

83.3HIV-related testing. (a) Except as noted in paragraph (b)(2) of this section, no physician or other person authorized pursuant to law may order an HIV-related test without first obtaining written informed consent.

(1) Informed consent shall include providing pre-test counseling to the person to be tested or, if such person lacks capacity to consent, to the person lawfully authorized to consent to health care for such person. In situations in which a person other than the test subject consents for the test, pretest counseling shall also be provided to the test subject to the extent that the person responsible for ordering the test deems that the test subject will benefit from counseling. Pretest counseling shall include:

(i) explanations regarding the nature of HIV infection and HIV-related illness, an explanation of the HIV-related test, including a description of the procedure to be followed, meaning of the test results, and the benefits of taking the test, including early diagnosis and medical intervention;

(ii) an explanation that discrimination problems may result from disclosure of confidential HIV-related information and that legal protections exist which prohibit discrimination (NYC and NYS Human Rights Law) and unauthorized disclosures (PHL article 27-F);

(iii) information on preventing exposure or transmission of HIV infection, including behavior which poses a risk of HIV transmission;

(iv) an explanation that the test is voluntary, that consent may be withdrawn at any time, and that anonymous testing is available, including the location and telephone numbers of anonymous test sites, and that for the purpose of insurance coverage, confidential, as opposed to anonymous testing is required; and

(v) information regarding psychological and emotional consequences of receiving the test result.

(b) (1) Written informed consent must be executed on a form developed by the department or on another form approved specifically by the department. At the time at which informed consent is obtained, the subject must be offered a copy of the informed consent form or a document that provides all pertinent information contained on the informed consent form.

(2) Informed consent is not required in the following situations:

(i) for court-ordered testing pursuant to Civil Practice Law and Rules, section 312(11);

(ii) when testing without informed consent is otherwise specifically authorized or required by State or Federal law;

(iii) for testing related to procuring, processing, distributing or use of a human body or human body part, including organs, tissues, eyes, bones,

arteries, blood, semen or other body fluids for use in medical research or therapy, or for transplantation to persons, provided that If the test results are communicated to the tested person, post-test counseling is required;

(iv) for research if the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher; and

(v) for testing of a deceased to determine cause of death or for epidemiological purposes.

(c) In addition to an explanation of the test result, the person who orders the test shall be responsible for ensuring that post-test counseling or referrals as appropriate with respect to a positive or negative test result, shall be provided to the person who consented to the test. Blood banks and tissue banks may report results as specified in sections 58-2.23 and 52-3.6, respectively, In situations in which a person other than the test subject consents for the test, post-test counseling and referrals should also be provided to the test subject, to the extent the person responsible for ordering the test deems that the test subject will benefit from counseling. Such post-test counseling and referrals must include specific referral information and must address:

(1) coping emotionally with the test results;

(2) discrimination issues relating to employment, housing, public accommodations, health care and social services;

(3) information on the ability to release or revoke the release of confidential HIV related information;

(4) information on preventing exposure to or transmission of HIV infection and the availability of medical treatment; and

(5) the need to notify contacts to prevent transmission, including information on State or county assistance in voluntary and nonvoluntary contact notification, if appropriate.

(6) information on the availability of medical evaluation and treatment, including use of HIV chemotherapeutics for prophylaxis and treatment and peer group support.

(d) A physician or other person authorized pursuant to law to order an HIV-related test shall certify on a laboratory requisition form that informed consent has been obtained. Authorized employees or agents of the department or of the New York City Department of Health may order HIV-related tests and certify, as appropriate, with respect to obtaining informed consent in approved anonymous testing sites.

63.4 Disclosure pursuant to a release. (a) No confidential HIV-related information shall be disclosed pursuant to a general release except to insurance companies as noted in section 63.5(a)(9) of this Part. Disclosure is

permitted for HIV-related information pursuant to a specific release form for a limited time period which has been developed or approved by the department. The release must be signed by the protected individual, or if the protected individual lacks capacity to consent, by a person authorized pursuant to law to consent to health care for the individual.

(b) All written disclosures of confidential HIV information must be accompanied by a statement prohibiting redisclosure. The statement shall include the following language or substantially similar language: "This information has been disclosed to you from confidential records which are protected by State law. State law prohibits you from making any further disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. Any unauthorized further disclosure in violation of State law may result in a fine or jail sentence or both. A general authorization for the release of medical or other information is not except in limited circumstances set forth in this Part, sufficient authorization for further disclosure. Disclosure of confidential HIV information that occurs as the result of a general authorization for the release of medical or other information will be in violation of the State law and may result in a fine or a jail sentence or both."

(c) If oral disclosures are necessary, they must be accompanied or followed as soon as possible, but no later than 10 days, by the statement required by subdivision (b) of this section.

(d) The statement required by subdivisions (b) and (c) of this section is not required for release to the protected person or when a person lacks the capacity to consent, to a person authorized pursuant to law to consent to health care for the person. for releases made by a physician or public health officer to a contact; or for releases made by a physician to a person authorized pursuant to law to consent to the health care of the protected person when the person has been counseled and has refused to disclose and the disclosure is medically necessary. For disclosures of confidential HIV-related information from the patient's medical record to persons who are permitted to access this information pursuant to section 63.5(a)(3), (4), (6), (7), (9) and (10) and (e) and (f) of this Part, it shall be sufficient for the statement required by subdivisions (b) and (c) of this section to appear as part of the medical record when a medical record is disclosed.

63.5 Confidentiality and disclosure. (a) No person who obtains confidential HIV related information in the course of providing any health or social service or pursuant to a release of confidential HIV-related information may disclose or be compelled to disclose such information, except to the following:

(1) the protected individual or, when the protected individual lacks capacity to consent, a person authorized pursuant to law to consent to health care for the individual;

(2) any person to whom disclosure is authorized pursuant to a release of confidential HIV-related information in accordance with section 63.4(a) of this Part;

(3) an agent or employee of a health facility or health care provider if:

(I) the agent or employee is authorized to access medical records;

(II) the health facility or health care provider itself is authorized to obtain the HIV-related information; and

(III) the agent or employee provides health care to the protected individual, or maintains or processes medical records for billing or reimbursement;

(4) a health care provider or health facility when knowledge of the HIV-related information is necessary to provide appropriate care or treatment to the protected individual or a child of the individual;

(5) a health facility or health care provider, in relation to the procurement, processing, distributing or use of a human body or a human body part, including organs, tissues, eyes, bones, arteries, blood, semen, or other body fluids, for use in medical education, research, therapy, or for transplantation to individuals;

(6) health facility staff committees, or accreditation or oversight review organizations authorized to access medical records, provided that such committees or organizations may only disclose confidential HIV-related information:

(i) back to the facility or provider of a health or social service;

(ii) to carry out the monitoring, evaluation, or service review for which it was obtained; or

(iii) to a Federal, State or local government agency for the purposes of and subject to the conditions provided in subdivision (e) of this section;

(7) a Federal, State, county or local health officer when such disclosure is mandated by Federal or State law;

(5) authorized agencies as defined by Social Services Law, section 371 and corporations incorporated or organized to receive children for adoption or foster care, in connection with foster care or adoption of a child. Such agency shall be authorized to redisclose such information only pursuant to the provisions of article 27-F of the Public Health Law or in accordance with the provisions of Social Services Law, section 373-A and regulations promulgated thereunder;

(9) third-party reimbursers or their agents to the extent necessary to reimburse health care providers, including health facilities, for health services, provided that, an otherwise appropriate authorization for such disclosure has been secured;

(10) an insurance institution, for other than the purpose set forth in paragraph (9) of this subdivision, provided the insurance institution secures a dated and written authorization that indicates that health care providers, health facilities, insurance institutions, and other persons are authorized to disclose information about the protected individual, the nature of the

information to be disclosed, the purposes for which the information is to be disclosed and which is signed by:

(i) the protected individual;

(ii) if the protected individual lacks the capacity to consent, such other person authorized pursuant to law to consent for such individual; or

(iii) if the protected individual is deceased, the beneficiary or claimant for benefits under an insurance policy, a health services plan, or an employee welfare benefit plan as authorized in article 27.F of the Public Health Law;

(11) to a funeral director upon taking charge of the remains of a deceased person when such funeral director has access in the ordinary course of business to HIV related information on the death certificate of the deceased individual, as authorized by Public Health Law, section 4142;

(12) any person to whom disclosure is ordered by a court of competent jurisdiction pursuant to Public Health Law, section 2785;

(13) an employee or agent of the Division of Probation, and Correctional Alternatives, Division of Parole, Commission of Correction, or any local probation department, to the extent the employee or agent is authorized to access records containing such information in order to carry out functions, powers and duties with respect to the protected person and in accordance with regulations promulgated pursuant to Public Health Law, article 27-F;

(14) a medical director of a local correctional facility in accordance with regulations promulgated pursuant to article 27-F to the extent the medical director is authorized to access records to carry out his/her functions relating to the protected person. Rediscovery by the medical director is prohibited except as permitted under Public Health Law, article 27-F and its implementing regulations;

(15) an employee or agent of the New York City Board of Corrections so that the board may continue to access records of inmates who die while in the custody of the New York City Department of Corrections when necessary for the board to carry out its duties, functions, and powers with respect to the protected individual, pursuant to the New York City charter; or

(16) a law guardian, appointed to represent a minor pursuant to the Social Services Law or the Family Court Act, for the purpose of representing that minor. If the minor has the capacity to consent, the law guardian may not redisclose confidential HIV related information without the minor's permission. If the minor lacks capacity to consent, the law guardian may redisclose confidential HIV-related information for the purpose of representing the minor.

(b) A State, county or local health officer may disclose confidential HIV-related information when:

(1) disclosure is specifically authorized or required by Federal or State law; or

(2) disclosure is made pursuant to a release of confidential HIV-related information; or

(3) disclosure is requested by a physician pursuant to section 63.7 of this Part; or if the contact resides outside the jurisdiction of the public health officer, the officer may inform a public health officer in the contact's jurisdiction to confidentially inform the contact; or

(4) disclosure is authorized by court order pursuant to the provisions of Public Health Law, section 2785.

(c) A physician may disclose the confidential HIV-related information during contact notification pursuant to section 63.7 of this Part.

(d) A physician may, upon the consent of a parent or guardian, disclose confidential HIV-related information to a State, county, or local health officer for the purpose of reviewing the medical history of a child to determine the fitness of the child to attend school.

(e) Confidential HIV-related information of a protected person may be disclosed to authorized employees or agents of a governmental agency pursuant to the regulations of the governmental agency when the person providing health or social services is regulated, supervised or monitored by the governmental agency or when the governmental agency administers the health program or a social services program and when such employees or agents have access to records in the ordinary course of business and when access is reasonably necessary for regulation, supervision, monitoring, administration or provision of services. Such authorized employees or agents may include attorneys authorized by a government agency when access occurs in the ordinary course of providing legal services and is reasonably necessary for supervision, monitoring, administration or provision of services. Such authorized employees or agents may also include public health officers as required for conducting epidemiological or surveillance investigations pursuant to the State Sanitary Code. Such surveillance or investigational data shall also be disclosed by the public health officer to the State Department of Health as required by the State Sanitary Code.

(f) Confidential HIV-related information of a protected person may be disclosed to authorized employees or agents of a provider of health or social services when such provider is either regulated, supervised or monitored by a governmental agency or when a governmental agency administers the provider's health or social service program, when such employees or agents have access to records in the ordinary course of business and when access is reasonably necessary for regulation, supervision, monitoring, administration or provision of services. Such authorized employees or agents may include attorneys authorized by persons providing health services when access occurs in the ordinary course of providing legal services and is reasonably necessary for supervision, monitoring, administration or provision of services.

(g) A physician may disclose confidential HIV-related information pertaining to a protected individual to a person, known to the physician, authorized pursuant to law to consent to the health care for a protected individual when the physician reasonably believes that:

(1) disclosure is medically necessary in order to provide timely care and treatment for the protected individual; and

(2) after appropriate counseling as to the need for such disclosure the protected individual will not inform a person authorized by law to consent to health care; provided, however, that the physician shall not make such disclosure if, in the judgment of the physician:

(i) the disclosure would not be in the best interest of the protected individual; or

(ii) the protected individual is authorized pursuant to law to consent to such care and treatment. A physician's decision to disclose pursuant to this subdivision, and the basis for that decision shall be recorded in the medical record.

(h) No person to whom confidential HIV-related information has been disclosed shall disclose the information to another person except as authorized by this Part; provided, however, that the provisions of this Part shall not apply to:

(1) the protected individual;

(2) a natural person who is authorized pursuant to law to consent to health care for the protected individual;

(3) a protected individual's foster parent, subject to Department of Social Services regulations, for the purpose of providing care, treatment or supervision to the protected individual; or

(4) a prospective adoptive parent, subject to Department of Social Services regulations, with whom a child has been placed for adoption.

(1) Nothing in this section shall limit a person's or agency's responsibility or authority to report, investigate, or redisclose child protective and adult protective services information in accordance with title 6 of article 6 and titles 1 and 2 of article 9-13 of the Social Services Law, or to provide or monitor the provision of child and adult protective or preventive services.

(j) Confidential HIV-related information shall not be disclosed to a health care provider or health care facility for the sole purpose of implementing infection control precautions when such provider or facility is regulated under the Public Health Law and required to implement such precautions with all individuals pursuant to this Title. This restriction shall not limit access to HIV-related information by a facility's infection control personnel for purposes of fulfilling their designated responsibilities in the facility.

(k) Confidential HIV-related information shall not be released pursuant to a subpoena. A court order pursuant to Public Health Law, section 2785 is required for release of confidential HIV-related information.

(1) Confidential HIV-related information shall be disclosed upon the request of the Health Care Worker HIV/HBV Advisory Panel (see Public Health Law

article 27-DD) to the panel or its designee(s) only when the panel considers the information reasonably necessary for the evaluation and monitoring of a worker who has voluntarily sought the panel's review.

#### 63.6 Documentation of HIV-related information and disclosures.

(a) Confidential HIV-related information shall be recorded in the medical record such that it is readily accessible to provide proper care and treatment.

(b) All disclosures of confidential HIV-related information must be noted in the record, except:

(1) only initial disclosures to insurance institutions must be noted;

(2) notation is not required for disclosure to agents or employees of health facilities or health care providers authorized under section 63.5(a)(3) of this Part; and

(3) notation is not required for persons engaged in quality assurance, program monitoring or evaluation, nor for governmental payment agents acting pursuant to contract or law.

(c) Confidential HIV-related information may be noted, as appropriate, in a certificate of death, autopsy report or related documents prepared pursuant to Public Health Law, article 41 or other laws relating to documentation of cause of death.

(d) The protected person shall be informed of disclosures of HIV information upon request of the protected person.

(e) Confidential HIV-related information shall not be disclosable pursuant to Public Officers Law, article 6 (the Freedom of Information Law).

63.7 Contact notification. (a) A physician may disclose HIV-related information, without the protected person's consent, to a contact or to a public health officer for the purpose of notifying a contact when:

(1) the physician reasonably believes disclosure is medically appropriate and a significant risk of infection exists to the contact; and

(2) the protected person has been counseled to notify his/her contacts and the physician reasonably believes the protected person will not inform the contacts.

(b) The physician must inform the protected person of the physician's intent to disclose, and inform the protected person that he/she may choose whether the physician or health officer will notify the contact. The physician shall honor the protected person's choice. All notification shall be in person, except where circumstances compel otherwise.



(c) The identity of the protected person shall not be disclosed to the contact.

(d) When a public health officer is requested to notify contacts, the officer may, in his/her own discretion, meet with the protected person, to counsel and verify information prior to any notification of such person's contacts. Local health units must make provisions for HIV contact notification services.

(e) The person notifying the contact shall provide counseling or make referrals for counseling as appropriate. Such counseling must address coping emotionally with potential exposure to HIV, an explanation regarding the nature of HIV infection and HIV-related illness, availability of anonymous and confidential testing, information on preventing exposure or transmission of HIV infection, information regarding discrimination problems that might occur as the result of disclosure of HIV-related information, and legal protections against such disclosures.

(f) If a protected person is now deceased and the physician reasonably believes the protected person had not informed his/her contacts and reasonably believes disclosure is medically appropriate and that a significant risk of infection exists, the physician may notify the contact or request the public health officer to notify the contact. All such notifications shall be in person, except where circumstances reasonably prevent doing so, and the identity of the deceased shall not be disclosed. The person notifying the contact shall provide counseling or make referrals for counseling as appropriate.

(g) A physician or public health officer shall have no obligation to identify or locate any contact.

63.8 Health care provider and health facility policy and procedures. Each health care provider and health facility employing persons or contracting with persons to perform any activity related to such provider's or facility's rendering of health services shall develop and implement policies and procedures to maintain the confidentiality of confidential HIV-related information. Such policies and procedures shall assure that such information is disclosed to employees or contractors only when appropriate under this Part. Such policies and procedures shall include:

(a) initial employee education and annual inservice education of employees regarding the legal prohibition against unauthorized disclosure in Public Health Law, article 27-F. A list of all employees who have had such training must be maintained by health care providers and health facilities. Health care providers and health facilities contracting with others for services in which HIV-related information may be disclosed to such contractors, must document evidence that such contractors have been informed of the confidentiality and disclosure requirements of this Part;

(b) maintenance of a list of job titles and the specific employee functions within those titles for which employees are authorized to access such information. This list shall describe the limits of such access to information and must be provided to the employees during employee education sessions;

(c) a requirement that only full-time or part-time employees, contractors and medical, nursing or health-related students who have received such education on HIV confidentiality, or can document that they have received such education or training, shall have access to confidential HIV-related information while performing the authorized functions listed under paragraph (2) of this subdivision;

(d) protocols for ensuring that records, including records which are stored electronically, are maintained securely and used for the purpose intended;

(e) procedures for handling requests by other parties for confidential HIV-related information;

(f) protocols prohibiting employees/agents/contractors from discriminating against persons having or suspected of having HIV infection; and

(g) review of the policies and procedures on at least an annual basis.

63.9 Significant risk. (a) The three factors necessary to create a significant risk of contracting or transmitting HIV infection are:

(1) the presence of a significant risk body substance;

(2) a circumstance which constitutes significant risk for transmitting or contracting HIV infection; and

(3) the presence of an infectious source and a noninfected person.

(b) Significant risk body substances are blood, semen, vaginal secretions, breast milk, tissue and the following body fluids: cerebrospinal, amniotic, peritoneal, synovial, pericardial, and pleural.

(c) Circumstances which constitute "significant risk of transmitting or contracting HIV infection" are:

(1) sexual intercourse (vaginal, anal, oral) which exposes a noninfected individual to blood, semen or vaginal secretions of an infected individual;

(2) sharing of needles and other paraphernalia used for preparing and injecting drugs between infected and noninfected individuals;

(3) the gestation, birthing or breast feeding of an infant when the mother is infected with HIV;

(4) transfusion or transplantation of blood, organs, or other tissues from an infected individual to an uninfected individual, provided such blood, organs or other tissues have not tested negatively for antibody or antigen and have not been rendered noninfective by heat or chemical treatment;

(5) other circumstances not identified in paragraphs (1) through (4) of this subdivision during which a significant risk body substance (other than breast milk) of an infected individual contacts mucous membranes (e.g., eyes, nose, mouth), nonintact skin (e.g., open wound, skin with a dermatitis condition,

abraded areas) or the vascular system of a noninfected person. Such circumstances include, but are not limited to needlestick or puncture wound injuries and direct saturation or permeation of these body surfaces by the infectious body substance.

(d) Circumstances that involve "significant risk" shall not include:

(1) exposure to urine, feces, sputum, nasal secretions, saliva, sweat, tears or vomitus that does not contain blood that is visible to the naked eye;

(2) human bites where there is no direct blood to blood, or blood to mucous membrane contact;

(3) exposure of intact skin to blood or any other body substance; or

(4) occupational settings where individuals use scientifically accepted barrier techniques and preventive practices in circumstances which would otherwise pose a significant risk.

63.10 Approved forms. (a) The following informed consent form is approved for purposes of section 63.3(b) (1) of this Part:

New York State Department of Health AIDS Institute Informed Consent to Perform an HIV Related Test\* (\*Human Immunodeficiency Virus that causes AIDS)

If you want to request an HIV related test in New York State, you must give your consent in writing.

Testing for HIV

There are a number of tests that can be done for HIV. Ask your doctor or counselor for specific information on these tests. A common test for HIV is the HIV antibody test, a blood test. A sample of blood is taken from your arm with a needle. The test shows if you are infected with HIV, the virus which is known to cause AIDS.

A negative HIV antibody test result means that you probably are not infected. However, it takes time for HIV infection to show up in your blood. If you think you have been exposed to HIV during the past six months, you will need to be retested to confirm that you are not infected. Your doctor or HIV counselor will explain this to you.

A positive HIV antibody test result means that you have been exposed to the virus and are infected. You can infect others.

Sometimes the test result is not clearly positive or negative. Your doctor or counselor will explain such a result and ask that you give consent for another sample of blood to be taken so that other tests can be done.

There are benefits to being tested

If you test negative:

- Your doctor or counselor will tell you how to protect yourself from getting infected with the virus in the future.

- You can end the fear which may come from not knowing if you are infected.

If you test positive:

- Your doctor can give you medical care and treatment that can help you stay healthy and can slow down HIV illness.

- Your doctor can tell you how to prevent passing the virus to others.

- If you have had a child since you were infected, your child may need additional care and treatment. Your doctor can provide information about medical care available for children who may be infected with HIV.

- If you are a pregnant woman, your doctor can provide the care you need and information about services and options available to you. Your doctor can tell you about the risks of passing HIV infection to your baby and the medical care available for babies who may be infected with HIV.

- If you are thinking of having a child, you will be told about the possibility of passing the virus to your baby.

#### Confidential or Anonymous Voluntary Testing

When you decide to be tested, you may choose either anonymous or confidential testing:

- If you do not want anyone to know your test results or that you were tested, you can go to an anonymous test site. You will not be asked your name or address.

- If you want your results to be used for your medical care and become part of your medical record, a confidential test can be done by your health care provider.

- If you need help finding a place to be tested either anonymously or confidentially call the New York State AIDS Hotline 1-800-541-2437.

#### Confidentiality of HIV Information and HIV Test Results

New York State law protects HIV related information, including HIV test results, from being disclosed by health and social service providers without the patient's consent. By law, giving HIV information about you without your consent or testing you for HIV without your written consent may be punished by a fine of up to \$5,000 and a jail term of up to one year.

In the law, there are some exceptions that give your health care providers permission to share HIV information about you without your written consent. These include:

- Medical professionals treating you or your child may discuss your HIV information with each other or with their supervisors, but only in order to provide necessary care for you or your child;

- A hospital or other health care provider may share HIV information with your insurance company if the information is necessary to pay for your medical care;
- A physician may inform your sexual or needle-sharing contacts without giving your identity and only after informing you of his/her intent to do so;
- A committee, organization or government agency, when it needs such information to supervise, monitor or administer a health or social service may have access to this information;
- Agencies or prospective adoptive or foster parents for foster care or adoption purposes may have access to this information;
- A Federal, State, county, or local health officer may have access to this information when State or Federal law requires disclosure;
- If you are a minor, your parent or guardian can be told HIV related information about you if it is necessary to provide timely care for you, unless it would not be in your best interest to do so;
- Any person to whom a court orders disclosure may have access to this information;
- Medical personnel and certain other supervisory staff may have access to your HIV information in order to provide services to you or to monitor services, if you are in jail or prison, or on parole.

#### Be Careful About Sharing HIV Information

Your HIV related information is important information to share with your health care providers so that they can give you the best care. However, you should be careful who else you tell if you test positive for HIV since not everyone understands what being HIV positive means. Some people who test positive for HIV are discriminated against by employers, landlords and others. If you are discriminated against because of HIV, you can call the New York State Division of Human Rights at (212) 870-8624 or the New York City Commission on Human Rights at (212) 566-5493 for help. These agencies are responsible for protecting your civil rights.

#### For More Information

If you have questions about informed consent for HIV related testing, questions about the laws protecting the confidentiality of your HIV test results, or feel that confidential HIV related information about you was disclosed without your consent, call the New York State Department of Health HIV Confidentiality Hotline at 1-800-962-5065.

My questions about the HIV test were answered. I agree to be tested for HIV.

Date:

Signature of the person to be tested or person authorized to consent for the person to be tested.

Print name of person to be tested. Print name of person consenting if different from person to be tested.

Pre-test counseling was verbally provided in accordance with Article 27-F of the New York State HIV Confidentiality Law including, how the HIV test is done, the meaning of the test and test results, the possible consequences of disclosing HIV information, and the protections against unauthorized disclosure of HIV related information provided by law, to the above individual. I answered the above individual's questions about the test and offered him/her an unsigned copy of the HIV Informed Consent Form at the time informed consent was obtained.

NAME

TITLE

FACILITY/PROVIDER NAME

(b) The following release form is approved for purposes of section 63.4(a) of this Part:

Authorization for Release of Confidential HIV\* Related Information (\*Human Immunodeficiency Virus that causes AIDS)

Confidential HIV Related Information is any information indicating that a person had an HIV related test, or has HIV infection, HIV related illness or AIDS, or any information which could indicate that a person has been potentially exposed to HIV.

Under New York State Law, except for certain people, confidential HIV related information can only be given to persons you allow to have it by signing a release. You can ask for a list of people who can be given confidential HIV related information without a release form.

If you sign this form, HIV related information can be given to the people listed on the form, and for the reason(s) listed on the form. You do not have to sign the form, and you can change your mind at any time.

If you experience discrimination because of release of HIV related information, you may contact the New York State Division of Human Rights at (212) 870-8624 or the New York City Commission of Human Rights at (212) 566-5493. These agencies are responsible for protecting your rights.

Name of person whose HIV related information will be released:

Name and address of person signing this form (if other than above):

Relationship to person whose HIV information will be released:

Name and address of person who will be given HIV related information:

Reason for release of HIV related information:

Time during which release is authorized:

From:

To:

My questions about this form have been answered. I know that I do not have to allow release of HIV related information, and that I can change my mind at any time.

Date

Signature

New York State approved form 2557

February 1989

80.135 Authorization to conduct hypodermic syringe and needle exchange programs. (a) Employees or trained volunteers of community-based not-for-profit organizations and government entities engaged in clean hypodermic syringe and needle exchange programs designed to reduce the transmission of human immunodeficiency virus may obtain, possess and furnish hypodermic syringes and hypodermic needles, without prescription, when authorized by the commissioner in connection with the distribution or collection of hypodermic syringes and hypodermic needles for the purpose of preventing the transmission of human immunodeficiency virus in users of injectable drugs. This authorization will be granted only in accordance with a plan submitted by the not-for-profit corporation or government entity and approved by the commissioner, using the standards contained in this section. This authorization will be based upon the plan meeting the requirements of the regulation.

(b) The department will review the plan submitted by the not-for-profit corporation or government entity using the following standards:

(1) the plan demonstrates the need for a hypodermic syringe and needle exchange program in the targeted community(ies) and in targeted populations within those communities;

(2) the plan demonstrates organizational capability and commitment necessary to conduct a hypodermic syringe and needle exchange program, to interact effectively with the community(ies) and with targeted populations within those communities where a hypodermic syringe and needle exchange program is planned, and to enlist support for and to further integration of hypodermic and needle exchange services within the community(ies);

(3) the plan demonstrates an adequacy of the design and protocol for the conduct of a hypodermic syringe and needle exchange program; and

(4) the plan demonstrates organizational capability to provide comprehensive harm reduction services, including HIV prevention education and other appropriate interventions such as counseling for program participants and direct provision of or referral to other health and human services, including drug treatment.

(c) This authorization extends only to those hypodermic needles and hypodermic syringes distributed or collected pursuant to the approved plan and

only as long as such employees or trained volunteers of the not-for-profit organizations or government entities are assigned to the program. The organization or entity must develop and maintain a list of employees and trained volunteers who are authorized to obtain, possess and furnish hypodermic syringes and hypodermic needles, and furnish this list to the department. All personnel changes to this list shall be reported to the department in a time period specified by the department.

(d) An approval obtained pursuant to subdivision (a) of this section shall continue until two years from the date of notification by the commissioner of approval of the plan submitted by the not-for-profit organization or government entity or until receipt by the organization or entity of a written notice of termination of the program from the commissioner, whichever shall first occur. The commissioner may approve extensions of the plan for additional two-year periods if the not-for-profit organization or government entity complied with the requirements of this section during the prior two-year period.

(e) Individuals participating in the approved plan may obtain and possess hypodermic syringes and hypodermic needles without prescription from individuals authorized pursuant to subdivision (a) of this section provided that:

(1) this authorization extends only to obtaining or possessing those hypodermic syringes and hypodermic needles which have been distributed or collected pursuant to the approved plan;

(2) this authorization is effective only so long as the person is an active participant in the approved plan; and

(3) this authorization shall be automatically void with respect to any hypodermic syringe or hypodermic needle which is sold or furnished or attempted to be sold or furnished by a participant in violation of State or Federal law.

(f) An approval pursuant to subdivision (a) of this section shall allow a not-for-profit organization or government entity to purchase hypodermic syringes or hypodermic needles as part of a needle exchange plan approved by the commissioner, and designed to reduce the transmission of human immunodeficiency virus.

(g) An organization or entity authorized by the commissioner to conduct a hypodermic syringe and needle exchange program must adhere to policies and procedures developed by the department for the conduct of a hypodermic syringe and needle exchange. An approved plan may propose revisions to the department's policies and procedures to reflect the specific conditions under which the plan is providing services. Any proposed revision must be approved by the department prior to implementation. Such policies and procedures will include, but not be limited to:

(1) requirements for training for staff and volunteers;

(2) procedures to ensure staff security;



(3) policies and procedures for enlisting community support for the program, including development of a community advisory board reflective of the community in which the hypodermic syringe and needle exchange program is located;

(4) procedures and reporting requirements involving community concerns regarding the conduct of a hypodermic syringe and needle exchange program, including those involving law enforcement agencies;

(5) policies and procedures for determining eligibility of individuals for participation in a hypodermic syringe and needle exchange program;

(6) policies and procedures to provide assessment and service referral for injecting drug users under the age of 18;

(7) procedures for enrollment of participants in a hypodermic syringe and needle exchange program and issuance of participant identification cards;

(8) procedures for obtaining and recording participant information;

(9) policies and procedures for distribution and collection of hypodermic syringes and needles, including the number of needles that can be provided to a plan participant in a single transaction;

(10) procedures to ensure that hypodermic syringes and needles are secured properly and that the handling and disposal of hypodermic syringes and needles is safeguarded and in accordance with State and Federal law and regulations;

(11) policies and procedures to terminate program participants;

(12) procedures for developing new sites or expanding or changing existing sites for hypodermic syringe and needle exchange programs;

(13) policies and procedures relating to the provision of HIV prevention education and other appropriate interventions such as counseling for program participants;

(14) policies and procedures for referring program participants to services, including developing formal written agreements with service providers and documenting referral linkages;

(15) procedures for data collection and program reporting; and

(16) policies and procedures for evaluation of hypodermic syringe and needle exchange programs.

(h) The following records of hypodermic syringes, hypodermic needles, participants and transactions shall be maintained by the organization or entity engaged in exchanging hypodermic syringes and hypodermic needles:

(1) an inventory of hypodermic syringes and hypodermic needles, including the number purchased and distributed, and the balance on hand;

(2) a record of the number of hypodermic syringes and hypodermic needles distributed to each participant in each transaction;

(3) a record of the number of used hypodermic syringes and hypodermic needles returned by each participant in each transaction;

(4) the number and manner of disposal of hypodermic syringes and hypodermic needles collected by the program; and

(5) a record of the number of participants provided HIV prevention education and other appropriate interventions such as counseling; a record of the number and types of services directly provided or provided by referral to participants, based upon an assessment of the client's needs, not limited to, referral to HIV antibody testing services, health care services, including evaluation and treatment for HIV infection, sexually transmitted diseases and tuberculosis, family planning, prenatal and obstetrical care, social services and drug abuse treatment services.

(I) An organization or entity functioning under a needle exchange plan approved under subdivision (a) of this section must ensure that hypodermic syringes and needles are secured properly and must safeguard the handling and disposal of hypodermic syringes and needles in accordance with State and Federal law and regulations.

(j) An organization or entity functioning under a needle exchange plan approved under subdivision (a) of this section must provide periodic reports of activities to the department in a format and time period specified by the department which shall include, but not be limited to:

(1) the number of program participants;

(2) aggregate information regarding the characteristics of program participants;

(3) the total number of hypodermic syringes and hypodermic needles distributed and the average number distributed per participant per transaction;

(4) the total number of hypodermic syringes and hypodermic needles collected, and the average number collected per participant per transaction;

(5) information regarding the service needs of plan participants, based upon the plan's assessment of those needs and the service needs expressed by plan participants. Information regarding the program's response to those needs, including, but not limited to program changes, the establishment of new services, and the provision of on-site referrals and referrals to off-site providers for other services. This information will include the number and types of services directly provided or provided by referral to plan participants, not limited to HIV prevention education and other appropriate interventions such as counseling, HIV antibody testing services, health care services, including evaluation and treatment for HIV infection, sexually transmitted diseases and tuberculosis, family planning, prenatal and obstetrical care, social services and drug abuse treatment services;

- (6) a list of employees and trained volunteers who are authorized to obtain, possess and furnish hypodermic syringes and needles;
- (7) significant problems encountered and program milestones achieved; and
- (8) other information deemed necessary by the department to ensure that the conduct of a hypodermic syringe and needle exchange program adheres to the requirements of this regulation.

(k) The organization or entity functioning under an approved needle exchange plan shall provide an annual report of plan activities to the department, summarizing the information previously provided as contained in sub division (J) of this section in a format provided by the department. In addition, the report shall contain an evaluation of the organization's progress in attaining the plan's goals. The annual report must be submitted to the department no later than 60 days after the program has been approved for a period of one year and at the same time annually thereafter.

(1) An organization or entity functioning under a needle exchange plan approved under subdivision (a) of this section may be inspected by authorized representatives of the State Commissioner of Health as necessary to ensure compliance with the requirements of this section. An organization or entity found to be in violation of these regulations will receive written notification of the violation from the department and a time period, not to exceed 30 days from the date of written notification, to correct the violation. If the organization or entity continues to be in violation of these regulations after the date required for correction, the commissioner may terminate approval of the plan. The commissioner may also terminate the plan immediately if s/he determines that approval of the plan is no longer in the interest of public health.

An organization or entity will receive notification of the termination from the commissioner or his/her designee, and a time period not to exceed 60 days to appeal the termination by written submission to the commissioner or his/her designee requesting reconsideration of the termination.

(m) Any not-for-profit organization or government entity seeking to obtain, possess and furnish hypodermic syringes and hypodermic needles, without prescription, must submit a plan to the commissioner for approval, which must be in a format specified by the department, and will include, but not be limited to:

- (1) the name and address of the not-for-profit organization or government entity;
- (2) the name and title of the individual authorized to represent the program in seeking approval;
- (3) information regarding organization, capability and commitment relating to the conduct of a hypodermic syringe and needle exchange program;
- (4) an assessment of the need for a hypodermic syringe and needle exchange program the targeted community(ies) and in targeted populations within the communities;

(5) a description of the applicant's previous and planned activities to interact with a community(ies) where a hypodermic syringe and needle exchange program is planned, to enlist support for and to further integration of the hypodermic syringe and needle exchange program within the community(ies) and within targeted populations in those communities;

(6) a description of staffing for the proposed program, including employees or trained volunteers;

(7) a description of training planned for employees and volunteers staffing the proposed program;

(8) a list of employees and trained volunteers staffing the proposed program;

(9) the design and protocols of the project, including the geographic area and the method of program operation; including procedures for determining eligibility of individuals for participation in the program; procedures to provide assessment and service referral to injecting drug users under the age of 18; procedures for enrollment of participants in the program, including issuance of participant identification cards; procedures for obtaining and recording participant information; procedures to ensure staff security; procedures for distribution and collection of hypodermic syringes and needles, including the number of needles that can be provided to a plan participant in a single transaction;

(10) the proposed plans for the proper safeguarding and handling and disposal of hypodermic syringes and needles, including inventory control, and securing injection equipment from theft, adherence to appropriate infection control practices and appropriate disposal of used hypodermic syringes and needles;

(11) the proposed plan to provide program participants with HIV prevention education and other appropriate interventions such as counseling regarding drug and sexual risk behaviors and risk reduction practices, including cleaning of injection equipment, use of condoms, and distribution of bleach kits and condoms, and referral for ongoing HIV prevention education and psychosocial support;

(12) the proposed plan for direct provision or referral to services, not limited to: HIV antibody testing services, health care, including evaluation and treatment for HIV infection, sexually transmitted diseases and tuberculosis, family planning, prenatal and obstetrical care, social services and drug abuse treatment services, including the plan to work with service providers and community-based organizations to establish service linkages; and

(13) the proposed plan for evaluating program services and goals.

86-4.35 Computation of basic rates for clinic services provided to Acquired immune Deficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) seropositive patients by freestanding ambulatory care facilities and hospital clinic outpatient services. (a) For payments made pursuant to this section and pursuant to section 86-1.11(h) of this Part, for ambulatory services to

AIDS patients, HIV positive patients, and patients seeking verification of HIV infection, reimbursement shall be based upon a single payment schedule with a discrete price for each of the five clinic services set forth in subdivision (c) of this section.

(b) To be eligible to receive reimbursement pursuant to this section, facilities must be licensed pursuant to article 28 of the Public Health Law and certified to provide general medical services and complete a written signed agreement with the commissioner to provide these discrete services. Facilities interested in establishing such agreements must submit in writing the required documentation in a manner acceptable to the commissioner. Such agreement shall describe the Medicaid patients who will be eligible for reimbursement under this section and shall establish the documentation and services required for patient assignment to each of the five clinic services. The five clinic services for which reimbursement shall be available according to the prices as established by this section are as follows:

(1) HIV counseling and testing visits. This visit shall mean the provision of pre test HIV counseling in a medical setting as performed in compliance with article 27-F of the State Public Health Law. This visit shall also include laboratory testing necessary to determine whether a person has HIV disease. This visit shall also mean the provision of post-test HIV counseling in a medical setting as performed in compliance with the confidentiality provisions of article 27-F of the State Public Health Law for those individuals whose test results are positive. This visit is available for the purpose of informing these individuals of their test results and providing supportive counseling for those HIV zero positive persons experiencing adverse psychological responses to their serostatus.

(2) Post-test counseling visit. This visit shall mean the provision of post-test HIV counseling in a medical setting as performed in compliance with the confidentiality provisions of article 27-F of the State Public Health Law for those persons whose test results are negative. This visit is available for the purpose of informing these individuals of their results and counseling them on preventive measures.

(3) Initial comprehensive HIV medical evaluation visit. This visit shall mean a comprehensive medical history and physical examination, and laboratory testing necessary for the evaluation of HIV disease and related conditions. The evaluation shall be complete enough to: establish the state of HIV illness, diagnose active opportunistic infections and tumors, identify appropriate prophylactic therapies to prevent future opportunistic infections, initiate indicated anti-HIV therapy, and identify significant psycho-social problems to be addressed in the care plan.

(4) Drug and immunotherapy visits for HIV infected patients. This visit shall mean to those HIV-related treatments that require active health care supervision during the treatment visit and/or extensive amount of provider monitoring following the treatment.

(5) Monitoring visit for asymptomatic HIV disease. This visit shall mean the clinical and laboratory evaluation necessary to monitor the status of HIV disease to indicate the appropriate stage to initiate active drug treatment for HIV or prophylactic treatment for opportunistic infections.

(d) The prices established pursuant to this section shall provide full reimbursement for the following:

(1) physician services, nursing services, technician services, and other related professional expenses directly incurred by the licensed facility;

(2) space occupancy and plant overhead costs;

(3) administrative personnel, business office, data processing, recordkeeping, housekeeping, and other related facility overhead expenses;

(4) all ancillary services including laboratory tests and diagnostic X-ray services where specified in the treatment regimes and as detailed in the agreement pursuant to subdivision (b) of this section; and

(5) all medical supplies, immunizations, and drugs directly related to the provision of the services except for those drugs used to treat AIDS patients for which fee for service reimbursement is available under section 7.0 of the Medicaid Ordered Ambulatory Services Fee Schedule as contained in the Medicaid Management Information Systems (MMIS) Clinic Services Provider Manual (revised October, 1988). Copies of the schedule may be obtained from the New York State Department of Social Services and are available for inspection and copying at the Department of Health, Records Access Office, 22nd Floor, Corning Tower Building, Governor Nelson A. Rockefeller Empire State Plaza, Albany, New York 12237-0042.

(e) The price for each service shall be adjusted for regional differences in wage levels, space occupancy and facility overhead costs.

(f) The commissioner shall establish trend factors to project increases in base year prices during the effective period of the reimbursement rates. The trend factors shall be developed using available price indices including elements of the United States Department of Labor consumer and producer price indices and special price indices developed by the commissioner for this purpose. The projected trend factors shall be updated on an annual basis, based upon current and available data.

(g) At the discretion of the commissioner, health services may be added or deleted from the visits contained in subdivision (c) of this section. The commissioner shall notify participating providers of such changes at least 60 days before such changes shall be effective and the agreements as outlined in subdivision (b) of this section shall be modified to encompass any such changes.

(h) Payment for any other clinic services which are not covered pursuant to subdivision (c) of this section shall be reimbursed as follows:

(1) for facilities with a cost-based all inclusive clinic visit rate established pursuant to this Subpart or to Subpart 86-1, services shall be reimbursed at the all inclusive clinic visit rate.

(2) for facilities without a cost-based all-inclusive rate, fee for service reimbursement is available under the Ordered Ambulatory Services Fee

Schedule as referenced in paragraph (d)(5) of this section for medical services ordered by the patient's attending physician.

(i) For financial reporting purposes and statistical reporting purposes, facilities which provide services pursuant to subdivision (c) of this section must comply as appropriate with the standards established for said reporting in section 86-1.3 or 86-4.3 of this Part.

86-4.41 Computation of basic rates for day health care services for AIDS/HIV patients. Computation of basic rates for day health care services provided to patients with acquired immune deficiency syndrome (AIDS) and other human immunodeficiency virus (HIV) related illnesses by free-standing ambulatory care facilities.

(a) For payments made pursuant to this section for day health care services rendered to patients who have AIDS or HIV-related illness, reimbursement shall be a single price per visit, with not more than one reimbursable visit per day per patient. For 1993 an initial price shall be determined taking into consideration reasonable projections of necessary costs, and the costs and statistics contained in proposed annual budgets for this service as defined in section 759.1(c) of this Title, including, but not limited to, utilization, staffing and salaries. For subsequent rate periods the price established pursuant to this section shall be adjusted by the trend factor described in subdivision (e) of this section after considering the actual allowable expenditures and statistics for the year which ended 15 months prior to the rate period.

(b) To be eligible to receive reimbursement pursuant to this section, a free-standing ambulatory care facility must be certified to provide general medical services and day health care services for AIDS/HIV patients.

(c) The price established pursuant to this section shall be full reimbursement for the following:

(1) physician services, nursing services, and other related professional expenses directly incurred by the licensed facility, including the provision of triage or sick call services;

(2) space occupancy and plant overhead costs;

(3) administrative personnel, business office, data processing, recordkeeping, housekeeping, food services, transportation, and other related facility overhead expenses;

(4) all ancillary services described in section 759.6 of this Title and laboratory tests and diagnostic X-ray services appropriate to the level of primary medical care required by the patient;

(5) all medical supplies, immunizations, and drugs directly related to the provision of services except for those drugs used to treat AIDS patients for which fee-for-service reimbursement is available as determined by the Department of Social Services (see section 7.0 of the Medicaid Ordered

Ambulatory Services Fee Schedule as contained in the Medicaid Management Information Systems [MMIS] Clinic Services Provider Manual [revised October 1992]. Copies of the schedule may be obtained from the Department of Social Services and are available for inspection and copying at the Department of Health, Records Access Office, 22nd Fl., Corning Tower, Empire State Plaza, Albany, NY 12237-0042).

(d) Components of the price may be adjusted for service capacity, urban or rural location, and for regional differences in wage levels, space occupancy, and facility overhead costs, by comparing anticipated utilization and costs with actual experiences. The downstate region shall be defined as the counties of Putnam, Rockland, Westchester, Bronx, Kings, New York, Queens, Richmond, Nassau, and Suffolk and the upstate region shall be defined as all remaining counties in the State.

(e) The commissioner shall establish trend factors to project increases in prices for the effective period of the reimbursement rates. The trend factors shall be developed using available price indices including elements of the United States Department of Labor consumer and producer price indices and special price indices developed by the commissioner for this purpose. The projected trend factors shall be updated on an annual basis, based upon current and available data.