors to disclose identifying information to sexual contacts of or individuals who have shared hypodermic needles with a

protected individual, we would recommend strengthening the language permitting such disclosure if medically appropriate to permit such disclosure only where medically appropriate to protect the health of the contact.

Proposed revision:

On page 36, line 23, insert before the semicolon "to protect the health of such spouse, sexual partner, or individual with whom the protected individual has shared a hypodermic needle".

Notification to patient of disclosures (sec. 2330)

The bill requires written notification to patients (if living) of all disclosures made with patient consent, and certain disclosures made without patient consent. It is inadvisable to require this without a clear provision requiring that the patient be given a choice as to whether he or she wants such notification. Mailing written statements regarding these records presents a serious risk of inadvertent disclosure of the patient's condition. Written notifications would go to homes with relatives, roommates, or others, or to workplaces with co-workers and managers, and are subject to being opened by these people. These may be the very people the patient most strongly wants to conceal his or her condition from. The very fact of correspondence from certain institutions conveys information about the patient.

The problem can be solved by requiring the record holder to keep a record of all disclosures, and giving the patient access to this record upon request, but also requiring that the patient receive written notification of each disclosure if the patient explicitly requests it. A model for this approach is the Privacy Act, applicable to Federal records, which requires recording of disclosures and permits subject access to this record (5 U.S.C. 552a(c)).

Proposed revision:

On page 37, line 5, strike "(A)".

On page 37, line 5, strike "(2)" and insert instead "(4)".

On page 37, strike lines 13 through 17 and insert instead the following:

"(2) Except as provided in paragraph (4), any person who, under any of sections 2322 through 2324, discloses any identifying information with respect to a protected individual shall--

"(A)(i) keep an accounting of the date, nature, and purpose of each disclosure of such information, and of the name and address of the person to whom the disclosure is made;

"(ii) retain the accounting made under subparagraph (i) for at least five years or the life of the record, whichever is longer, after the disclosure for which the accounting is made;

"(iii) make the accounting made under subparagraph (i) available to the protected individual at his request; and

"(3) Except as provided in paragraph (4), each person providing testing and counseling services subject to this part shall offer each protected individual the opportunity for notification in writing of the fact of each disclosure of identifying information under any of sections 2322 through 2327, and of the date, and of the name and address of the person to whom the disclosure is made, at the time each such disclosure is made, and shall provide such notification if the protected individual requests it.".

On page 37, line 18, strike "(2)" and insert instead "(4)".

On page 37, lines 18 and 19, strike "paragraph (1)" and insert instead "paragraphs (1), (2), and (3)".

Criminal penalties (sec. 2332)

The bill provides for criminal penalties for disclosure or redisclosure other than as permitted under the bill. The presence of such criminal sanctions in the bill will have the effect of requiring that the relevant provisions of the bill be construed narrowly, and that any provision found by a court to be overbroad or vague be given no effect. Since the prohibited conduct must be clear on the face of a statute establishing criminal sanctions, we would not be able to clarify vague or ambiguous statutory provisions (of which there are not a few) in regulations. One example: the bill permits disclosure of

identifying information within an organization, but does not define the term "organization".

To eliminate these problems, we recommend that the authority for criminal penalties be deleted. It would seem that the remaining authority for civil penalties and private suits would be a sufficient deterrent to violations of the prohibitions.

Proposed revision:

On page 41, strike lines 3 through 14.

On page 42, lines 3 to 4, strike "or 2332".

PART C --EMERGENCY RESPONSE EMPLOYEES

Protection of emergency response employees (secs. 2341(a), 2351(e) and (f))

The bill as drafted would create unnecessary fear and panic among emergency service employees by mandating the employer to notify each employee who may have been exposed. It is preferable to educate the employees regarding what constitutes a significant exposure and how to properly report such an exposure. This would permit the designated officer to focus his efforts on the individual employee at risk when it becomes known subsequently that the victim of the emergency was infected with the human immunodeficiency virus.

Notification of everyone involved with the transport of an HIV-infected victim, including the location/date/time of the emergency involved, is more likely to breach the confidentiality of the victim. Assuming that many such victims will be transported in the future, the procedure outlined in the bill will be very expensive and will cause alarm among many emergency service providers unnecessarily.

The "window" period, the time during which an infected person has not yet developed antibodies, is generally from 6 to 12 weeks after initial infection. The bill contains a 60-day limitation period for notification by the medical facility, beginning on the date that the victim is transported by emergency response employees. This should be extended to 90 days, thus allowing adequate time for the development of HIV antibodies if the victim is in the window period at the time of exposure. It should be noted that a medical facility is not required to perform the HIV-antibody test but must report a positive test if the test is performed by the medical facility within the limitation period.

Proposed revisions:

On page 43, line 25, strike out "and".

On page 44, line 6, strike out the period and insert instead "; and".

On page 44, insert below line 6 the following:

"(C) procedures for reporting of any exposure of an emergency response employee to blood or infectious body fluids of a victim of an emergency.".

On page 49, line 24, strike out "may have been exposed to" and insert instead "reported exposure to the blood or infectious body fluids of the emergency victim determined to be infected with".

On page 51, line 6, strike "60-day" and insert instead "90-day".

federal register

Tuesday
June 9, 1987

Part II

Department of Health and Human Services

Public Health Service

42 CFR Part 2

Confidentiality of Alcohol and Drug Abuse Patient Records; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 2

Confidentiality of Alcohol and Drug Abuse Patient Records

AGENCY: Alcohol, Drug Abuse, and Mental Health Administration, PHS, HHS.

ACTION: Final rule.

SUMMARY: This rule makes editorial and substantive changes in the "Confidentiality of Alcohol and Drug Abuse Patient Records" regulations. These changes are an outgrowth of the Department's commitment to make its regulations more understandable and less burdensome. The Final Rule clarifies and shortens the regulations and eases the burden of compliance.

EFFECTIVE DATE: August 10, 1987.

FOR FURTHER INFORMATION CONTACT: Judith T. Galloway (301) 443–3200.

SUPPLEMENTARY INFORMATION: The "Confidentiality of Alcohol and Drug Abuse Patient Records" regulations, 42 CFR Part 2, implement two Federal statutory provisions applicable to alcohol abuse patient records (42 U.S.C. 290dd–3) and drug abuse patient records (42 U.S.C. 290ee–3).

The regulations were originally promulgated in 1975 (40 FR 27802). In 1980 the Department invited public comment on 15 substantive issues arising out of its experience interpreting and implementing the regulations (45 FR 53). More than 450 public responses to that invitation were received and taken into consideration in the preparation of a 1983 Notice of Proposed Rulemaking (48 FR 38758). Approximately 150 comments were received in response to the Notice of Proposed Rulemaking and were taken into consideration in the preparation of this Final Rule.

The proposed rule made both editorial and substantive changes in the regulations and shortened them by half. This Final Rule adopts most of those changes, with some significant substantive modifications and relatively few editorial and clarifying alterations.

Synopsis of Substantive Provisions

The Confidentiality of Alcohol and Drug Abuse Patient Record regulations (42 CFR Part 2) cover any program that is specialized to the extent that it holds itself out as providing and provides alcohol or drug abuse diagnosis, treatment, or referral for treatment and which is federally assisted, directly or indirectly (§ 2.12 (a) and (b)).

The regulations prohibit disclosure or use of patient records ("records" meaning any information whether recorded or not) unless permitted by the regulations (§ 2.13). They do not prohibit giving a patient access to his or her own records (§ 2.23). However, the regulations alone do not compel disclosure in any case (§ 2.3(b)).

The prohibition on disclosure applies to information obtained by the program which would identify a patient as an alcohol or drug abuser (§ 2.12(a)(1)). The restriction on use of information to investigate or to bring criminal charges against a patient applies to any alcohol or drug abuse information obtained by the program (§ 2.12(a)(2)).

Any disclosure premitted under the regulations must be limited to that information which is necessary to carry out the purpose of the disclosure (§ 2.13).

The regulations permit disclosure of information if the patient consents in writing in accordance with § 2.31. Any information disclosed with the patient's consent must be accompanied by a statement which prohibits further disclosure unless the consent expressly permits further disclosures or the redisclosure is otherwise permitted by the regulations (§ 2.32). Special rules govern disclosures with the patient's consent for the purpose of preventing multiple enrollments (§ 2.34) and for criminal justice referrals (§ 2.35).

The regulations permit disclosure without patient consent if the disclosure is to medical personnel to meet any individual's bona fide medical emergency (§ 2.51) or to qualified personnel for research (§ 2.52), audit, or program evaluation (§ 2.53). Qualified personnel may not inlcude patient identifying information in any report or otherwise disclose patient identities except back to the program which was the source of the information (§§ 2.52(b) and 2.53(d)).

The regulations permit disclosure pursuant to a court order after the court has made a finding that "good cause" exists. A court order may authorize disclosure for noncriminal purposes (§ 2.64); for the purpose of investigating or prosecuting a patient if the crime involved is extremely serious (§ 2.65); for the purpose of investigating or prosecuting a program or a person holding the records (§ 2.66); and for the purpose of placing an undercover agent or informant to criminally investigate empolyees or agents of the program (§ 2.67).

A court order may not authorize disclosure of confidential communications unless disclosure is necessary to protect against an existing threat to life or serious bodily injury of another person; to investigate or prosecute an extremely serious crime; or if the patient brings the matter up in any legal proceedings (§ 2.63).

A court order may not authorize qualified personnel who received information without patient consent for the purpose of conducting research, audit, or program evaluation, to disclose that information or to use it to conduct any criminal investigation or prosecution of a patient (§ 2.62). Information obtained under a court order to investigate or prosecute a program or other person holding the records or to place an undercover agent or informant may not be used to conduct any investigation or prosecution of a patient or as the basis for a court order to criminally investigate or prosecute a patient (§ 2.66(d)(2) and § 2.67(e)).

These regulations do not apply to the Veteran's Administration, to exchanges within the Armed Forces or between the Armed Forces and the Veterans' Administration; to the reporting under State law of incidents of suspected child abuse and neglect to appropriate State or local authorities; to communications within a program or between a program and an entity having direct administrative control over the program; to communications between a program and a qualified service organization; and to disclosures to law enforcement officers concerning a patient's commission of (or threat to commit) a crime at the program or against personnel of the program (§ 2.12(c)).

If a person is not now and never has been a patient, there is no patient record and the regulations do not apply (§ 2.13(c)(2)).

Any answer to a request for a disclosure of patient records which is not permitted must not affirmatively reveal that an identified individual has been or is an alcohol or drug patient. One way to make such an answer is to give a copy of the confidentiality regulations to the person who asked for the information along with general advice that the regulations restrict the disclosure of alcohol or drug abuse patient records and without identifying any person as an alcohol or drug abuse patient (§ 2.13(c)).

Each patient must be told about these confidentiality provisions and furnished a summary in writing (§ 2.22).

There is a criminal penalty for violating the regulations: not more than $500 for a first offense and not more than $5,000 for each subsequent offense (§ 2.4).

COMPARISON WITH PROPOSED RULE

Subpart A—Introduction

Reports of Violations

Both the existing and proposed rules provide for the reporting of any violations of the regulations to the United States Attorney for the judicial district in which the violations occur, for reporting of violations on the part of methadone programs to the Regional Offices of the Food and Drug Administration, and for reporting violations by a Federal grantee or contractor to the Federal agency monitoring the grant or contract. (See §§ 2.7 and 2.5, respectively.)

Inasmuch as it is the Department of Justice which has ultimate and sole responsibility for prosecuting violations of these regulations, the Final Rule continues to provide for the reference of reports of any violations to the United States Attorney for the judicial district in which the violations occur.

It also continues to provide for the reference to the Regional Offices of the Food and Drug Administration of any reports of violations by a methadone program. As a regulatory agency, the Food and Drug Administration has both the organization and authority to respond to alleged violations.

The Final Rule no longer directs reports of violations by a Federal grantee or contractor to the Federal agency monitoring the grant or contract or, as in the proposed revision of the rules, violations by a Federal agency to the Federal agency responsible for the program. This change is made in recognition of the lack of investigative tools available to granting and contracting agencies and of the ultimate referral which must be made to the Department of Justice. Of course, if alleged violations come to the attention of the Department of Health and Human Services, they will be forwarded to an appropriate representative of the Department of Justice.

Subpart B—General Provisions

Specialized Programs

Like the proposed rule at § 2.12, the Final Rule is applicable to any alcohol and drug abuse information obtained by a federally assisted alcohol or drug abuse program. "Program" is defined in § 2.11 as a person which says it provides and which actually provides alcohol or drug abuse diagnosis, treatment, or referral for treatment. A program may provide other services in addition to alcohol and drug abuse services, for example mental health or psychiatric services, and nevertheless be an alcohol or drug abuse program within the meaning of these regulations so long as the entity is specialized by holding itself out to the community as providing diagnosis, treatment, or referral for treatment for alcohol and/or drug abuse.

If a facility is a provider of general medical care, it will not be viewed in whole or in part as a program unless it has either (1) an identified unit, i.e., a location that is set aside for the provision of alcohol or drug abuse diagnosis, treatment, or referral for treatment, or (2) it has personnel who are identified as providers of diagnosis, treatment, or referral for treatment *and* whose primary function is the provision of those alcohol or drug abuse services.

Regardless of whether an entire legal entity is a program or if a part of the entity is a program, the confidentiality protections cover alcohol or drug abuse patient records within any federally assisted program, as "program" is defined in these regulations.

Those comments opposed to limiting applicability of the regulations to "specialized" programs focused on the desirability of full and uniform applicability of confidentiality standards to any alcohol or drug abuse patient record irrespective of the type of facility delivering the services.

The Department takes the position that limiting applicability to specialized programs, i.e., to those programs that hold themselves out as providing and which actually provide alcohol or drug abuse diagnosis, treatment, and referral for treatment, will simplify administration of the regulations without significantly affecting the incentive to seek treatment provided by the confidentiality protections. Applicability to specialized programs will lessen the adverse economic impact of the current regulations on a substantial number of facilities which provide alcohol and drug abuse care only as an incident to the provision of general medical care. We do not foresee that elimination of hospital emergency rooms and general medical or surgical wards from coverage will act as a significant deterrent to patients seeking assistance for alcohol and drug abuse.

While some commenters suggested that there will be an increased administrative burden for organizations operating both a specialized alcohol and/or drug abuse program and providing other health services, we view this as the same burden facing all general medical care facilities under the existing rule.

In many instances it is questionable whether applicability to general medical care facilities addresses the intent of Congress to enhance treatment incentives for alcohol and drug abuse inasmuch as many alcohol and/or drug abuse patients are treated in a general medical care facility not because they have made a decision to seek alcohol and drug abuse treatment but because they have suffered a trauma or have an acute condition with a primary diagnosis of other than alcohol or drug abuse.

In sum, we are not persuaded that the existing burden on general medical care facilities is warranted by the benefit to patients in that setting. Therefore, the Final Rule retains the language of the proposed rule at § 2.11 defining "program" and making the regulations applicable at § 2.12 to any information about alcohol and/or drug abuse patients which is obtained by a federally assisted alcohol or drug abuse program for the purpose of treating, making a diagnosis for treatment, or making a referral for treatment of alcohol or drug abuse.

Communications between a Program and an Entity Having Direct Administrative Control

The existing regulations at § 2.11(p)(1) and the proposed rule at § 2.12(c)(3) exempt from the restrictions on disclosure communications of information within a program between or among personnel in connection with their duties or in connection with provision of patient care, respectively. The Department has previously interpreted the existing provision to mean that communications within a program may include communications to an administrative entity having direct control over the program.

The Final Rule has incorporated that legal opinion into the text by amending § 2.12(C)(3) to exempt from restrictions on disclosure "communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis treatment, or referral for treatment of alcohol or drug abuse" if the communications are within a program or between a program and an entity that has direct administrative control over the program. Paragraph (d) of that same section is accordingly amended to restrict any further disclosure by an administrative entity which receives information under § 2.12(c)(3).

Explanation of Applicability

The existing regulations are applicable to patient records maintained in connection with the performance of

any alcohol abuse or drug abuse prevention function which is federally assisted. Applicability is determined by the nature and purpose of the records, not the status or primary functional capacity of the recordkeeper. The definition of "alcohol abuse or drug abuse prevention function" includes specified activities "even when performed by an organization whose primary mission is in the field of law enforcement or is unrelated to alcohol or drugs."

The proposed regulations and the Final Rule at § 2.12 make the regulations applicable to any information about alcohol and drug abuse patients which is obtained by a federally assisted alcohol or drug abuse program. A program is defined to be those persons or legal entities which hold themselves out as providing and which actually provide diagnosis, treatment, or referral for treatment for alcohol and/or drug abuse. Thus, there is a fundamental shift toward determining applicability on the basis of the function of the recordkeeper and away from making that decision based solely on the nature and purpose of the records.

No alcohol and drug abuse patient records, whether identified by the nature and purpose of the records or the function of the recordkeeper, are covered by these regulations unless the diagnosis, treatment, or referral for treatment with which the records are connected is federally assisted.

Several commenters pointed out that while the regulatory language of the proposed rule on its face applies the rule to information about alcohol and drug abuse patients in federally assisted programs, the explanation of the applicability provision at § 2.12(e)(2) obscures the otherwise forthright statement by an additional standard based on the type of Federal assistance going to the program, i.e., some patient records in a federally assisted program would be covered and others would not. Those who commented on this section urged that coverage distinctions under the explanation in § 2.12(e)(2) be omitted because they result in disparate treatment of patient records within an alcohol and/or drug abuse program based on the type of Federal assistance going to the program. Other commenters asserted that basing coverage on the type of assistance is inconsistent with the clear meaning of the applicability provision in the proposed and Final Rule.

The Final Rule revises the proposed explanatory material at § 2.12(e)(2) to show that all alcohol and drug abuse patient records within a covered program are protected by the confidentiality provisions and that the record of an individual patient in an uncovered program, whose care is federally supported in some way which does not constitute Federal assistance to the program under § 2.12(b), is not afforded confidentiality protections. Thus, where a Federal payment is made to a program on behalf of an individual patient and that program is not otherwise federally assisted under § 2.12(b), the record of that individual will not be covered by the regulations. Although the Department expects them to be rare, it would be possible for such instances to occur. For example, if a Federal court places an individual in a for-profit program that is not certified under the Medicare program, that is not authorized to conduct methadone treatment, and is not otherwise federally assisted in any manner provided in § 2.12(b), the patient record of that individual would not be covered by the regulations even though the Federal court paid for the individual's treatment.

Comments to the proposed rule were persuasive that the type of assistance should not affect the scope of records covered within a covered program. When the determination of covered records was based on the purpose and nature of each record, it was consistent to view Federal assistance from the perspective of each individual record. However, when the determination of which records are covered is based on who is keeping the records, as in the proposed and Final Rule, it is consistent with the approach to view Federal assistance from the program level as applying to all alcohol and drug abuse patient records within the program.

Determining coverage based on Federal assistance to the program rather than to an individual represents a change in policy from the current regulations under which the Department views a Federal payment made on behalf of an individual as sufficient to cover that individual's record. However, any disadvantage in not covering individual records in those rare cases which may occur is outweighed by the advantages of consistency and efficiency in management of the program as a result of all alcohol and drug abuse patient records in the program being subject to the same confidentiality provisions.

The Final Rule includes new material at § 2.12(e)(3) which briefly explains the types of information to which the restrictions are applicable, depending on whether a restriction is on disclosure or on use. A restriction on disclosure applies to any information which would identify a patient as an alcohol or drug abuser. The restriction on use of information to bring criminal charges or investigate a patient for a crime applies to any information obtained by the program for the purpose of diagnosis, treatment, or referral for treatment of alcohol or drug abuse.

Several commenters strongly urged the explicit inclusion of school-based education and prevention programs in the applicability of the regulations. School-based education and prevention activities may fall within the definition of a program if they provide alcohol or drug abuse diagnosis, treatment, or referral for treatment and if they hold themselves out as so doing. That is reflected in the Final Rule at § 2.12(e)(1) with the inclusion of "school-based programs" in the list of entities which may come under the regulations.

An example of how diagnosis affects coverage has been omitted at § 2.12(e)(3)(ii). It is omitted not because the example could never occur under the Final Rule, but because it is very unlikely that a "specialized" program, as program is defined under these regulations, would be treating a patient for a condition which is not related to alcohol or drug abuse such that the reference to a patient's alcohol or drug abuse history would not be related to the condition for which treatment is rendered. Inasmuch as the regulations only apply to programs, this example is more likely to confuse than provide guidance and for that reason has been taken out.

Notifying a Parent or Guardian of a Minor's Application for Treatment

The proposed rule at § 2.14 reorganized and revised but did not substantively amend the existing § 2.15 dealing with the subject of minor patients. Under both the existing and proposed rules, a minor patient's consent is generally required prior to notifying the minor's parent or guardian of his or her application for treatment. This is true even though without notification it is impossible to obtain parental consent in those cases where State law requires a parent, guardian, or other person to consent to alcohol or drug abuse treatment of a minor.

While this issue was not raised in the proposed rule, the Department has received several inquiries on it from the public since the proposed rule was published suggesting that in those States, where the parent's or guardian's consent is needed for the minor's treatment, the program should be free to notify the parent or guardian of the minor's application for treatment without constraint. The Department has considered this issue and decided to

make no substantive changes in the existing section dealing with minor patients.

Although both the current rule and the proposed rule generally prohibit parental notification without the minor's consent, they also provide for an exception. Under this exception such notification would be permitted when, in the program director's judgment, the minor lacks the capacity to make a rational decision on the issue of notification, the situation poses a substantial threat to the physical well-being of the minor or any other person, and this threat may be alleviated by notifying the parent or guardian. Under this provision, the program director is vested with the authority to determine when the circumstances permitting parental notification arise. In discussing the Department's philosophy behind this provision, § 2.15–1(e) of the existing rule states: "It [this provision] is based upon the theory that where a person is actually as well as legally incapable of acting in his own interest, disclosures to a person who is legally responsible for him may be made to the extent that the best interests of the patient clearly so require."

While this exception would not permit parental notification without constraint whenever the program director feels it is appropriate, the Department believes it does provide the program director with significant discretion and does permit parental notification in the most egregious cases where the "best interests of the patient clearly so require." Accordingly, the Department has determined not to make any substantive changes in the manner in which the existing rule handles the issue of parental notification. However, proposed § 2.14 has been revised to clarify that no change in meaning is intended from the current rule.

Finally, it should be noted that this rule in no way compels a program to provide services to a minor without parental consent.

Separation of Clinical from Financial/Administrative Records

The current rules governing research, audit, or evaluation functions by a governmental agency at § 2.53 state that "programs should organize their records so that financial and administrative matters can be reviewed without disclosing clinical information and without disclosing patient identifying information except where necessary for audit verification." The proposed rule transformed this hortatory provision for maintenance of financial/administrative records apart from clinical records into a requirement in § 2.16 dealing with security for written records.

Several commenters predicted that such a requirement will pose an extremely cumbersome burden on programs, perhaps tantamount to requiring maintenance of two systems of files. The Final Rule has adopted the recommendation of those commenters to drop this requirement, primarily on the basis of the potential administrative and recordkeeping problems it poses in the varied treatment settings to which these regulations are applicable.

While it is desirable to withhold clinical information from any research, audit, or program evaluation function for which that clinical information is not absolutely essential, the Final Rule does not require recordkeeping practices designed to guarantee that outcome. The Final Rule does, of course, implement the statutory provisions which prohibits those who receive patient identifying information for the purpose of research, audits, or program evaluation from identifying, directly or indirectly, any individual patient in any report of such research, audit, or evaluation or otherwise disclosing patient identities in any manner (see §§ 2.52(b) and 2.53(d)).

Subpart C—Disclosures with Patient's Consent

Notice to Patients

Like the proposed rule, the Final Rule at § 2.22 requires that notice be given to patients that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records. The response to this provision in the proposed rule reflects strong support for notifying patients of confidentiality protections, although many stressed that the notice should be simplified in order to be useful rather than confusing to the patient. Some of those who recommended against adoption of a notice provision did so on grounds that the notice as proposed is too complex. Therefore, in response to many who supported the notice provision and those who opposed it on grounds that it is too complex, the Final Rule substantially revises the elements which must be included in the written notice to each patient and accordingly rewrites the sample notice which a program may adopt at its option in fulfillment of the notice requirement.

Form of Written Consent

The proposed rule retains the requirements in § 2.31 of the existing regulations for written consent to disclosure of information which would identify an individual as an alcohol or drug abuser. There was a great deal of support among those who commented on this provision for the retention of the existing elements of written consent on grounds that the present system is working well and that the elements which go to make up written consent are sufficiently detailed to assure an opportunity for a patient to make an informed consent to disclose patient identifying information. Others recommended a more generalized consent form.

The Final Rule retains all elements previously required for written consent, though in one instance it will permit a more general description of the required information. The first of the required elements of written consent in both the existing and proposed rule (§ 2.31 (a)(1)) asks for the name of the program which is to make the disclosure. The Final Rule will amend that element by calling for "(1) The specific name or general designation of the program or person permitted to make the disclosure." This change will permit a patient to consent to disclosure from a category of facilities or from a single specified program. For example, a patient who chooses to authorize disclosure of all his or her records without the necessity of completing multiple consent forms or individually designating each program on a single consent form would consent to disclosure from all programs in which the patient has been enrolled as an alcohol or drug abuse patient. Or, a patient might narrow the scope of his or her consent to disclosure by permitting disclosure from all programs located in a specified city, from all programs operated by a named organization, or as now, the patient might limit consent to disclosure from a single named facility. (In this connection, the Department interprets the existing written consent requirements to permit consent to disclosure of information from many programs in one consent form by listing specifically each of those programs on the form.)

This change generalizes the consent form with respect to only one element without diminishing the potential for a patient's making an informed consent to disclose patient identifying information. The patient is in position to be informed of any programs in which he or she was previously enrolled and from which he or she is willing to have information disclosed.

With regard to deficient written consents, the Final Rule at § 2.31(c) reverts to language from the existing regulations rather than using the language of the proposed rule to express the idea that a disclosure may not be made on the basis of a written consent

which does not contain all required elements in compliance with paragraph (a) of § 2.31. There was no intention in drafting the proposed rule to establish a different or more stringent standard than currently exists prohibiting disclosures without a conforming written consent. Because that was misunderstood by some, the Final Rule will not permit disclosures on the basis of a written consent which, "On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section . . ."

Express Consent to Redisclosure Permitted

Both the existing and proposed rules at § 2.32 prohibit redisclosure by a person who receives information from patient records pursuant to the written consent of the patient and who has been notified that the information is protected by Federal rules precluding redisclosure except as permitted by those Federal rules. However, the statement of the prohibition on redisclosure at § 2.32 does not make evident the Department's interpretation that it is possible for a patient, at the same time consent to disclosure is given, to consent to redisclosure in accordance with the Federal rules. The Final Rule rewords the statement of prohibition on redisclosure and adds the phrase shown in quotes below to the second sentence as follows:

> 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 is otherwise permitted by 42 CFR Part 2.

The purpose of the added phrase is to acknowledge that redisclosure of information may be expressly permitted in the patient's written consent to disclosure. For example, a patient may consent to disclose pertinent information to an employment agency and at the same time permit the employment agency to redisclose this information to potential employers, thus making unnecessary additional consent forms for redisclosures to individual employers. Similarly, a patient may consent to disclose pertient information to an insurance company for the purpose of claiming benefits, and at the same time consent to redisclosure by that insurance company to another organization or company for the purpose of administering the contract under which benefits are claimed by or on behalf of the patient.

Patient Consent to Unrestricted Communications for the Purpose of Criminal Justice System Referrals

Most of those who commented on the revision of § 2.35 generally supported the proposed changes. However, two State commenters encouraged retention of language in the existing regulations which explicitly permits a patient to consent to "unrestricted communications." Otherwise, those commenters say, the revision will act as a deterrent to criminal justice system referrals.

Both the proposed and Final Rule omit most limitations on disclosures to which a patient may consent. The criteria for permitting release of information with patient consent under the Final Rule are: (1) A valid consent under § 2.31 and (2) a determination that the information disclosed is necessary to carry out the purpose for which the consent was given (§ 2.13(a)). Although special rules for disclosures in connection with criminal justice system referrals were retained, they do not restrict "how much and what kind of information" a patient may consent to have disclosed under § 2.31. Section 2.31(a)(5) places no restrictions on how much or what kind of information a patient may consent to have disclosed. That section simply requires that each written consent describe how much and what kind of information the patient consents to have disclosed. A patient may consent to disclosure of any information concerning his or her participation in a program. In the case of a consent for the purpose of a criminal justice system referral, consent to disclose "any information concerning my participation in the program" pursuant to § 2.31(a)(5) would permit "unrestricted communications" from the program to appropriate persons within the criminal justice system to the same extent permitted by the existing rule. Therefore, the Final Rule does not substantively alter § 2.35 as proposed. (Paragraph (c) has been reworded for clarity.)

Subpart D—Disclosures Without Patient's Consent

Elimination of the Requirement to Verify Medical Personnel Status

The proposed regulations at § 2.51 implement the statutory provision which permits a disclosure "to medical personnel to the extent necessary to meet a bona fide medical emergency." The proposed rule added a requirement not contained in the existing § 2.51 that the program make a reasonable effort to verify that the recipient of the information is indeed medical personnel.

The Final Rule deletes the proposed verification requirement in response to comments from several sources that such a requirement is unnecessary, will cause delay, and could possibly impede emergency treatment. In view of those comments and our interest in easing the burden of compliance where possible, the Final Rule does not require verification of the "medical personnel" status of the recipient of information in the face of a medical emergency.

However, the statute permits disclosures only to medical personnel to meet a medical emergency and elimination of the verification requirement does not in any way expand upon the category of persons to whom a disclosure may be made to meet a medical emergency. Neither does elimination of the verification requirement affect the provision in the Final Rule at § 2.51(c) that a program document in the patient's records any disclosure which is made in the face of a medical emergency.

Assessment of Research Risks

The proposed regulations at § 2.52 modified and streamlined existing provisions in §§ 2.52 and 2.53 governing disclosures for scientific research. The proposal clarified that the determination of whether an individual is qualified to conduct scientific research would be left to the program director, and required that such qualified personnel have a research protocol which includes safeguards for storing patient identifying information and prohibits redisclosures except as allowed by these regulations.

The Final Rule adds an additional condition: The program director must ensure that a written statement is furnished by the researcher that the research protocol has been reviewed by an independent group of three or more individuals who found that the rights of patients would be adequately protected and that the potential benefits of the research outweigh any potential risks to patient confidentiality posed by the disclosure of records.

This revision was prompted by comment from both the public and private sectors that review of the research protocol for the purpose of ensuring the protection of human subjects participating in the research (in this case, the patients whose records are proposed for use in research) is imperative prior to permitting disclosure of patient identifying information for the conduct of scientific research. The requirement that researchers state in writing that the protocol has been reviewed for the protection of human subjects will provide an additional point

of reference for the program director in determining whether to release patient identifying information for research purposes.

Researchers who receive support from the Department and many other Federal agencies are required under regulations for the protection of human subjects to obtain review of their protocol from an "institutional review board (IRB)." Such boards generally are set up by the institution employing the researcher. Regulations require that IRBs be composed of persons with professional competence to review research, as well as persons who can judge sensitivity to community attitudes and ethical concerns. Documentation of review and approval by an IRB or by another group of at least three individuals, appropriately constituted to make judgements on issues concerning the protection of human subjects, would meet the new requirement in § 2.52(a)(3).

Audit and Evaluation Activities by Nongovernmental Entities

The proposed regulations at § 2.53 simplify and shorten the provisions on audit and evaluation activities and divide them into two categories: (1) Those activities that do not require copying or removal of patient records, and (2) those that require copying or removal of patient records. The proposed rule permits governmental agencies to conduct audit and evaluation activities in both categories. In addition, if no copying or removal of the records is involved, the program director may determine that other persons are "qualified personnel" for the purpose of conducting audit and evaluation activities. There is no provision for nongovernmental entities to perform any audit or evaluation activity if copying or removal of records is involved.

In response to the proposed rule the Department received comment that third party payers should be permitted to copy or remove records containing patient identifying information as is permitted by governmental agencies that finance or regulate alcohol or drug abuse programs.

Recognizing that private organizations, like governmental agencies, have a stake in the financial and programmatic integrity of treatment programs arising out of their financing of alcohol and drug abuse programs directly, out of peer review responsibilities, and as third party payers, the Final Rule permits access to patient identifying information for audit and evaluation activities by private organizations in circumstances identical to the access afforded governmental agencies. Specifically, if a private organization provides financial assistance to a program, is a third party payer covering patients in the program, or is a peer review organization performing a utilization or quality control review, the Final Rule permits the private organization to have access to patient identifying information for the purpose of participating in audit and evaluation activities to the same extent and under the same conditions as a governmental agency.

Audit and Evaluation of Medicare or Medicaid Programs

In response to specific questions which have come to the Department's attention and in recognition of the continued importance of the integrity of the Medicare and Medicaid programs to the delivery of alcohol and drug abuse services, the Final Rule includes a new paragraph (c) in § 2.53 which clarifies the audit and evaluation provisions as they pertain to Medicare or Medicaid.

Specifically, the new paragraph clarifies that the audit and evaluation function includes investigation for the purpose of administrative enforcement of any remedy imposed by law by any Federal, State, or local agency which has responsibility for oversight of the Medicare or Medicaid programs. The new paragraph makes explicit that the term "program" includes employees of or providers of medical services under an alcohol or drug abuse program. Finally, it clarifies that a peer review organization may communicate patient identifying information for the purpose of a Medicare or Medicaid audit or evaluation to the agency responsible for oversight of the Medicare or Medicaid program being evaluated or audited.

Subpart E—Court Orders Authorizing Disclosure and Use

Court-Ordered Disclosure of Confidential Communications

The existing regulations at § 2.63 limit a court order to "objective" data and prohibit court-ordered disclosure of "communications by a patient to personnel of the program." The proposed regulations delete the provision restricting a court order to objective data and precluding an order from reaching "communications by a patient to personnel of the program." Deletion of that provision provoked considerable discussion and concern on the part of a large number of persons, 85% of whom opposed allowing court-ordered disclosure of nonobjective data.

The Final Rule at § 2.63 restores protection for many "communications by a patient to personnel of the program" and information which is of a nonobjective nature, but it does not protect that information from court order in the face of an existing threat to a third party or in connection with an investigation or prosecution of an extremely serious crime.

Because the existing regulations seem to be dealing uniformly with two related but not necessarily identical types of information, i.e., "objective" data and "communications by a patient to personnel of the program," the Final Rule drops those terms in favor of the term "confidential communications," a term in use since 1975 in existing § 2.63–1. "Confidential communications" are the essence of those matters to be afforded protection and are as readily identified as "objective" data. Furthermore, protection of "confidential communications" is more relevant to maintaining patient trust in a program than is protection of "communications by a patient to personnel of the program," a term which does not distinguish between the innocuous and the highly sensitive communication.

Most comments in opposition to relaxing the court order limitations on confidential communications said that the potential for court-ordered disclosure of confidential communications will compromise the therapeutic environment, may deter some alcohol and drug abusers from entering treatment, and will yield information which may be readily misinterpreted or abused.

While freedom to be absolutely candid in communicating with an alcohol or drug abuse program may have therapeutic benefits and may be an incentive to treatment, it is the position of the Department that those therapeutic benefits cannot take precedence over two circumstances which merit court-ordered disclosure of confidential communications.

The first of these is a circumstance in which the patient poses a threat to any third party. Existing rules do not permit a court to authorize disclosure of any communication by a patient to a program; for example, that the patient is abusing a child or has expressed an intention to kill or seriously harm another person. The balance between patient confidentiality and an existing threat posed by the patient to life or of serious bodily injury to another person must be weighted in favor of permitting a court to order disclosure of confidential communications which are necessary to protect against such an existing threat.

The second of these circumstance is one in which a patient's confidential

communications to a program are necessary in connection with investigation or prosecution of an extremely serious crime, such as a crime which directly threatens loss of life or serious bodily injury. The Department takes the position that it is consistent with the intent of Congress and in the best interest of the Nation to permit the exercise of discretion by a court, within the context of the confidentiality law and regulations, to determine whether to authorize disclosure or use of confidential communications from a patient's treatment record in connection with such an investigation or prosecution.

Our aim is to strike a balance between absolute confidentiality for "confidential communications" on one side and on the other, to protect against any existing threat to life or serious bodily harm to others and to bring to justice those being investigated or prosecuted for an extremely serious crime who may have inflicted such harm in the past. While many confidential communications will remain beyond the reach of a court order, revised § 2.63 of the Final Rule will permit a court to authorize disclosure of confidential communications if the disclosure is neccessary to protect against an existing threat to life or serious bodily injury, if disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, or, as in the existing rule, if disclosure is in connection with a legal proceeding in which the patient himself/herself offers testimony or evidence concerning the confidential communications.

Open Hearing on Patient Request in Connection with a Court Order

Courts authorizing disclosure for noncriminal purposes are required at § 2.64(c) of the Final Rule to conduct any oral argument, review of evidence, or hearing in the judge's chambers or in some manner that ensures patient identifying information is not disclosed to anyone who is not a party to the proceeding, to a party holding the record, or to the patient. The existing rules provide that a patient may request an open hearing. The proposed rule did not provide for the patient to request an open hearing.

The existing and proposed rule provides that a patient may consent to use of his or her name rather than a fictitious name in any application for an order authorizing disclosure for noncriminal purposes. The existing rule requires "voluntary and intelligent" consent. The proposed rule ensures the quality of the consent by requiring that it be in writing and in compliance with § 2.31.

Upon reconsideration, the Department has reinstated the provision permitting a patient to consent to an open hearing in a noncriminal proceeding but with the same formality as is required by the proposed rule for a consent by the patient to use his or her name in an application for an order. Therefore, the Final Rule at § 2.64(c) requires that any hearing be held in such a way as to maintain the patient's confidentiality "unless the patient requests an open hearing in a manner which meets the written consent requirements of these regulations."

Content of Court Order—Sealing of Record as an Example

The content of a court order authorizing disclosure for noncriminal purposes and any order for disclosure and use to investigate or prosecute a program or the person holding the records is limited at § 2.64(e) to essential information and limits disclosure to those persons who have a need for the information. In addition, the court is required to take such other measures as are necessary to limit disclosure to protect the patient, the physician-patient relationship, and the treatment services. We have included at § 2.64(e)(3) an example of one such measure which may be necessary: sealing the record of any proceeding for which disclosure of a patient's records has been ordered. It is the Department's experience that heightened awareness of this possibility by members of the treatment community and legal profession can limit dissemination of patient identifying information to those for whom the court determined "good cause" exists without turning all or a part of a patient's treatment record into public information. The Final Rule adds as an example of a measure which the court might take to protect the patient, the physician-patient relationship and the treatment service "sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered." A similar change has also been made in § 2.67(d)(4).

Extremely Serious Crime as a Criterion for a Court Order to Investigate or Prosecute a Patient

The proposed rule at § 2.64 purported to retain the existing standard with regard to court orders which may be issued for the purpose of investigating or prosecuting a patient; i.e., the standard that no court order may authorize disclosure and use of patient records for investigation or prosecution of nonserious crimes. In an effort to clarify the nature of those crimes for which a court may order disclosure and use of patient records to investigate or prosecute the patient, the proposed rule dropped the term "extremely serious" crime in favor of a more specific functional definition of a crime which "causes or directly threatens loss of life or serious bodily injury." While the proposed rule purported to retain the existing standard, comments received from law enforcement agencies have contested that outcome, asserting that the criterion as proposed would be significantly narrowed. Arguing in favor of a broader standard, law enforcement interests advocated a more flexible criterion which would permit courts to weigh relevant factors on a case-by-case basis.

Inasmuch as the change in the proposed rule was intended to clarify—not to further limit—those crimes for which a court may authorize use of a patient's record to investigate or prosecute the patient, the Final Rule reinstates the existing language, "extremely serious." This broader criterion will permit more flexibility and discretion by the courts in deciding whether a crime is of a caliber which merits use of a patient's treatment record to investigate or prosecute the patient.

The Final Rule names as examples of "extremely serious" crimes homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect. Deleted from the list of proposed examples is "sale of illicit drugs."

Based on the view that most patients in drug abuse treatment are vulnerable to a charge of sale of illicit drugs, many commenters asked that "sale of illicit drugs" not be categorically named as an extremely serious crime. To do so, they asserted, would make almost all patients in drug rehabilitation or treatment programs vulnerable to investigation or prosecution by means of court-ordered use of their own treatment records.

While the Final Rule eliminates "sale of illicit drugs" as an example of an extremely serious crime, it does not alter the authority of a court to find that under appropriate circumstances sale of an illicit drug is, in fact, an extremely serious crime, and it reflects a decision to leave any such determination up to a court of competent jurisdiction which is called upon to order the use of a patient's treatment records to prosecute the patient in view of any circumstances known to the court.

New Law To Permit Reporting of Child Abuse and Neglect

Section 106 of Pub. L. 99–401, the Children's Justice and Assistance Act of 1986, amends sections 523(e) and 527(e) of the Public Health Service Act (42 U.S.C. 290dd–3(e) and 42 U.S.C. 290ee–3(e)) to permit the reporting of suspected child abuse and neglect to appropriate State or local authorities in accordance with State law. The amended sections of the Public Health Service Act provide:

> The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

This newly enacted statutory exception to the restrictions on disclosure of information which would identify an alcohol or drug abuse patient provides a straightforward avenue for making reports of incidents of suspected child abuse and neglect in accordance with State law without resort to devices explained in the preamble to the proposed rule, i.e., obtaining a court order, reporting without identifying the patient as an alcohol or drug abuser, getting the patient's written consent, entering into a qualified service organization agreement, or reporting a medical emergency to medical personnel. While the potential still exists for using the devices described in the proposed rule, there is no foreseeable reason to use them to report suspected child abuse and neglect in view of the amendment.

Although the new law excepts reports of suspected child abuse and neglect from the statutory restrictions on disclosure and use, it does not affect the applicability of the restrictions to the original alcohol and drug abuse patient record maintained by the program. Accordingly, if, following a report of suspected child abuse or neglect, the appropriate State authorities wish to subpoena patient records (or program personnel to testify about patient records) for civil or criminal proceedings relating to the child abuse or neglect, appropriate authorization would be required under the statutes and regulations. While written patient consent would suffice for a civil proceeding, it would be necessary to obtain an authorizing court order under paragraph (b)(2)(C) of the confidentiality statutes and § 2.65 of the regulations for use of the record to criminally investigate or prosecute a patient.

Editorial Changes

The Final Rule makes very few editorial or clarifying changes to the regulations as proposed.

Number, tense, punctuation, and sequential numbering are changed where appropriate. Definitions applicable only to prevention of multiple enrollments in detoxification and maintenance treatment programs are moved from the definitions section to § 2.34. Section 2.35(c) has been rewritten for clarity. A clarifying phrase or word is added to the definition of "patient identifying information" at § 2.11, to § 2.19 (a)(1) and (b)(1) and to § 2.31(a)(8). The phrase "or other" has been added to § 2.53(c) because a court order under § 2.66 may be issued to investigate a program for criminal or administrative purposes. At § 2.65(d)(3) alternative language is adopted consistent with language used elsewhere to express a similar thought. At § 2.65 (d)(4) the term "program" is used in lieu of "person holding the records" inasmuch as none but a program will be providing services to patients.

Regulatory Procedures

Executive Order 12291

This is not a major rule under Executive Order 12291. Overall costs to general medical care facilities will be reduced as a result of the decision to apply the regulations only to specialized alcohol and drug abuse treatment programs. Cost to covered programs will be reduced somewhat by simplification of the rules. The amendments do not have an annual effect on the economy of $100 million or more or otherwise meet the criteria for a major rule under the Executive Order. Thus, no regulatory analysis is required.

Regulatory Flexibility Act

As a result of the decision to apply the regulations only to specialized alcohol and drug abuse treatment programs, the Final Rule will not have a significant economic impact on a substantial number of small entities. The regulations will no longer apply to general medical care providers which render alcohol or drug abuse services incident to their general medical care functions; thus, the number of small entities affected will be less than substantial. The economic impact will be less than significant because much of that impact arises from the cost of determining that the records of a general medical care patient are subject to the regulations and thereafter treating those records differently than all others in the general medical care facility. It is anticipated that programs covered by these rules will realize a small savings as a result of the simplification of the rules.

Information Collection Requirements

Information collection requirements in this Final Rule are:

(1) Obtaining written patient consent (§ 2.31(a)),

(2) Notifying each patient of confidentiality provisions (§ 2.22), and

(3) Documenting any disclosure to meet a medical emergency (§ 2.51).

The information collection requirements contained in these final regulations have been approved by the Office of Management and Budget under section 3504(h) of the Paperwork Reduction Act of 1980 and have been assigned control number 0930–0099, approved for use through April 30, 1989.

List of Subjects in 42 CFR Part 2

Alcohol abuse, Alcoholism, Confidentiality, Drug abuse, Health records, Privacy.

Dated: July 3, 1986.

Robert E. Windom,

Assistant Secretary for Health.

Approved: April 9, 1987.

Otis R. Bowen,

Secretary.

The amendments to 42 CFR Part 2 are hereby adopted as revised and set forth below:

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

Subpart A—Introduction

Sec.

Subpart B—General Provisions

Subpart C—Disclosures With Patient's Consent

Subpart D—Disclosures Without Patient Consent

Subpart E—Court Orders Authorizing Disclosures and Use

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

Subpart A—Introduction

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

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

now § 548

Section 290ee–3. Confidentiality of patient records.

(a) Disclosure authorization

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) Penalty for first and subsequent offenses

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

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

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

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

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

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

now § 544

which is codified at 42 U.S.C. 290dd–3. The amended statutory authority is set forth below:

Section 290dd–3. Confidentiality of patient records

(a) Disclosure authorization

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) Penalty for first and subsequent offenses

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

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

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

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

§ 2.3 Purpose and effect.

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

(1) Definitions, applicability, and general restrictions in Subpart B (definitions applicable to § 2.34 only appear in that section);

(2) Disclosures which may be made with written patient consent and the form of the written consent in Subpart C;

(3) Disclosures which may be made without written patient consent or an authorizing court order in Subpart D; and

(4) Disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders in Subpart E.

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

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

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

§ 2.4 Criminal penalty for violation.

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

§ 2.5 Reports of violations.

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

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

Subpart B—General Provisions

§ 2.11 Definitions.

For purposes of these regulations:

Alcohol abuse means the use of an alcoholic beverage which impairs the

physical, mental, emotional, or social well-being of the user.

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

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

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

Informant means an individual:

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

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

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

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

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

Program means a person which in whole or in part holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment. For a general medical care facility or any part thereof to be a program, it must have:

(a) An identified unit which provides alcohol or drug abuse diagnosis, treatment, or referral for treatment or

(b) Medical personnel or other staff whose primary function is the provision of alcohol or drug abuse diagnosis, treatment, or referral for treatment and who are identified as such providers.

Program director means:

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

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

Qualified service organization means a person which:

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

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

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

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

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

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

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

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

§ 2.12 Applicability.

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

(i) Would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such an identification by another person; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) within a program or

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

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

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

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

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

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

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

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

(i) Third party payers with regard to records disclosed to them by federally assisted alcohol or drug abuse programs;

(ii) Entities having direct administrative control over programs with regard to information communicated to them by the program under § 2.12(c)(3); and

(iii) Persons who receive patient records directly from a federally assisted alcohol or drug abuse program and who are notified of the restrictions on redisclosure of the records in accordance with § 2.32 of these regulations.

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

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

(3) *Information to which restrictions are applicable.* Whether a restriction is on use or disclosure affects the type of information which may be available. The restrictions on disclosure apply to any information which would identify a

patient as an alcohol or drug abuser. The restriction on use of information to bring criminal charges against a patient for a crime applies to any information obtained by the program for the purpose of diagnosis, treatment, or referral for treatment of alcohol or drug abuse. (Note that restrictions on use and disclosure apply to recipients of information under § 2.12(d).)

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

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

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

§ 2.13 Confidentiality restrictions.

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

(b) *Unconditional compliance required.* The restrictions on disclosure and use in these regulations apply whether the holder of the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement or other official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by these regulations.

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

(2) Any answer to a request for a disclosure of patient records which is not permissible under these regulations must be made in a way that will not affirmatively reveal that an identified individual has been, or is being diagnosed or treated for alcohol or drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

§ 2.14 Minor patients.

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

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

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

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

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

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

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

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

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

§ 2.15 Incompetent and deceased patients.

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

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

of obtaining payment for services from a third party payer.

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

(2) *Consent by personal representative.* Any other disclosure of information identifying a deceased patient as an alcohol or drug abuser is subject to these regulations. If a written consent to the disclosure is required, that consent may be given by an executor, administrator, or other personal representative appointed under applicable State law. If there is no such appointment the consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.

§ 2.16 Security for written records.

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

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

§ 2.17 Undercover agents and informants.

(a) *Restrictions on placement.* Except as specifically authorized by a court order granted under § 2.6 of these regulations, no program may knowingly employ, or enroll as a patient, any undercover agent or informant.

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

§ 2.18 Restrictions on the use of identification cards.

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

§ 2.19 Disposition of records by discontinued programs.

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

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

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

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

(1) Sealed in envelopes or other containers labeled as follows: "Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]"; and

(2) Held under the restrictions of these regulations by a responsible person who must, as soon as practicable after the end of the retention period specified on the label, destroy the records.

§ 2.20 Relationship to State laws.

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

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

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

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

§ 2.22 Notice to patients of Federal confidentiality requirements.

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

(1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and

(2) Give to the patient a summary in writing of the Federal law and regulations.

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

(1) A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.

(2) A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.

(3) A statement that information related to a patient's commission of a crime on the premises of the program or

against personnel of the program is not protected.

(4) A statement that reports of suspected child abuse and neglect made under State law to appropriate State or local authorities are not protected.

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

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

(d) *Sample notice.*

Confidentiality of Alcohol and Drug Abuse Patient Records

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

(1) The patient consents in writing:

(2) The disclosure is allowed by a court order; or

(3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations.

Federal law and regulations do not protect any information about a crime committed by a patient either at the program or against any person who works for the program or about any threat to commit such a crime.

Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.

(See 42 U.S.C. 290dd–3 and 42 U.S.C. 290ee–3 for Federal laws and 42 CFR Part 2 for Federal regulations.)

(Approved by the Office of Management and Budget under Control No. 0930–0099.)

§ 2.23 Patient access and restrictions on use.

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

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

Subpart C—Disclosures With Patient's Consent

§ 2.31 Form of written consent.

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

(1) The specific name or general designation of the program or person permitted to make the disclosure.

(2) The name or title of the individual or the name of the organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 2.15 in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

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

1. I (name of patient) ☐ Request ☐ Authorize:
2. (name or general designation of program which is to make the disclosure)

---

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

---

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

---

5. For (purpose of the disclosure)

---

6. Date (on which this consent is signed)

---

7. Signature of patient

---

8. Signature of parent or guardian (where required)

---

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

---

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

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

(1) Has expired:

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

(Approved by the Office of Management and Budget under Control No. 0930–0099.)

§ 2.32 Prohibition on redisclosure.

(a) *Notice to accompany disclosure.* Each disclosure made with the patient's written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

§ 2.33 Disclosures permitted with written consent.

If a patient consents to a disclosure of his or her records under § 2.31, a program may disclose those records in accordance with that consent to any individual or organization named in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of § 2.34 and 2.35, respectively.

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

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

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

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

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

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

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

(1) The disclosure is made when:

(i) The patient is accepted for treatment;

(ii) The type or dosage of the drug is changed; or

(iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

(i) Patient identifying information:

(ii) Type and dosage of the drug; and

(iii) Relevant dates.

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

(i) The consent must list the name and address of each central registry and each known detoxification or maintenance treatment program to which a disclosure will be made; and

(ii) The consent may authorize a disclosure to any detoxification or maintenance treatment program established within 200 miles of the program after the consent is given without naming any such program.

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

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

(1) The name, address, and telephone number of the member program(s) in which the patient is already enrolled to the inquiring member program; and

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

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

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

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

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or posttrial release, probation or parole officers responsible for supervision of the patient); and

(2) The patient has signed a written consent meeting the requirements of § 2.31 (except paragraph (a)(8) which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.

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

(1) The anticipated length of the treatment;

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

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

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

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

Subpart D—Disclosures Without Patient Consent

§ 2.51 Medical emergencies.

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

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

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

(1) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;

(2) The name of the individual making the disclosure;

(3) The date and time of the disclosure; and

(4) The nature of the emergency (or error, if the report was to FDA).

(Approved by the Office of Management and Budget under Control No. 0930–0099.)

§ 2.52 Research activities.

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

(1) Is qualified to conduct the research; and

(2) Has a research protocol under which the patient identifying information:

(i) Will be maintained in accordance with the security requirements of § 2.16 of these regulations (or more stringent requirements); and

(ii) Will not be redisclosed except as permitted under paragraph (b) of this section.

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

§ 2.53 Audit and evaluation activities.

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

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

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

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

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

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

(1) Agrees in writing to:

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

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

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

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

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

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

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

(2) Consistent with the definition of program in § 2.11, program includes an employee of, or provider of medical services under, the program when the employee or provider is the subject of a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section.

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

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

(d) *Limitations on disclosure and use.* Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under § 2.66 of these regulations.

Subpart E—Court Orders Authorizing Disclosure And Use

§ 2.61 Legal effect of order.

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

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

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

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

A court order under these regulations may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information

or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under § 2.66 may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records.

§ 2.63 Confidential communications.

(a) A court order under these regulations may authorize disclosure of confidential communications made by a patient to a program in the course of diagnosis, treatment, or referral for treatment only if:

(1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;

(2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or

(3) The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.

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

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

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

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

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

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

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

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

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

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

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

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

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

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

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

(1) Adequate notice (in a manner which will not disclose patient identifying information to third parties) of an application by a person performing a law enforcement function;

(2) An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order; and

(3) An opportunity to be represented by counsel independent of counsel for an applicant who is a person performing a law enforcement function.

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

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

(1) The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.

(2) There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.

(3) Other ways of obtaining the information are not available or would not be effective.

(4) The potential injury to the patient, to the physician-patient relationship and to the ability of the program to provide services to other patients is outweighed by the public interest and the need for the disclosure.

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

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

(ii) Any person holding the records which is an entity within Federal, State, or local government has in fact been

represented by counsel independent of the applicant.

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

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

(2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of extremely serious crime or suspected crime specified in the application; and

(3) Include such other measures as are necessary to limit disclosure and use to the fulfillment on only that public interest and need found by the court.

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

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

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

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

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

(d) *Limitations on disclosure and use of patient identifying information:* (1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

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

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

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

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

(1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or

(2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.

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

(1) There is reason to believe that an employee or agent of the program is engaged in criminal activity;

(2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and

(3) The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the program, physician-patient relationships and the treatment services.

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

(1) Specifically authorize the placement of an undercover agent or an informant;

(2) Limit the total period of the placement to six months;

(3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the program; and

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

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

[FR Doc. 87-11785 Filed 6-8-87; 8:45 am]

BILLING CODE 4160-17-M

DRAFT
12/9/88

MEMORANDUM FOR WHITE HOUSE CHIEF OF STAFF

FROM: DONALD IAN MACDONALD, M.D.

SUBJECT: Press coverage for December Update on President's Ten point action plan for combatting the AIDS/HIV epidemic

I will soon be submitting to the President the final update on his ten point action plan for combatting the AIDS/HIV epidemic. This report summarizes progress made by Federal agencies in responding to his plan as well as to the 597 recommendations of the Presidential Commission on the HIV Epidemic.

I recommend that highlights of my report to the President be released to the press to demonstrate that he has taken his Commission's recommendations seriously and that much work is accomplished or ongoing. I further recommend that the President devote one of his Saturday radio addresses to the overall issue of responding to HIV infection.

The address should focus on the enormous progress that has been made during this Administration in combatting the AIDS/HIV epidemic. The fact is that more scientific and public health advances have been made in a shorter time than for any other complex new disease in the history of medicine. AIDS was first recognized in 1981. By 1983, the Public Health Service had identified the major routes of transmission. By 1984, scientists had identified human immunodeficiency virus (HIV) as the cause of AIDS. A year later blood tests were licensed which allowed blood to be screened, greatly adding to the ability to protect the blood supply. By 1986, through Federal funding, every State has established an HIV prevention program. In 1987, a significant AIDS drug (AZT) was approved in record time. Over the past two years, the Federal government has continued to make enormous scientific strides as well as conducting a major AIDS information campaign which included the mailing of an educational booklet on AIDS to every household in the United States.

The radio address would provide an excellent opportunity for the President to summarize the progress in combatting this terrible epidemic as well reiterate the points he has made previously about compassion for individuals with HIV infection.

AIDS Treatment

AIDS Discrimination

328-4805

8th Our target

15th to RR

→ include some rec

→ Nursing Rpt Carolyn Davis

→ Roper piece

→ ⊙ Organization of HHS

TP → drugs → wants - non-fed

✓ Packet for over thanksgiving

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✓ w/Sally re: Mae from a/p on Wednesday.

Targetting
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User focus
Rx

THE WHITE HOUSE

WASHINGTON

November 16, 1988

Dear Secretary Bowen:

In December, we must submit to the President a progress report on the implementation of the President's 10-Point Action Plan to fight the human immunodeficiency virus (HIV). According to the President's directive of August 5, 1988, two specific items from HHS are to be included in the December report:

- An assessment of private incentives for development and marketing of HIV products; and
- The updated PHS plan for combatting HIV infection.

In addition, please provide the following information so that I may update the September report:

- A progress report on each of the nine items listed in the President's directive of August 5.
- A list of the AIDs-related provisions of the Health Omnibus Programs Extension of 1988 and the Omnibus Drug Initiative of 1988 which relate to the Commission's report and the agency assigned implementation.
- A report on any of the specific Commission recommendations sent to me in September that have changed in status.

In order to meet the President's deadline, please provide to me all information requested by December 2, 1988. If you have any questions please do not hesitate to call. I appreciated your assistance with the September report and look forward to working with you again for this December update.

Sincerely,

Donald Ian Macdonald, M.D.
Deputy Assistant to the President and
Director, Drug Abuse Policy Office

The Honorable Otis Bowen
Secretary
Department of Health and Human Services
200 Independence Ave, S.W.
Washington, D.C. 20201

THE WHITE HOUSE

WASHINGTON

November 16, 1988

Dear Attorney General Thornburgh:

In December, we must submit to the President a progress report on the implementation of the President's 10-Point Action Plan to fight the human immunodeficiency virus (HIV). I would appreciate receiving any further analysis DOJ has done on the need for national anti-discrimination legislation for HIV-infected individuals.

In addition, please provide a report on any of the specific Commission recommendations sent to me in September that have changed in status because of new legislation or other initiatives undertaken by the Department.

In order to meet the President's deadline, please provide to me all information requested by December 2, 1988. If you have any questions please do not hesitate to call. I appreciated your assistance with the September report and look forward to working with you again for this December update.

Sincerely,

Donald Ian Macdonald, M.D.
Deputy Assistant to the President and
Director, Drug Abuse Policy Office

The Honorable Richard L. Thornburgh
Attorney General
Department of Justice
10th & Constitution Ave, N.W.
Washington, D.C. 20530

THE WHITE HOUSE

WASHINGTON

November 16, 1988

Dear Mr. Wright:

In December, we must submit to the President a progress report on the implementation of the President's 10-Point Action Plan to fight the human immunodeficiency virus (HIV). I would appreciate receiving a progress report on each of the nine items listed in the President's directive to you of August 5.

In addition, please provide a report on any of the specific Commission recommendations sent to me in September that have changed in status because of new legislation or other initiatives undertaken by OMB.

In order to meet the President's deadline, please provide to me all information requested by December 2, 1988. If you have any questions please do not hesitate to call. I appreciated your assistance with the September report and look forward to working with you again for this December update.

Sincerely,

Donald Ian Macdonald, M.D.
Deputy Assistant to the President and
Director, Drug Abuse Policy Office

The Honorable Joseph Wright
Acting Director
Office of Management and Budget
Old Executive Office Building
Washington, D.C. 20500

THE WHITE HOUSE

WASHINGTON

November 16, 1988

Dear Secretary Shultz:

In December, we must submit to the President a progress report on the implementation of the President's 10-Point Action Plan to fight the human immunodeficiency virus (HIV). According to the President's directive of August 5, 1988, the three-year plan for international efforts against HIV infection is to be included in the December report.

In addition, I would appreciate receiving a progress report on each of the nine items listed in the President's directive to you of August 5 as well as a report on any of the specific Commission recommendations sent to me in September that have changed in status because of new legislation or other initiatives undertaken by the Department.

In order to meet the President's deadline, please provide to me all information requested by December 2, 1988. If you have any questions please do not hesitate to call. I appreciated your assistance with the September report and look forward to working with you again for this December update.

Sincerely,

Donald Ian Macdonald, M.D.
Deputy Assistant to the President and
Director, Drug Abuse Policy Office

The Honorable George P. Shultz
Secretary
Department of State
2201 C Street, N.W.
Washington, D.C. 20520

THE WHITE HOUSE

WASHINGTON

November 16, 1988

Dear Ms. Horner:

In December, we must submit to the President a progress report on the implementation of the President's 10-Point Action Plan to fight the human immunodeficiency virus (HIV). I would appreciate receiving a progress report on OPM's efforts to assist Federal departments and agencies to implement your AIDS guidelines as well as any progress made with the private sector.

In addition, please provide a report on any of the specific Commission recommendations sent to me in September that have changed in status because of new legislation or other initiatives undertaken by OPM.

In order to meet the President's deadline, please provide to me all information requested by December 2, 1988. If you have any questions please do not hesitate to call. I appreciated your assistance with the September report and look forward to working with you again for this December update.

Sincerely,

Donald Ian Macdonald, M.D.
Deputy Assistant to the President and
Director, Drug Abuse Policy Office

The Honorable Constance Horner
Director
Office of Personnel Management
1900 E Street, N.W.
Washington, D.C. 20415

INTERNATIONAL ACTIVITIES OF THE U.S. GOVERNMENT AGAINST THE HIV PANDEMIC: A THREE-YEAR PLAN

TABLE OF CONTENTS

EXECUTIVE SUMMARY

In his memorandum of August 5, 1988 to the Secretary of State, the President directed the development of a three-year plan for international efforts against human immunodeficiency virus (HIV) infection, with emphasis on less-developed countries. The attached plan summarizes the current international efforts by federal departments and agencies against the HIV pandemic and presents the strategy and plan for the period from FY 1989 through FY 1991.

HIV infection can be transmitted through sexual activity, by the exchange of blood or blood products, or perinatally from mother to child. Worldwide, the dominant mode of transmission is through sexual activity. At present, there is no vaccine to protect against infection and no treatment for those who are infected to prevent them from infecting others. Furthermore, there is at present no cure for the acquired immunodeficiency syndrome (AIDS) or other HIV-related disease, and the limited methods of treatment available are only partially effective and very costly.

The data available indicate that the HIV pandemic continues to grow rapidly. At present, 142 countries report 124,114 cases of AIDS worldwide. The AIDS case count, however, represents only a fraction of the extent of HIV infection and is also subject to substantial under-reporting. Because of the long latency period between initial infection with HIV and the onset of AIDS or other HIV-related disease, a given AIDS case reflects an HIV infection that may have begun eight or more years earlier. Furthermore, AIDS manifests as a variety of opportunistic infections which may be recorded as tuberculosis or common diarrhea, or in many parts of the infrastructure-poor developing world, not recorded at all.

The extent of HIV infection in many parts of the world and the potential for further spread make control and treatment of infection and related disease a major public policy issue in many countries. The potential implications for the economic and political stability of these countries, as well as their internal security and regional security, make the control of HIV infection an important public policy issue for the United States.

Given the extent of infection and methods of transmission, a worldwide effort will be required to control the further spread of infection. With current technologies, control of the spread of infection will involve changes in sexual practices. This is a matter of exceptional public and private sensitivity in all societies. Programs to control the spread of infection will require extraordinary social, cultural, and political specificity. These factors require that policy leadership in the worldwide effort be given to an organization such as the World Health Organization (WHO), which has the capacity to interact

effectively on international health issues and can provide the framework for effective multilateral and bilateral coordination.

The principal program tools for eliciting voluntary changes in the behavior of those at risk of transmitting the infection are provision of information and education. This must be targeted to those at risk and specific to their social, cultural, and political environment. There are encouraging signs that behavior will change when those at risk understand the full extent of the risks and the methods for avoiding them. However, the process of changing behavior will, even under the best of conditions, be slow.

The urgent need for HIV prevention and control worldwide requires that we have better tools. Of highest priority for research are a better understanding of the process of behavior change, an affordable, heat-stable vaccine against HIV infection, and affordable treatment regimens that prevent HIV transmission and development of disease, and, ideally, eliminate infection. Successful development and testing of these tools is likely to depend on international collaboration.

The United States has committed itself internationally to lead the effort to control spread of HIV infection and find a cure. The strategy presented in this plan furthers that commitment. The strategy involves:

1. Continued enhancement of a framework of international cooperation to plan and coordinate programs to control the spread of HIV and on the research needed to eventually eliminate infection.

2. Support for the implementation of multilateral and bilateral programs to directly impact the spread of infection.

3. Support for the research and research cooperation needed to strengthen our capacity to control the spread of infection and treat those already infected.

This three-pronged approach represents a continuation of extensive programs that this Administration has already put into place, is consistent with and supportive of the major international recommendations of the Report of the President's Commission chaired by Admiral Watkins, and is affordable within the current budget plans of the concerned agencies for the period from FY 1989 through FY 1991. This approach anticipates expansion of technical assistance and other activities for AIDS prevention and control worldwide and increasing effectiveness of these activities. The budgetary plans and strategies assume some improvement in technologies, such as HIV blood transfusion screening tests appropriate for the developing world. However, we do not now anticipate that a cure or a vaccine will be

available for widespread international application during the planned period. Should there be more rapid advances in these areas, a revision of both this plan and its associated budget would be required.

INTRODUCTION

On August 5, 1988 the President directed the Secretary of State to develop a three-year plan for international efforts by the U.S. government against HIV infection, with emphasis on less-developed countries. This plan was coordinated through the Department of State's Interagency Working Group on International AIDS Issues, which focuses largely on the foreign policy aspects of the epidemic, and through the International Subcommittee of the Public Health Service Federal Coordinating Committee on AIDS (FCC), which focuses on the prevention and control of the epidemic internationally, and on related research.

U.S. Departments and Agencies are involved in the international effort to control the spread of HIV infection in a variety of ways (Appendix 1). Several have an explicit mandate for the health and welfare of the United States citizenry and undertake programs of research, analysis, and service delivery for the U.S. public at large. International collaboration can strengthen these programs. In important respects, international cooperation may be essential to their success. This plan covers the international, particularly developing world, part of their programs1. Other agencies have responsibility for a discrete segment of U.S. citizens at risk. For example, the Department of State medical department has responsibility for the health of Foreign Service personnel, the Veterans Administration for U.S. veterans, and the Department of Defense for U.S. military personnel. For these agencies, the level of their involvement in HIV-related issues is dependent on the degree to which HIV infection becomes important to their mission. A third category includes the Department of State, which has foreign policy responsibility, and the Agency for International Development, which has the mandate to help other nations in their economic development.

This plan reflects contributions by all U.S. government agencies known to be involved in international efforts to control the global HIV epidemic. It is a summary of existing activities and a plan for the period from FY 1989 through FY 1991.

1 The Department of Health and Human Services (DHHS) has primary responsibility in this area. This plan covers only the quantifiable international portion of the DHHS program. The domestic DHHS program and the importance of its contribution, particularly in research, is enormous. Any effort to segment the international portion will significantly understate the value of continuing international scientific collaboration and research capacity-building to the people of the developing world.

The plan is divided into seven sections: 1) a global review of the ever-changing status of the pandemic and its relationship to U.S. interests, 2) international collaboration to control the spread of infection, 3) international AIDS prevention and control activities of U.S. Departments and Agencies, 4) international AIDS-related research activities of U.S. Departments and Agencies, 5) coordination mechanisms, 6) budgetary implications of the plan, and, finally, 7) conclusions about the directions and goals of the U.S. government in its efforts to control HIV and AIDS.

THE PANDEMIC AND ITS RELATIONSHIP TO U.S. INTERESTS

The HIV pandemic was first recognized seven years ago. It is still in its early stages. Our knowledge about the magnitude of the pandemic, its modes of transmission, its impact, and its relationship to U.S. interests has progressed rapidly.

The Magnitude of the Pandemic

At present, 142 countries on every continent report 124,114 cases of AIDS. The AIDS case count, however, represents only a fraction of the extent of HIV infection and is also subject to substantial under-reporting. Because of the long latency period between initial infection with HIV and the onset of AIDS or other HIV-related disease, a given AIDS case reflects an HIV infection that may have begun eight or more years earlier. More recent infections often remain asymptomatic and undetected. Furthermore, AIDS manifests as a variety of opportunistic infections which may be recorded as tuberculosis or common diarrhea, or in many parts of the infrastructure-poor developing world, not recorded at all.

Current estimates are that over 250,000 cases of AIDS have already occurred worldwide and that five to ten million people are infected with HIV, the causative agent of AIDS. Within the next five years, about one million new cases of AIDS will occur. The global situation will get much worse before it gets better.

The best AIDS case reporting is in the developed world, where the count continues to grow. The largest number of cases already reported is in the United States, which had recorded 76,670 AIDS cases by October 26, 1988. In western Europe, as in the United States, Canada and Australia, the incidence is moderate to high.

The continent which is hardest hit by HIV infection, however, is Africa, where under-reporting has resulted in marked underestimates of the number of cases to date. The actual total

is estimated to be higher than the number reported for the United States. Studies of the prevalence of HIV infection have provided alarming results. In many urban centers of Southern and Central Africa, 5% to 20% of the sexually active population has been infected with HIV. Rates of infection of some urban prostitute groups range from 27% in Zaire to 88% in Rwanda. Over half of the patients on some medical wards of hospitals in these countries are infected with HIV, as are from 10% to 25% of the women of childbearing age.

Latin America and Asia have smaller but growing problems. In Latin America, approximately 8,000 cases had been reported by June 1988 but, because of under-reporting, the actual incidence is estimated to be several times that number. In several urban areas of the Caribbean, HIV infection levels among heterosexual men and women and their children are similar to those in Central and East Africa. In Asia and the Pacific, the incidence of AIDS is quite low, but there are disturbing reports that 16% of the drug users in Bangkok, Thailand and 13% of the paid professional blood donors in some cities of India are infected with HIV.

Modes of Transmission

As our knowledge increases, we remain convinced that HIV can be spread in only three ways: sexually, by blood-blood contact and perinatally from mother to child. Sexual transmission predominates worldwide and can occur during both heterosexual and homosexual intercourse. Although early cases of AIDS in the United States were largely confined to adult males, in many developing countries, men and women have been equally affected. The risk of sexual transmission increases proportionally with the number of sexual partners an individual has. Sexually transmitted diseases that produce genital sores, such as chancroid, herpes, and syphilis, also facilitate transmission.

Blood-blood contact is the second most important mode of HIV transmission worldwide. While transmission via contaminated blood transfusion in the United States has been virtually eliminated by screening, the required equipment, reagents and training are only sporadically available in other parts of the world. Intravenous drug users, who often share their needles, can also transmit HIV. Nevertheless, the use of needles and syringes for therapeutic injection appears to carry a low risk of infection, even when sterile procedures are not followed. Contrary to early fears, childhood immunization programs in the developing world have not been associated with HIV infection.

Finally, HIV can be transmitted from mother to child during pregnancy and childbirth. There is some evidence that the virus can also be passed via a mother's milk to a nursing child, but that route of transmission has not been confirmed.

The Impact of AIDS on the Developing World

The greatest impact of the pandemic will be on the individuals who suffer the ravages of the infection. Nevertheless, the impact and costs of the infection will spread far beyond the individual to family and society. Economic consequences include increased direct health-care costs, lost wages and the costs of lost business (e.g. tourism). The effects on society could include changes in family, social, and political structures.

A very large number of people are infected with HIV or will become infected. This means that they will develop symptoms of one or more opportunistic infections, develop a type of cancer, suffer diminished mental capacity and/or require frequent hospitalizations during the last 12 to 24 months of their lives. During this time, they will no longer be able to support and care for those who are dependent on them, but they will become dependent themselves, draining the emotional and financial resources of those around them.

The spread of HIV among adults also threatens the survival of children. The HIV pandemic threatens children directly, through HIV transmission from mother to infant and through blood transfusions for children with diseases like malaria. It also threatens children indirectly. A child with an infected parent is likely to lose that parent, and in time, both parents. In Central Africa as many as 1 in 5 urban children face this situation. Thus the AIDS epidemic may well undermine the hard-won gains made in increasing the health status and survival of children in the developing world.

The economic consequences of the pandemic are easy to conceptualize. First, the medical needs and costs of medical care for afflicted individuals will far exceed the capacity of health systems in the developing world. Second, the premature deaths in the 20-to-49 age group will be felt economically in loss of manpower, wages and production. Financial responsibility for surviving family members will fall on grandparents, siblings and more distant relatives. The ratio of dependent children and elderly adults to productive young adults may change significantly. Third, AIDS may affect tourism. The effect on tourism in Haiti was seen after that country was identified as an endemic area. Tourist travel plummeted with an immediate effect on the hotel, transportation and related industries.

Other consequences of AIDS for societies may include changes in population size, changes in the education and achievement levels of the population as a whole, and political destabilization. AIDS-related increases in death rates have led

to speculation that sub-Saharan Africa would be depopulated. These dire predictions are probably incorrect, however. The substantially increased death rate will likely be offset by ongoing fertility-related population increases of 3 percent or more annually. The virus, however, preferentially strikes young urban adults, the most productive members of society. The loss of these individuals will have a disproportionate effect on productivity, economic development and education. The pandemic may also have a destabilizing political influence. HIV infection may have a profound effect on military forces and readiness in developing countries. The size of the population available for military forces will decrease because of the increased death rate in the 20-to-49 year old age group. The potential for strategic imbalance and military aggression may increase.

Impact on U.S. Foreign Policy

U.S. foreign policy interests will continue to be impacted by the pandemic. As outlined above, the pandemic may result in diminished political stability of the hardest-hit countries. It has also, however, impaired the ability of the State Department to carry out its political mission. Areas of impact include travel restrictions (imposed by the U.S. on incoming travelers and on U.S. travelers by foreign countries), and the use by other countries of disinformation campaigns.

One need only look at HIV-related travel restrictions to see some of the global political implications of the pandemic. Testing for HIV has been instituted for employees and dependents of the Department of State who are scheduled for foreign assignments. Employees and dependents of 40 other agencies who are beneficiaries of the Department's health program are also tested. The policy was prompted by political concerns, by the recognition that overseas health-care facilities are often inadequate, and because of concern for the supply of HIV-free blood. Similar concerns factored into the decision by the Department of Defense to test military employees.

The U.S. is also one of the growing number of nations that requires HIV testing for immigrants or travelers. HIV-related travel restrictions limit freedom of travel, restrict business transactions, and, in the case of student travel, curtail educational opportunities. The U.S. implemented a testing requirement on December 1, 1987 for those applying for immigrant or refugee status. HIV-infected individuals are automatically ineligible to enter the U.S. The U.S. has not established testing requirements for tourists, students, businessmen or other temporary visitors with the exception of the requirement by the Department of Defense that all foreign military trainees enrolled in Defense-sponsored programs in the U.S. be tested.

Our foreign policy has also been impacted by disinformation campaigns. In 1985, the Soviet Union launched a disinformation program alleging that the AIDS virus was a man-made organism which had escaped from a U.S. military facility devoted to germ warfare. The allegation was ludicrous but the disinformation took on a life of its own. The U.S. has vigorously refuted these charges by making available as much factual information on the campaign and on AIDS as possible.

In summary, the HIV pandemic is clearly a worldwide problem of major importance to the United States. U.S. federal agencies have evolved quickly in their participation in the multilateral response to the pandemic as well as in their bilateral prevention and control and research efforts. The next three sections will describe these activities.

THE WORLD HEALTH ORGANIZATION GLOBAL PROGRAMME ON AIDS

Given the extent of HIV infection and methods of transmission, a worldwide effort will be required to control the further spread of infection. With current technologies, control of the spread of infection will involve changes in sexual practices. This is a matter of exceptional public and private sensitivity in all societies. Programs to control the spread of infection will require extraordinary social, cultural, and political specificity. These factors require that policy leadership in the worldwide effort be given to an organization such as the WHO Global Programme on AIDS (WHO/GPA), which has the capacity to interact effectively on international health issues and can provide the framework for effective multilateral and bilateral coordination. Through the Agency for International Development (A.I.D.), the U.S. government has supported this program from the outset, both morally and financially, and will continue to do so.

The WHO/GPA is funded by a group of donors whose contributions are made in addition to any assessed dues to the United Nations or WHO. The U.S., through A.I.D., was the first such donor, contributing $2 million in 1986 directly for AIDS control. In 1987 the U.S. contribution to the WHO/GPA was $5.5 million; in 1988 it was $15 million; and in 1989 the amount is $25.5 million.

The U.S. also plays a strong role in the management and direction of the WHO/GPA. The current WHO/GPA Director is a U.S. civil servant detailed from the Public Health Service. A.I.D., as the largest donor to the program, is a key member of the WHO/GPA Management Committee, which acts as an advisory body and makes recommendations to the Director-General of WHO. U.S. government scientists are members of most or all of the WHO/GPA's

scientific and technical advisory bodies.

The WHO/GPA provides two critical services. It undertakes the planning of, and provides support for, national AIDS plans in all countries seeking cooperation, and it provides a mechanism and support for international coordination in all scientific areas necessary to the control of HIV infection.

By 1991, the WHO/GPA projects the following programmatic results. In the area of support to National AIDS Programs, the WHO/GPA will have provided support to 131 countries, and it will have undertaken technical collaboration with 54 more. National AIDS Prevention Plans will have been implemented in all 131 countries, with review and reprogramming completed in 120 of them. In the area of research, one of the primary objectives of the WHO/GPA, functioning centers for drug and vaccine trials will have been established and will be operational; vaccine and treatment trials will be underway. The reagent bank will be expanded, and new diagnostic technologies will have been evaluated in the field. The results from communications research will have been applied in the field. Finally, demographic models for projecting the course and implications of the epidemic will be evaluated and improved.

The WHO/GPA budget has risen rapidly since the program began. In 1987, the worldwide WHO/GPA program cost $23 million. In 1988, the budget rose to $66 million. The preliminary budget for 1989 is $94 million. WHO/GPA anticipates that its annual costs will rise to $100-110 million and stabilize at that level in real terms. Within this budget, approximately 50% is devoted to national AIDS programs and the balance to research and regional and multilateral coordination and collaboration. The U.S. provides approximately 25% of the WHO/GPA budget through A.I.D.

The WHO/GPA national plans are the best available approximation of the cost of AIDS prevention and control programs in the developing world. When all national plans are in place, their total annual cost could approach $700 million. Field implementation of prevention and control programs on this scale would require a massive expansion of WHO/GPA staff and supporting bureaucracy and would duplicate the existing field program capacities of many donors. Consequently, the WHO/GPA is focusing its attention and resources on planning, coordination, and evaluation needs and is the financier of last resort to ensure that all national programs are adequately supported.

The WHO/GPA has done an outstanding job of putting into place a national AIDS prevention planning process and ensuring its timely implementation. The success of this process depends on the existence of a set of vigorous, flexible, and responsive bilateral programs capable of meeting the priority needs of these

national plans. Originally, the WHO/GPA budgeted funds sufficient to cover 20% of the cost of any national plan. To date, there have been 14 country pledging sessions to fund these plans, all of them in Africa. All of the plans were oversubscribed by bilateral and other multilateral donors with the result that the WHO/GPA was only required to support 8.5% of the cost of the plans. These first 14 pledging sessions were held in the hardest-hit African countries and had received worldwide attention. Consequently, they may not be a reliable indicator of the support likely in other countries where HIV infection is not considered as urgent a priority. The U.S. was the largest contributor to these first pledging sessions and will need to continue a bilateral as well as a multilateral leadership role if the WHO/GPA worldwide efforts to control the spread of HIV infection are likely to succeed.

PREVENTION AND CONTROL ACTIVITIES

U.S. international prevention and control activities focus on the developing world. This section describes the U.S. strategy, current activities, and plans for the next three years.

Prevention and Control Strategies

Sexual transmission is the most common mode of transmission of HIV and is therefore the highest priority for prevention. Although prevention and treatment of sexually transmitted diseases may have some effect on transmission, the principal tool currently available is provision of information and education aimed at reducing high-risk behavior. Information and education programs can be divided into three categories: public education campaigns, education and counseling of infected individuals and education targeted specifically at those who practice high-risk behavior. Massive public education campaigns, such as the one undertaken by the Surgeon General in the U.S., are one way to teach people about HIV infection and ways to avoid it. They are underway around the world and have had mixed results. Although these campaigns have resulted in rapid knowledge gains, there is little evidence that they have changed behavior.

A second way to prevent sexual transmission is to counsel individuals who are infected. It is unfortunately true, however, that a person can be infected and infectious long before the onset of any symptoms. In order for a person to know that he or she is infected, that person must know that he or she is engaging in a high-risk behavior and therefore seek confidential counseling, or must develop symptoms which require medical testing or treatment. Thus the disease is being spread

by people who are unaware that they are doing so.

Because these factors make it difficult to reach all infected individuals, an important third strategy for reduction of sexual transmission is to target individuals who practice high-risk behaviors with AIDS counseling and education. This counseling and education focuses on faithful relationships and condom use. If it were possible to ensure that every sexual union outside of a faithful relationship involved a condom, sexual transmission of HIV would be dramatically slowed today. This is obviously an unrealistic goal, given the extremely low rates of condom usage worldwide. Nevertheless even a doubling or quadrupling of condom usage could have a significant impact on the spread of HIV. The condom is still one of the best tools presently available for limiting the spread of the disease.

The second priority for limiting the spread of HIV is to prevent transmission via transfusion of blood and blood products. The techniques involve testing donated blood for the presence of HIV antibodies and discarding infected blood. In the U.S., the necessary training and equipment are generally available, and the blood supply is considered to be safe. This has not been the case in developing countries, however. Therefore, one major element in the strategy of HIV prevention and control has been to provide training for blood testing technicians, and reagents and equipment for the routine testing of blood samples.

Other modes of transmission appear to be less important and therefore of lower priority in the developing world. To date, intravenous drug use has not emerged as a major mode of transmission. Prevention efforts will rely on behavior-change methods similar to those used to reduce sexual transmission. Use of contaminated needles and syringes for therapeutic purposes such as immunization, while not a major mode of transmission, can and should be avoided by upgrading of supplies and training. Mother-to-child transmission is best approached at present through primary prevention by avoidance of sexual transmission to women of child-bearing age.

Agency for International Development

A.I.D. is the lead U.S. agency in international AIDS prevention and control efforts. A.I.D.'s field staff and its cooperating agencies responsible for implementation are experienced and active in over 70 countries. The Health, Child Survival, Population, and Education programs of A.I.D. have pioneered work in service delivery and communications as well as in technical assistance and training immediately relevant to the prevention of HIV transmission. The Agency's policy and programs are built on these strengths in areas in which the U.S. has a

particular comparative advantage.

The Agency's AIDS policy, adopted formally in April 1987, can be summarized as follows:

1. Support for the WHO/GPA is the cornerstone of the Agency's program, and all bilateral programs will operate within the framework of WHO/GPA's national plans.

2. Aggressive bilateral programs to implement the WHO/GPA national plans will focus on prevention and control.

3. Research will be limited and intervention-oriented.

4. Treatment of AIDS and other HIV-related disease will not be supported.

Since the adoption of this policy, the Agency has moved rapidly to develop a program of bilateral support for prevention and control of HIV transmission in developing countries. This support is provided in 6 major areas: 1) technical assistance and training, 2) provision of commodities, including condoms, 3) private voluntary organization (PVO)-led programs, 4) dissemination of technical information and materials, 5) intervention-oriented research, and 6) modelling to project the impact of the pandemic. The first four will be discussed here and the latter two in the next section on research.

The Agency provides short-term and long-term technical assistance and training in the areas of surveillance, behavior change and risk reduction, blood transfusion screening, sexually transmitted disease management and control, and planning for sustainable health-care financing. As of December 1988, the Agency has provided short-term technical assistance to 34 countries in Africa, Asia and the Near East, and Latin America and the Caribbean. In addition, long-term resident advisors have been stationed in the Dominican Republic and the Philippines, and long-term prevention projects, most often in the area of behavior change and risk reduction, have been organized in the majority of the countries.

Through its Population program, the Agency has extensive experience and mechanisms for procurement, shipping, and distribution of commodities. In the last two years, these mechanisms have been used to deliver condoms and blood screening reagents and equipment to more than 20 countries worldwide.

Recognizing the rapid response capacity of PVOs, the Agency is also seeking to stimulate and support PVO-led AIDS prevention and control activities. In 1987 and 1988, A.I.D. and its cooperating agencies have conducted and participated in a number of workshops and conferences on PVO programs for AIDS prevention.

The Agency and its field missions are funding PVO AIDS prevention projects in 13 countries. New, innovative activities are being encouraged by small grants programs funded at $500,000 in FY 1988.

In addition to providing direct technical assistance, the Agency supports AIDS prevention programs by worldwide dissemination of technical information and materials. These consist largely of journal articles and prevention program-related guidelines distributed on a bi-monthly basis to over 400 individuals and institutions in 70 countries.

The Agency's budget for this bilateral support has increased rapidly. In FY 1986, the Agency had no bilateral program. In FY 1987, the budget was $11.4 million. In FY 1988, it increased to approximately $15 million. In FY 1989, the Agency expects to provide $14.5 million, a slight decrease due to Congressional reordering of the Administration request. In FY 1990, a further increase to $20 million is expected. In addition to these amounts, related support from the Health and Population programs totals approximately $5 million a year.

Although the Agency funding for bilateral HIV-related activities has increased from nothing to $20 million a year in a four-year period while the total available for foreign assistance has remained relatively constant, it is clear that the staff resources and program funds are not meeting the need. There is a backlog of unfunded requests approaching $7 million, and requests are frequently delayed or reduced because of competing demands. Even this $7 million figure may understate the real needs as delays in meeting existing requests discourage the formulation of needed new programs. At present, funding for bilateral programs is relatively more constrained than that available for the WHO/GPA. This will affect the global effort and progress in controlling the spread of HIV infection. The WHO/GPA has performed outstandingly in the coordination and planning of a system of national AIDS control programs. However, WHO is not field implementation agency and is encountering understandable bottlenecks in attempting to build such a capacity. Delayed delivery of goods and services requested from the WHO/GPA by cooperating countries is increasing. Bilateral programs can be organized to meet and can meet many of these needs, but U.S. funding of bilateral activities is a serious limiting factor.

In the next three years, the A.I.D. program will continue in the general direction already established. The basic framework is in place. The policy approach focusing on prevention and control and the comparative advantage the Agency has in field delivery of health and communications services has proven to be sound and cost-effective. Working relationships and coordination with the WHO/GPA are excellent. The level of commitment of all governments involved in the global AIDS prevention effort is

extraordinary. The issues that arise usually concern how to get something done, not what to do. Progress in implementing the bilateral program will be limited primarily by the resources available and the inherent constraints to rapid change in developing countries. Geographically, relatively more focus will probably be placed on Asia and the Near East and Central and South America as the pandemic becomes more evident there. A.I.D. will continue to work within the framework of the WHO/GPA national plans.

Public Health Service

Of the six Public Health Service (PHS) agencies, four are engaged in international AIDS-related activities. The Centers for Disease Control (CDC) in Atlanta works in the area of epidemiology. The Food and Drug Administration (FDA) is working to provide drugs for testing and treatment in the developing world. The National Institutes of Health (NIH) and the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) have the lead in promoting and carrying out research in AIDS. Of these, only the CDC is engaged in AIDS prevention and control internationally. These activities are discussed here, while the research activities of CDC and the other agencies are discussed in the next section.

The CDC provides leadership and direction for a broad range of programs designed to safeguard and improve the health of the American people. It is involved in health risk reduction in the workplace, and general health promotion. It also provides support in the basic areas of epidemiology, disease surveillance, laboratory science, and training to local, state, national and international disease prevention efforts. The CDC supports a number of AIDS efforts under its international mission. CDC activities include: 1) providing staff to A.I.D. for short term technical assistance for AIDS in developing countries. This occurs both in the host country and, for visiting foreign scientists, in the Atlanta facilities. 2) Staff from the CDC provide technical assistance to health programs in developing countries in support of the capacity-building mission of the WHO/GPA. 3) The CDC also collaborates in the development of a WHO Center on Health Education & Health Promotion for School- and College-Aged Youth; this WHO Center has a major new focus on AIDS. 4) Training in HIV antigen and antibody detection methods for laboratory personnel is being provided by the CDC for a PAHO/WHO project.

The CDC is committed to continued support for this bilateral and multilateral effort. The CDC will spend $1.8 million from A.I.D. over the next two years and a projected total of $6 million over a five year period for its technical assistance

programs.

Peace Corps

The Peace Corps sends volunteers abroad to help people of other nations to meet their need for trained manpower. Volunteers promote better understanding of Americans among the people with whom they live and work as well as promote a better understanding of other peoples on the part of the American people. Peace Corps programs are designed to meet the basic needs of those living in the poorest areas of the countries in which the Peace Corps operates.

The Peace Corps has committed its resources to responding to the AIDS crisis. Although it does not presently have a specific technical assistance program on AIDS, it is attempting to establish a series of pilot projects in AIDS education. These projects will be developed in close cooperation with the host countries within the frameworks of the hosts' national priorities, and within the guidelines of the WHO/GPA. These programs will then be evaluated to determine what services the volunteers can deliver best and what kinds of capacities can be built in other countries by replicating these projects.

There are presently six thousand volunteers working in sixty-five countries. Their programs involve health, education, agriculture, rural development, small business enterprise,and conservation of natural resources. The health volunteers are placed to improve the health service delivery and capacity-building for the section of the country assigned; AIDS has been a very specific topic many health centers have been able to accommodate. In the general and specific capacity of the volunteers, the Peace Corps is able to contribute to the local community by using the knowledge and skills of the volunteers to prevent further AIDS spread.

The costs of these programs are difficult to predict because they will represent only a portion of a volunteer's efforts. Furthermore, health issues are only a secondary function for many of the non-health volunteers, and diseases other than AIDS are more frequently encountered by the health volunteers. Nevertheless, the Peace Corps is committed to maintain and enlarge its efforts as opportunities in host countries and volunteer availability may allow.

Veterans Administration

The Veterans Administration has many hospitals and facilities at which AIDS patients are treated. These represent a resource which could be used for training of developing country

personnel in blood screening techniques, surveillance methods and other technical issues related to AIDS. The Veterans Administration plans to consider developing this possibility during the next three years.

RESEARCH ACTIVITIES

Current Research Priorities

Because of the difficulties in preventing the spread of AIDS it is imperative that alternative tools for combatting it be developed. These will be the product of research, both basic and applied.

The first tool likely to be developed is a treatment to decrease the destruction of the immune system caused by HIV or to reduce transmission from those who are infected. When AIDS was first shown conclusively to be caused by HIV, in 1984, prospects for a therapeutic agent seemed grim. Antiviral agents are generally scarce and have little effectiveness against the diseases they cause, and retroviruses, of which HIV is an example, are particularly difficult. That grim outlook has improved dramatically, however. One treatment, AZT, while far from being a cure, has shown some promise already. Study of the life cycle of the virus has enabled researchers to design potential treatments which capitalize on vulnerabilities of the virus.

A second research priority is development of a vaccine against HIV infection. Production of a vaccine against HIV has several inherent technical difficulties. First, the virus attacks the very cells which should attack it. Second, the virus can change its coat, thus disguising itself against attack by the body's immune system. Third, there is no good animal model of the disease in which to develop vaccine candidates. Fourth, the virus often wraps itself in fragments of the host's own cell membranes, cloaking itself against recognition as an invader. Nevertheless there are several potential vaccines which are being tested in humans at this time. Although few scientists are optimistic about their effectiveness, new and improved vaccine candidates are being developed constantly.

A third research priority is the natural history and epidemiology of the disease itself. For example, we still do not what role other infections play in the progression of disease. The role of other sexually transmitted diseases in facilitating transmission demands further study. The possibility that close relatives of the virus might have evolved in their relationships with their own hosts in such a way as to reduce the mortality or morbidity of the infection is also a candidate for scrutiny.

Finally, operations research to improve existing methods of prevention and control must be continued and expanded. While great strides have been made in changing the high-risk behaviors of some groups of people (e.g. the homosexual populations in the U.S. and elsewhere) there are other examples in which little has been accomplished. Use of condoms, although increasing, is still at an appallingly low level. In the United States, only 10% of people use condoms. In Africa, where HIV is raging out of control, the rate of condom use is well less than 1%. There are recent reports that this trend is being reversed, however. In Kinshasa and in Bangui, both cities where condom distribution is being handled by commercial enterprise, the demand exceeds the supply. Research into extending and replicating these changes is needed.

Agency for International Development

AIDS-related research funded by A.I.D. is applied and intervention-oriented. Of highest priority is program-oriented operations research in behavior change, condom and viricide promotion, and blood transfusion screening. Epidemiological research is examining HIV transmission, in particular the influence of other sexually transmitted diseases. New prevention technologies important for developing countries are being field-tested.

Examples of this research can be found in all regions of the developing world. In Ghana and Mexico, operations research is being conducted to determine the best means of extending short-term successes in reduction of high-risk behavior. In Zaire, a recent clinical trial examined the utility of five simple and rapid HIV antibody tests for blood transfusion screening in developing countries. A follow-on study will attempt to reproduce these results in isolated rural hospitals. In cooperation with WHO and UNICEF, A.I.D. is funding the development and testing of disposable, non-reusable syringes and needles to ensure that immunization programs do not transmit HIV.

Public Health Service

The PHS agencies have taken the lead in international HIV-related research as well as development of international research collaboration and cooperation. The CDC has a major domestic and international role in research on the natural history of HIV-related disease as well as on epidemiological surveillance systems. The international research activities in these areas involve Cote d'Ivoire (Ivory Coast), Kenya, Sierra Leone, and Zaire; the Zaire project is also sponsored by the NIH

(NIAID) and began in 1983. These have major importance to the host country and to the U.S. investigators as opportunities for longitudinal studies are made available. A major contribution will be in the study of HIV-2 in the African continent. CDC researchers will also be able to investigate HIV infection in areas where diarrheal and respiratory diseases are very prevalent in the general population and may often confuse or delay the diagnosis of HIV infection. A total of about $9 million will be spent by CDC on these programs during the next three years.

The FDA role is one of drug and vaccine development and regulation. It has provided a major contribution to building the capacity of host countries to carry out this role. One area for this leadership is as a major WHO Collaborating Center on AIDS; this allows the FDA, among other things, to collaborate on assay assessment, to provide technical assistance on safety of blood-derived products and serological testing systems, provide reference panels of sera, and provide training for laboratory and public health personnel. The FDA also reviews and permits the use of drugs which are not yet approved for use in U.S. clinical investigations in foreign countries under strict guidelines; this allows items under development to have wider clinical evaluations while insuring host country approval of the trials. The FDA provides technical assistance to the regulatory agencies of about 60 countries; Development of AIDS drugs and vaccines has increasingly been the focus of the consultation provided. There is also a monthly collection of information on FDA-related articles, speeches, and other non-journal based information which is furnished to PAHO and WHO.

The National Institutes of Health are the center of the Federal government's health research. Their mission is to uncover new knowledge that will lead to better understanding of the fundamental life processes that underlie human health and better means to prevent, detect, diagnose, and treat disease. NIH works toward these goals by conducting research in its own laboratories; supporting research of non-Federal scientists in universities, medical hospitals, and research institutions throughout the U.S. and abroad; supporting the training of promising new researchers; and fostering and supporting biomedical communication. The NIH has made a significant contribution to the definition of AIDS, understanding its progression, and investigating preventive/therapeutic options. The NIH plans to continue to make contributions through its research programs and training programs, on which it will spend $21 million in FY 1989.

The NIH also contributes to capacity-building through the Fogarty International Center (FIC). The FIC will spend nearly $4 million through the International Training Grants In Epidemiology Related To AIDS program. This program operates through eight

universities which take responsibility for development work with selected countries; this year the program will impact 21 different countries. The FIC also has a International Postdoctoral Research and Training Grant program which operates through five universities. The program will expend $700,000 in FY 89 and will recruit Fellows from at least nine countries.

The National Institute of Drug Abuse has two major projects which focus on the intravenous drug use transmission route. This effort involves some mathematical modeling and the building of a database of experiences in developing countries. About $600,000 will be expended in FY 89 and each year until FY 1991.

Department of Defense

The Assistant Secretary of Defense for Health Affairs is responsible for Department of Defense health matters, including preventive medicine, medical readiness, health-care delivery, drug and alcohol abuse prevention, and procurement, development, and retention of medical personnel. The Department has a worldwide scope of activities and, as such, has operating bilateral and multilateral defense agreements. These agreements allow the U.S. to maintain laboratories which can study region-specific disease impact on military forces and develop effective preventive and treatment techniques. These laboratories also allow the U.S. to provide consultation to host country or multilateral member medical personnel.

AIDS is one of the health problems studied by this worldwide system of laboratories. The system is in place in Egypt, Japan, Peru, Philippines, Zaire, and Zambia. Expansion of the programs to include AIDS began as early as FY 1986. Most of the AIDS studies are epidemiological and the results have immediate application for host military and civilian organizations, especially in developing countries and are focused on the region-specific aspects of the natural history of the disease. Plans call for these laboratories to continue to support the U.S. defense mission and responsibilities through AIDS-related research.

Projecting the Impact of the Pandemic: Modelling

The complexities of the HIV pandemic lend themselves to mathematical modelling. The modelling process simulates reality and forecasts possible trends and provides insights into the dynamics of the pandemic. A primary response of the U.S. Government to the HIV pandemic abroad has been the establishment of an Interagency Working Group on AIDS Models and Methods by concerned agencies including A.I.D., the Intelligence Community, and the Bureau of the Census. The Working Group is a

subcommittee of the State Department's Interagency Working Group on International AIDS Issues, established in 1985. The subcommittee is a vehicle for sharing information and coordinating research. Its mission is to develop mathematical models and to make projections on the impacts of HIV infection and AIDS in affected countries. The subcommittee seeks information and expertise on a variety of subjects ranging from HIV seroprevalence, sexual practices, viral genetics, and blood screening. The subcommittee is assisted by consultants from outside the government.

The task of the subcommittee is to refine and validate a model currently under development and use it to forecast the epidemiologic scope and the demographic impact of the pandemic in affected countries. As specific data become available, the model will become more faithful to reality. The subcommittee expects to have a fully tested model by the end of FY 1989.

COORDINATION MECHANISMS

Coordination mechanisms to ensure that international HIV-related activities by the U.S. government are as cost-effective as possible can be divided into two categories, those aimed at multilateral coordination and those aimed at coordination within the U.S. government. In both of these areas, the value of informal coordination through close ongoing relationships cannot be overstated, however, formal mechanisms exist. Coordination with multilateral agencies such as the WHO/GPA, other United Nations agencies, and other governments and bilateral donors occurs through the committees of the WHO/GPA. These include the Management Committee for prevention and control activities and the scientific and technical committees for research.

Two formal coordination mechanisms exist within the U.S. government. Prevention and control activities and related research are reviewed in the FCCIS, convened by the Public Health Service. The impact of the pandemic on other countries and on U.S. foreign policy is reviewed by the Interagency Working Group on International AIDS Issues, convened by the State Department. The FCCIS has compiled a database of all international AIDS activities by U.S. government agencies. It allows consideration of activities by agency, by country, by type of activity, etc. A print-out from that database is contained in Appendix 1.

BUDGET IMPLICATIONS

Estimates of U.S. government obligations for international AIDS activities, to date, and in FY 1989, are shown below. Table 1 shows the obligations by agency, Table 2 by geographic region.

Table 1. U.S. Government Obligations for International AIDS Activities, by Agency and Fiscal Year, in Thousands of Dollars

AGENCY	To Date	FY89
A.I.D.	48900	40000
ADAMHA	613	0
CDC	3801	2939
D.o.D.	4986	1426
NIH	37518	50154
TOTAL	95818	94519

Source: International Subcommittee of the Federal Coordinating Committee on AIDS

Table 2. U.S. Government Obligations for International AIDS Activities, by Region and Fiscal Year, in Thousands of Dollars

Region	To Date	FY89
Africa	37174	55833
Asia	7061	6452
Latin America	23308	21835
Worldwide Programs	5775	10373
WHO/GPA	22500	25500
TOTAL	95818	94519

Source: International Subcommittee of the Federal Coordinating Committee on AIDS

At the present time, the U.S. government is spending approximately $95 million a year on research and prevention and control activities; this is about equally divided between the two. This total is equal to the sum of all that we have spent to date on this problem: the programs have grown tremendously over the past four years. This growth roughly parallels the growth of the epidemic and of the WHO/GPA.

CONCLUSIONS

The United States has committed itself internationally to lead the effort to control spread of HIV infection and find a cure. The strategy presented in this plan furthers that commitment. The strategy involves:

1. Continued enhancement of a framework of international cooperation to plan and coordinate programs to control the spread of HIV and on the research needed to eventually eliminate infection.

2. Support for the implementation of multilateral and bilateral programs to directly impact the spread of infection.

3. Support for the research and research cooperation needed to strengthen our capacity to control the spread of infection and treat those already infected.

This three-pronged approach represents a continuation of extensive programs that this Administration has already put into place, is consistent with and supportive of the major international recommendations of the Report of the President's Commission chaired by Admiral Watkins, and is affordable within the current budget plans of the concerned agencies for the period from FY 1989 through FY 1991.

Over the next three years, we can expect the following specific achievements:

1. All countries with which the U.S. is working will have implemented AIDS and HIV public information campaigns.

2. All of these countries will also have implemented, and most will have evaluated, targeted educational programs aimed at the reduction of high-risk behavior.

3. All of these countries will have implemented blood transfusion screening programs for HIV, although few will have ensured complete freedom of the blood supply from the HIV infection.

4. New rapid, simple HIV diagnostics appropriate for developing countries will have been field-tested and will be in common use.

5. Development of vaccine field trial sites will have taken place.

6. A mathematical model of the impact of the impact in the developing world will have been completed and validated.

THE WHITE HOUSE

WASHINGTON

June 29, 1987

MEMORANDUM FOR GARY L. BAUER

FROM JAMES H. WARNER

SUBJECT Accuracy of Testing For HIV

The President has decided that federal agencies, when appropriate, should test blood to identify individuals infected with the Human Immunodeficiency Virus (HIV). However, some agencies believe that it would be unwise to test, routinely, individuals who are not members of risk groups. These agencies point to the danger of falsely identifying an individual as having the virus when he does not, the "false positive." Other agencies insist that the possibility of a "false positive" is too remote to be considered. The question is, how often would the testing procedure give a false indication that an individual is infected if he is not?

In the first place, no numerical probability may be assigned to this event, as there is insufficient data to permit an accurate prediction. The data are sufficient, however, that when taken in conjunction with the rules which have been devised by the Department of Defense, and the definition of "positive" which is given in those rules, then the probability is of such an order of magnitude that the possibility need not be considered.

The ELISA Test

The first test to be used is the Enzyme Linked Immunosorbent Assay (ELISA) test. This test was developed to protect the blood supply. Accordingly, it is very sensitive, and will produce a reaction to blood components which are similar to those in persons infected with HIV. That is, as a screening test, it must be sensitive, and, therefore, lacks specificity. No harm is done if individuals who are not infected with HIV, but who react to the test, are kept from donating blood. Accordingly, DOD uses the test only as a screening tool, and the results of ELISA tests cannot, by definition, show a person to be positive. If there is a reaction to the first test, then the individual is tested again, using different ELISA procedures. If there is a reaction to subsequent ELISA tests, then the individual is defined as "repeatedly reactive."

The Western Blot Test

Individuals who are repeatedly reactive are given the Western Blot Test. In contrast with the ELISA test, this test is designed to be specific. In this test the virus particles must first be "lysed," or broken down into their component proteins.

Certain of these proteins will have specific electric charges, depending upon the molecular structure. To measure the presence of these proteins, a solution containing the lysed particles is subjected to an electric charge. If the charge on the specific proteins be known, then it is possible to predict how far that specific molecule will move when under the influence of the electric charge. This movement is measured on a sensitive strip of paper which records the migrations of molecules as "bands." In the case of HIV, the developer of the strip, DuPont, determined that the presence of proteins in ban 24 and band 41 would indicate the presence of the HIV virus. DOD, however, defined the test more specifically, and requires the presence of three proteins, (band 31, in addition to the bands which DuPont determined would be necessary). TWO WESTERN BLOT TESTS, WITH ALL THREE BANDS FILLED, ARE REQUIRED BEFORE AN INDIVIDUAL IS CONSIDERED POSITIVE UNDER THE CURRENT RULES FOR THE TESTING OF RECRUIT APPLICANTS.

In view of the degree of testing required, and the specificity of the Western Blot Test, it can be seen that there is no realistic possibility of a false positive, and any argument against testing based upon such danger is, in fact, a red herring which is dragged across the trail to divert attention away from testing.

CC:SD

7885

DEC 23 1988

UNITED STATES OF AMERICA
RAILROAD RETIREMENT BOARD
844 RUSH STREET
CHICAGO, ILLINOIS 60611

OFFICE OF CHIEF EXECUTIVE

DEC 20 1988

Donald Ian Macdonald, M.D.
Deputy Assistant to the President for
Drug Abuse Policy
Office of Policy Development
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Dr. Macdonald:

The Railroad Retirement Board has developed a draft policy statement on AIDS. We are currently in the process of discussing the policy and related issues with our exclusively recognized Union, the Council of AFGE Locals in the Board. We have also drafted guidelines for managers and supervisors to use in dealing with cases of AIDS, and a memorandum to all employees which provides them with some of the information included in the Office of Personnel Management's AIDS guidelines. Copies of these documents are enclosed.

If there are any changes to our policy statement as a result of our discussion with the Union, we will send you a copy of the revised statement.

Sincerely,

Kenneth P. Boehne

Kenneth P. Boehne
Chief Executive Officer

Enclosures

Railroad Retirement Board Policy on AIDS

DRAFT

The following policy is issued to increase the awareness, understanding, and effectiveness of Railroad Retirement Board (RRB) managers, supervisors, and employees in dealing with Acquired Immune Deficiency Syndrome (AIDS).

AIDS is caused by the HIV virus which attacks a person's immune system and damages his/her ability to fight other diseases. Guidelines issued by the Public Health Service's Centers for Disease Control state that "the kind of nonsexual person to person contact that generally occurs among workers and clients or consumers in the workplace does not pose a risk for transmission of AIDS." Therefore, consistent with Office of Personnel Management guidelines, the RRB has adopted a policy that:

a. Any HIV-infected employee will be allowed to continue working as long as that employee is able to maintain acceptable performance and does not pose a safety or health threat to himself/herself or others within the agency.

b. When an employee is unable to perform safely and effectively, the RRB will treat that employee in the same manner as employees who suffer from other serious illnesses.

c. Under normal conditions, employees will not have a basis upon which to refuse to work or to withhold their services out of fear of contracting AIDS by working with or providing service to an HIV-infected person.

d. Employees who refuse to work or are found to have withheld their services, harassed, intimidated, or in any other manner discriminated against HIV-infected persons may be subject to disciplinary action.

e. Any medical documentation or other information relating to the condition of an HIV-infected employee will remain confidential. Officials who have access to such information are required to maintain the confidentiality of that information.

f. HIV-infected employees may request sick leave, annual leave, or leave without pay to pursue medical care or to recuperate from the ill effects of their medical condition. The RRB will make its determination on whether to grant leave in the same manner as it would for other employees with medical conditions.

g. Educational programs and written information on AIDS will be provided to RRB employees as they become available.

Guidelines for Managers and Supervisors on Dealing with AIDS

DRAFT

The Railroad Retirement Board (RRB) recently issued a policy on Acquired Immune Deficiency Syndrome (AIDS). The agency's policy is consistent with guidelines from the Office of Personnel Management (OPM) and is based on five key points:

-- prohibition of discrimination against persons with AIDS or AIDS-related illnesses;

-- treatment of employees with AIDS or AIDS-related illnesses in the same manner as employees who suffer from other serious illnesses;

-- confidentiality of medical information submitted by employees;

-- treatment of leave requests from employees with AIDS or AIDS-related illnesses in the same manner as leave requests from employees with other medical conditions; and,

-- education of employees with regard to AIDS.

Managers and supervisors should be fully aware of an employee's rights as well as their own responsibilities. The agency will provide all assistance necessary to enable managers and supervisors to carry out their responsibilities appropriately, effectively, and humanely. The agency offers the following guidelines when dealing with employees who have, or are concerned about, AIDS or AIDS-related illnesses.

Managers and supervisors should:

-- be sensitive to a fellow employee's health condition;

-- be aware that an employee's health condition is personal and confidential;

-- know that employees with AIDS or other life threatening illnesses are covered by laws and regulations that protect handicapped people from discrimination; and,

-- utilize the agency's Employee Assistance Program (EAP) whenever possible. The counselors are professionals who can help both managers and employees deal with the issue of AIDS in a confidential and private manner.

The bureau of personnel's employee and labor relations section is available to assist managers with any problems that may arise when dealing with an HIV-infected employee. They can be reached on extension 4569.

Often a supervisor is first alerted to employee problems, including AIDS, by noting work deficiencies or leave problems. In such cases, the supervisor should discuss the performance problem with the employee. Although supervisors should provide positive support to any employee attempting to deal with a personal problem, they should not attempt to counsel employees concerning these problems. In these cases, employees should be referred to

DRAFT

the EAP. A supervisor's role is to identify work deficiencies, to explain that they must be corrected, and to inform employees of available assistance.

Managers and supervisors are reminded that an employee with AIDS or any related illness may continue to work as long as the employee can perform his or her job. If warranted, a manager may make reasonable accommodations for an employee with AIDS as long as those accommodations do not hamper the business needs of the unit. Some possible accommodations are as follows:

-- flexible working schedule;

-- part-time work schedule;

-- liberal approval of annual leave, sick leave, and leave without pay;

-- advanced leave, if appropriate, usually not to exceed 30 days;

-- counseling time with the EAP;

-- light duty assignments;

-- making facilities and equipment readily accessible and usable by the handicapped;

-- restructuring the job; and,

-- voluntary downgrading or reassignment to a more appropriate job in another qualified series.

The above accommodations may not be necessary because some individuals who test positive for AIDS may require little or no accommodation. An employee with an AIDS-related condition or clinically diagnosed AIDS may require no greater accommodation than any other employee with a serious illness. Managers and supervisors should always remember that as long as an employee with AIDS can meet reasonable and acceptable performance standards and his or her condition is not a threat to others, the employee should be treated like any other employee. However, when accommodations are needed for an employee, managers should be careful not to isolate the employee from the normal work environment in any way that could be interpreted as discriminatory.

No data has been presented to show that AIDS constitutes a health risk for office workers. The fact remains, however, that some employees will have concerns about contracting AIDS in the workplace. In such situations, an outside expert on AIDS or the employee assistance counselor may be called on to meet and discuss such concerns with the employees. However, in the final analysis, agency employees will be expected to continue normal working relationships with any fellow employee recognized as having AIDS and to continue to provide service to any railroad worker or beneficiary who has AIDS.

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Through an increased awareness and understanding of AIDS, managers and supervisors can help reduce unfounded fears and facilitate sensible approaches to AIDS-related issues in the agency. This will help to maintain a safe and healthy working environment for all employees.

FORM G-115 (7-89)

DRAFT

UNITED STATES GOVERNMENT

RAILROAD RETIREMENT BOARD

Memorandum

TO : All Board Employees

FROM : Director of Personnel
Through: Chief Executive Officer

SUBJECT: AIDS in the Workplace

In March 1988, the Office of Personnel Management (OPM) issued policy guidance on Acquired Immune Deficiency Syndrome (AIDS) in the workplace. This guidance was designed to help agencies develop a policy and program to increase the awareness, understanding, and effectiveness of managers, supervisors, and employees in dealing with AIDS. The following information is based on OPM guidelines and is intended to be used in handling those employee issues that may arise at the Railroad Retirement Board (RRB) because of AIDS.

The U.S. Public Health Service's Centers for Disease Control state that AIDS is an infectious disease that is transmitted by either intimate sexual contact or intravenously through the use of contaminated needles or by receipt of transfusions of contaminated blood. There is no medical evidence that the AIDS virus is transmitted through casual contact such as that which occurs in ordinary social or occupational settings and conditions.

There is no evidence that AIDS is spread through any of the following:

-- Working in the same office, shop, etc.

-- Being a blood donor.

-- Sneezing, coughing or spitting.

-- Handshakes or non-sexual physical contact.

-- Toilet seats, bathtubs or showers.

-- Various utensils, dishes, or linens used by persons with AIDS.

-- Articles handled or worn by persons with AIDS (i.e., telephones).

-- Riding in the same vehicle with a person with AIDS.

-- Eating in the same places or with a person with AIDS.

Subject to any additional information from recognized medical authorities, it is the policy of the RRB that an agency employee with AIDS or its related conditions will be allowed to work as long as the employee can meet reasonable

and acceptable performance standards and his or her condition is not a threat to other employees. When an employee is unable to perform safely and effectively, the agency will treat that employee in the same manner as employees who suffer from other serious illnesses; established personnel policies and procedures will be observed.

Agency employees may not refuse to work with, or withhold their services from, an AIDS-infected person out of fear of contracting AIDS. Employees who refuse to work with an AIDS-infected person or who refuse to provide service to an AIDS-infected railroad worker or beneficiary could be subject to disciplinary action. Additionally, disciplinary action can also be brought against a person who is found to have harassed, intimidated, or in any other manner discriminated against an AIDS-infected co-worker or a railroad worker or beneficiary.

In some cases, accurate and complete medical documentation may be required to make competent decisions about an employee's ability to work. Any medical documentation submitted for the purpose of making employability decisions will remain confidential. Officials who have access to such information are required to maintain the confidentiality of that information.

Employees with AIDS or AIDS-related illnesses may request sick or annual leave or leave without pay to pursue medical care or to recuperate from the ill effects of their medical condition. Agency management will make its determination on whether to grant the leave in the same manner as it would for other employees with medical conditions.

Employees with AIDS or AIDS-related illnesses can continue insurance coverage under the Federal Employees' Health Benefits (FEHB) and the Federal Employees' Group Life Insurance (FEGLI) programs. Continued participation in either of these programs cannot be jeopardized because of one's health condition. Under FEGLI, death benefits are payable and are not subject to cancellation due to health status. Any employee who is in a leave without pay status for 12 continuous months will face statutory loss of FEHB and FEGLI coverage, but the employee does have the right to convert to a private policy without demonstrating proof of insurability.

An employee with AIDS may be eligible for disability retirement if the employee's medical condition warrants, and if the employee has the requisite years of Federal service to qualify. OPM considers an application for disability retirement from an employee with AIDS in the same manner as for other employees, focusing on the extent of the employee's incapacitation and ability to perform his or her assigned duties. OPM makes every effort to expedite any applications where the employee's illness is in an advanced stage and is life threatening.

Any employee with personal concerns about AIDS and its related conditions is encouraged to contact the agency's employee assistance counselor. The counselor can be reached on extension 4985 and can provide information in a private and confidential atmosphere.

DRAFT

Education is an important tool in the fight against AIDS. The agency will continue to provide educational programs and written information on AIDS as it becomes available. The agency's Equal Employment Opportunity Office has books and pamphlets that are available to employees. That office can be reached at extension 4925. Medical questions concerning AIDS can be directed to the medical services section at extension 4732.

Questions regarding health or life insurance or disability retirement should be directed to the employee and labor relations section in the bureau of personnel at extension 4569.

Listed below are two organizations that can provide information and referrals concerning AIDS and AIDS-related illnesses. The employee assistance counselor can provide additional information on other organizations that provide AIDS information.

Public Health Service
National AIDS Hotline (Nationwide, 24 hours daily)
1-800-342-AIDS
1-800-344-SIDA (Spanish)

Illinois Department of Public Health
AIDS Informational Hotline (For calls originating in Illinois,
10 a.m. to 10 p.m. daily)
1-800-AID-AIDS

All of us at the Railroad Retirement Board should attempt to increase our awareness and understanding of AIDS. This increase in awareness will help to alleviate unfounded fears and help maintain a safe and healthy working environment.

John F. Malich

cc: Director of LAS

CC:SD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

7864

DEC 19 1988

December 19, 1988

Dr. Donald Ian Macdonald
Deputy Assistant to the President
Director, Drug Abuse Policy Office
The White House
Washington, D.C. 20500

Dear Mac:

The enclosed is a response to your request regarding our AIDS program.

Please note in 1990 there is a substantial decrease in FTE's. Additionally our absorption of the raise in 1989 has resulted in a compromise of all of our functions including the AIDS budget. This is particularly important as the FDA is primarily personnel intense. I have also included the comments on the training grant. Please note for us to recruit the types of reviewers we need to it is imperative that we have a feeder system such as the Army, Navy and the Air Force. In this way we would bring trainees into the Uniformed Corps for post-residency training and regulatory medicine and then have them pay back each year of training for a year of service in the FDA. This modest amount would greatly influence and augment our AIDS program

Please let me know if you have any further questions.

Sincerely yours,

Frank E. Young, M.D., Ph.D.
Commissioner of Food and Drugs

Enclosures

TRAINING GRANTS

1989 Budget--FDA requested $4 million for training grants, as a means to enhance/recruit/retain physicians in our new drug evaluation program.

OMB removed this from our 1989 budget request.

1990 Budget--FDA requested $4 million for training grants as a means to enhance recruitment/retention of physicians in our AIDS program.

OMB only approved enough funds in our 1990 increase to meet minimum payroll and support requirement for the increase of 183 FTE they approved, thus eliminating funds for training grants.

AIDS RESOURCES

1989: FDA received all FTE and dollars requested for AIDS.

1990: A summary of our 1990 increase request follows:

	TO PHS		TO DHHS		TO OMB		TO CONGRESS	
	FTE	$(Mil)	FTE	$(Mil)	FTE	$(Mil)	FTE	$(Mil)
Drugs/Biologics/ Devices	243	$19.4	243	$19.4	243	$19.4	183	$11.0
Training Grants	-	4.0	-	4.0	-	4.0	-	-
Animal Drugs	12	1.0	-	-	-	-	-	-
2nd New Building	-	37.3	-	-	-	-	-	-
Total	255	$61.7	243	$23.4	243	$23.4	183	$11.0

Items Removed From Request

- o $37.3 million to construct second new building - by PHS
- o $1 million and 12 FTE for animal drugs - by PHS
- o $4 million for training grants - by OMB
- o $9.4 million and 72 FTE for drugs/devices/biologics - by OMB

1989 PAY COSTS BEING ABSORBED

- $9.2 million - cost of 4.1% pay increase for 9 months.
- $2.5 million - cost of new performance awards for GS 1-GS 13 employees
- $1.6 million - unanticipated increase in Government's cost of health benefits increase.

$13.3 million - Total Pay Raise Absorption

Division of Anti-Viral Drug Products

STAFFING

	Estab. March '88	End of FY 88 Staffing Level	Expected End of FY 89 Staffing Level	Planned FY 90 Staffing Level
Reviewers	0	21	35	49
Support Staff	0	14	17	23
Total	0	35	52	71

Space

- Division established with no increase in existing CDER space allocation
- All 35 accommodated as one colocated functioning unit by end of FY 88
- No existing offices available for staff expansion for 14 needed reviewers in 1989