

**FLORIDA'S OMNIBUS AIDS ACT:
A BRIEF LEGAL GUIDE
FOR
HEALTH CARE PROFESSIONALS**

Originated by

JACK P. HARTOG, Esq.
Gray Robinson, Attorneys at Law
jhartog@gray-robinson.com

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Jack P. Hartog, the author who originated and revised this pamphlet, is a health care attorney with Gray Robinson, a large Florida law firm that, among its broad array of services, specializes in health care law. He received his law degree from Stanford University after completing his undergraduate education at Cornell University.

Before joining Gray Robinson in 2008, Mr. Hartog served as an Assistant County Attorney for Miami-Dade County, Florida, for more than 21 years as counsel for the Public Health Trust of Miami-Dade County. The Trust governs and operates the Jackson Health System, including Jackson Memorial Hospital (Florida's largest and busiest hospital) and the South Florida AIDS Network. Since the enactment of Florida's Omnibus AIDS Act in 1988, Mr. Hartog has conferred extensively with legislators and staff of the Department of Health (formerly the Department of Health and Rehabilitative Services) regarding amendments to and implementation of the Omnibus AIDS Act. He has lectured throughout Florida to hospital staff, physicians, osteopaths, dentists, nurses, social workers, mental health professionals, medical records custodians, risk managers, and lawyers about Florida's HIV laws and other health care matters.

The Florida Department of Health expresses its gratitude to Mr. Hartog as author of this informative and important publication. While Mr. Hartog drafted the original and all versions through 2009 of this pamphlet under contract, the Department takes full responsibility for and ownership of its contents.

INTRODUCTION

This pamphlet was first issued in 1990 after the Florida Legislature amended its 1988 comprehensive legislation, commonly referred to as the "Omnibus AIDS Act" (now codified principally at §381.004, *F.S.*). This law addresses the many ways human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) affect the public health and welfare, comprehensively creating numerous programs and establishing various requirements for state agencies and health care providers.

The Omnibus AIDS Act (referred to in this booklet simply as "the Act") and its related laws directly affect doctors, nurses, health care administrators, and other front-line health care providers. This booklet summarizes these laws for health care providers. It contains a detailed table of contents to facilitate the identification and resolution of issues that may arise. This updated edition includes all significant changes in this law since 1988 as they affect health care providers.

The information in this booklet is not intended to be a substitute for legal advice from an attorney. In the interest of clarity and brevity, some general rules have been simplified and some exceptions and qualifications have been omitted. In addition, factual details surrounding a particular health care delivery problem or complaint can easily change not only which rule applies but also how it applies and whether it is workable. Finally, the legal citations that are included are not intended to be complete, but only to serve as guides to the most essential information. Before acting on the material in this booklet, health care providers are strongly urged to consult with a lawyer or risk manager.

I. OVERVIEW

In 1988, through the Omnibus AIDS Act, Florida became one of the first states with high rates of HIV infection to enact comprehensive legislation addressing the AIDS epidemic. In 2010, the Act, although amended several times, remains largely consistent with the recommendations of many national organizations, including the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services that have carefully examined the issues. The Act is premised on the health policy judgment that this illness can best be controlled through an informed public that knows how to avoid contracting and transmitting the disease and that voluntarily agrees to be tested. §381.004(1), *F.S.*

The rationale for this approach is straightforward. It is based upon the limited methods by which this relatively weak virus can be transmitted. Transmission occurs through direct contact of virus-containing body fluids with exposed membranes as in sexual activity; or introduction into the blood stream through transfusion or needle sharing, as in intravenous drug use; or from infected mother to fetus or nursing infant. These activities almost always involve private, consensual conduct. Government cannot easily, much less constitutionally, regulate or prevent such activity. Consequently, short of wholesale invasions of civil liberties and fundamental rights to privacy, governmental responses must rely primarily upon education of the public and its cooperation with health care recommendations.

The Omnibus AIDS Act advances its public health objectives principally through education of health care providers and Florida residents. To keep or get a license to practice in Florida, every licensed health care provider must take a course on HIV/AIDS tailored to the profession, and every licensed health care facility must educate its entire work force about HIV infection. §§381.0035 and

381.0036, *F.S.* The Act also mandated similar education for various institutionalized patients, school children, university and college students, and law enforcement and correctional officers, much of which has been folded into continuing disease prevention efforts, §§1006.68 and 381.981, *F.S.* In 1999, the legislature directed the Department of Health to develop and implement a statewide HIV and AIDS prevention campaign to strengthen HIV and AIDS prevention programs and early intervention and treatment efforts in the state's black, Hispanic, and other minority communities. §381.0046, *F.S.*

The Act's declared policy as applied to performing HIV tests is that HIV testing should be "informed, voluntary, and confidential." §381.004(1), *F.S.* The Act attempts to create an environment in which people will agree to or seek out HIV testing because they are sufficiently informed about HIV infection and assured about the privacy of a decision to be tested. To promote knowledgeable patient decision-making, the Act prohibits HIV testing without a person's knowledge and consent except in tightly defined circumstances and gives the patient special rights to control who learns of the HIV test results. To safeguard further these rights to confidentiality, the Act amends civil rights laws to prohibit discrimination against persons who have or are thought to have the infection. Its anti-discrimination provisions apply in such areas as employment, housing, public services, public accommodations, and health and life insurance, §760.50, *F.S.*

The scope of the Act in confronting the AIDS epidemic remains extremely broad. New approaches and powers added in 1988, in addition to those described above, included authorizing the Florida Department of Health to undertake HIV testing and patient care services throughout the state as well as conducting epidemiologic research, clarifying general public health measures for testing, hospitalizing, and isolating persons with sexually transmissible diseases who behave irresponsibly, as well as strengthening criminal laws against prostitution and sexual activity by those infected with HIV.

In 1988, four key facts about HIV infection and AIDS formed the foundation of the Act's approach to controlling the spread of the epidemic. Although each characteristic alone was not particularly unusual, the four taken together made a unique impact on public health. These facts were:

(1) **The limited modes of transmission.** Because this disease cannot be spread from one person to another through casual contact, education regarding behavior choices — abstaining from unprotected sex and from needle sharing, and following appropriate universal precautions at work — is stressed more than isolation or other restrictions on infected individuals.

(2) **The "window period" during which undetected infection exists.** The period between infection and antibody production for most people is three weeks to three months, but may take up to six months or even longer in unusual cases. If improved antibody testing technology eliminated the window period — so that a negative result meant that the test subject was totally HIV virus-free (not just HIV antibody-free) and therefore incapable of spreading the disease — there might be fewer restraints on HIV testing in such areas as testing for the purpose of infection control.

(3) **The lack of any cure or effective treatment.** If there had been an effective intervention for this disease in 1988, such as we have for other sexually transmitted diseases and tuberculosis, the law would have directed public health authorities to spend more energy on early detection, mandatory reporting, and partner notification. The benefits of immediate therapy to the affected and potentially exposed population would have outweighed any other consideration.

(4) **The excessively anxious and sometimes intensely hostile public reaction.** If the public understood HIV disease and were as accepting of people

with this illness as it is of those suffering from other chronic illnesses, special confidentiality and anti-discrimination protections might not be needed.

Florida's Omnibus AIDS Act responded directly to this group of characteristics distinguishing HIV infection from other communicable diseases.

Some of these essential facts have begun to change. New treatment options continue to emerge as researchers discover drugs that delay the onset of illness. Prior public hostility is being increasingly replaced with public knowledge and acceptance of this disease.

Responding to these changes, the legislature has amended the Act. For example, in 1996 an amendment authorized the Department of Health to require physicians and laboratories to report HIV positive test results to state health authorities. At about this same time, the Department of Health devoted additional resources to voluntary partner notification efforts and increasing patient access to HIV/AIDS medical and support services. Both these actions stem from improvements in drug regimens for treating HIV infection, which are transforming the illness from a relatively progressive killer to a long term, chronic infection, and from knowledge that early detection followed by treatment with these drugs can yield substantial health benefits. Similarly, when drugs were found that could reduce transmission from mother to newborn from as high as 30% to nearly zero, the law moved away from strict informed consent for pregnant women to a system that mandates providers test all pregnant women for HIV infection, unless they elect to decline testing.

In 1998, amendments "streamlined" HIV testing procedures by eliminating many required counseling efforts, which were burdensome to both testers and their subjects, on the premise that public knowledge regarding prevention and

transmission of AIDS had increased sufficiently to end universal mandatory pre-test counseling and face-to-face post-test counseling.

More recently, new rapid HIV testing technology, which gives nearly 100% certain results in 20 minutes or less, is starting to shape changes in informed consent processes. This technology is also changing testing procedures related to significant exposures among health care workers. Further changes can be expected as aspects of these key facts and technology continue to evolve.

II. PERFORMING HIV TESTS

Health care providers performing HIV tests must have procedures in place for securing patient consent, testing samples, and informing patients of test results. Florida's Omnibus AIDS Act requires, with few exceptions, health care providers ordering HIV tests to (A) obtain the "informed consent" of the test subject, (B) confirm positive preliminary test results through corroborating tests before informing the test subject of the result, and (C) take "all reasonable efforts" to notify the test subject about the test results. Performing HIV testing also requires providers to consider procedures addressing other aspects of HIV law described in the subsequent sections of this booklet. These include the special handling of "superconfidential" HIV test results within their medical records (Section III.), obligations to notify parties other than the patient (Section IV.), and mandatory reporting of positive HIV test results to public health authorities (Section V.).

A. INFORMED CONSENT

In Florida, an HIV test subject must essentially understand (be "informed" about) and then explicitly agree ("consent") to the test. No Florida law authorizes providers to perform an HIV test based on a "general consent"

from a patient to draw blood and run unspecified tests on the sample. Except in the limited situations described below in subsection 4, "Exceptions to Informed Consent Requirements," a patient's informed and specific consent to the HIV test must first be obtained. §§381.004(3)(a) and (h), *F.S.*

These informed consent requirements for performing a test for HIV infection are similar to those for performing an invasive diagnostic procedure, such as for a tissue biopsy or spinal fluid collection. Unlike these procedures, an HIV test poses virtually no health risk to the patient. It can, however, cause potentially devastating emotional, social, and economic consequences to the test subject. Since these risks are almost all non-medical, the Act's informed consent requirements empower the test subject, not the health care provider, to control whether, when, and where an HIV test may occur.

1. Information Requirements

Satisfying the legal standard of "informed consent" in general depends on whether the information provided to the patient meets accepted standards of medical practice and whether a reasonable patient would have a sufficient understanding of the procedure to make an intelligent decision from the information provided.

Since the 1998 amendments to the Act, health care providers **must**, as a matter of law, convey three pieces of information, all essentially involving the choice of a testing site, as part of the process of obtaining informed consent:

- Disclose that the provider is required by law to report the test subject's name to the local county health department if the HIV test results are positive;

- Alert the patient that as an alternative, the patient may secure the HIV test at a site that tests anonymously, the locations of which the provider must make available; and
- Relate the extent of the confidentiality rights that adhere to the test results in the provider's patient records.

§381.004(3)(a), *F.S.* What other information is sufficient to obtain "informed" consent is a factual question. The provider must consider the age, mental capacity, and language skills of the test subject when explaining the test.

The Act originally specified the following minimum information that had to be explained to the test subject before the test was administered:

- The nature of the test itself.
- Its purposes (why the test is being performed).
- Its potential uses (such as for assisting in diagnosis or treatment).
- The limitations and meaning of the test results (the reliability of the results and what positive or negative results do and do not mean)
- The voluntary nature of the test.
- The right to withdraw consent to the testing process prior to the performance of the test.
- The confidentiality requirements that will attach to information identifying the test subject and the test results.
- Any other special procedures to be followed (for example, if the test actually will be performed at a later date).

Department of Health Rule 64D-2.004, *F.A.C.* now states that an explanation of the following information constitutes sound and reasonable

practice in providing information sufficient to secure informed consent from an HIV test subject:

- An HIV test is a test to determine if an individual is infected with the virus that causes AIDS.
- The potential uses and limitations of the test.
- The procedures to be followed.
- HIV testing is voluntary and consent to be tested can be withdrawn at any time prior to testing.

In accordance with CDC recommendations in 2006, the Department of Health continues to explore ways to “streamline” these and other HIV testing requirements to increase HIV testing and to remove barriers to obtaining patient consent for such tests.

As with other informed consent legal requirements, health care providers should consult with their risk managers or attorneys in developing their procedures and forms to meet their particular situations.

2. Minors

Minors in Florida (unemancipated children under 18) are adults for the purposes of consenting to examination and treatment of sexually transmissible diseases, including HIV testing and treatment. §384.30, *F.S.*, and Rule 64D-2.004(5), *F.A.C.* The general rule that parental consent is required prior to medical diagnosis or treatment of a minor does **not** apply when sexually transmitted diseases such as HIV infection are involved. Indeed, Florida specifically forbids telling parents the fact of the minor's consultation, examination, or treatment for a sexually transmissible disease, such as HIV infection, either directly or indirectly

(such as by billing a parent or their insurer for an HIV test without the child's permission). Infants and young children are treated as unable to make an informed decision and consent of their parents or legal guardian is required. For older children (such as teenagers), however, the provider must make an individual judgment whether the child, as phrased in Department of Health rules, "demonstrates sufficient knowledge and maturity to make an informed judgment," meaning, whether the child has the cognitive and emotional capacity to understand the risks and benefits of the test or treatment to which the child is being asked to consent.

3. Documenting Informed Consent

As with other medical procedures requiring informed consent, informed consent for HIV testing does not necessarily mean **written** consent. Except for donations of blood and other tissues and to obtain health or life insurance, Florida does not require providers to have the test subject sign a document authorizing the test. The health care provider need only enter a note in the medical record that the test was explained and consent was obtained.

Providers are well advised, however, to create an HIV test consent form for test subjects to sign because providers acquire important practical advantages when they obtain written consent. For example, for doctors and certain other health care practitioners, a signed consent form shifts the burden of proof to the test subject to prove that the information provided was insufficient. §766.103, *F.S.* For hospitals, signed consent can exempt them from most "superconfidentiality" obligations, as discussed below in Section III. B. 5.

4. Exceptions to Informed Consent Requirements

The statute lists the very limited and specific circumstances in which an HIV test may be performed without the test subject's informed consent.

PREGNANCY: The most notable exception to Florida's legal requirement of informed consent for HIV testing concerns pregnancy. This different consent process for pregnant women was spurred by dramatic medical advances reducing the chances of transmission of HIV infection at birth to nearly zero. Following federal legislation and recommendations from CDC, Florida law in 1996 first imposed "mandatory offering" of HIV tests for all pregnancies upon presentation. In 2005, the statute was further amended to establish the present system of "opt out" testing, in which pregnant women are advised that the health care provider attending them will conduct an HIV test but that they have the right to refuse. The pregnant woman's objection is required in writing, which must be placed in her medical record. §384.31, *F.S.*

The Department has two administrative rules that address the testing of pregnant women. The most recent, Rule 64D-3.042, *F.A.C.*, outlines sexually transmitted disease testing related to pregnancy, including testing for HIV. According to Rule 64D-3.042, *F.A.C.*, prior to testing, practitioners must notify the woman of the tests that will be conducted and of her right to refuse any and all tests.

Rule 64D-2.004(6), *F.A.C.*, addresses HIV testing in general and includes a provision on the testing of pregnant women. This rule, which imposes outdated HIV testing obligations on professionals attending pregnant women, is being amended by the Department to make this rule consistent with the law and Rule 64D-3.042, *F.A.C.*

These rules require repeat testing procedures at 28-32 weeks of gestation for all sexually transmissible diseases, including HIV. Finally, because the law expressly mandates that the HIV testing be done through only a "laboratory," so called "HIV rapid testing" (discussed below in Section II. B.) of pregnant women may be performed at a clinic or doctor's office not licensed to perform laboratory tests only after obtaining a waiver under the Clinical Laboratory Improvement Amendments (CLIA) and a corresponding Florida Certificate of Exemption from the Agency for Health Care Administration.

OTHER PERMITTED EXCEPTIONS: Various Florida laws exempt the following areas from informed consent requirements.

- Emergencies: A provider may test without consent in "bona fide medical emergencies," but only if the provider documents in the medical record that the test results are medically necessary to provide appropriate emergency care or treatment to the test subject and the test subject is unable to consent. §381.004(3)(h)3, *F.S.*
- Therapeutic Privilege: The Act allows a "therapeutic privilege" that bypasses informed consent requirements when the provider's medical record documents that obtaining informed consent would be detrimental to the health of a patient suffering from an acute illness and that the test results are necessary for medical diagnostic purposes to provide appropriate care or treatment to the patient. This same privilege applies to all medical procedures for which informed consent is required. The statute emphasizes that this provision provides no basis for routinely testing patients for HIV without their informed consent. §381.004(3)(h)4, *F.S.*

- Sexually Transmissible Diseases: State laws permit HIV testing for sexually transmissible diseases on certain subjects, such as convicted prostitutes (§796.08, *F.S.*), inmates prior to release (§945.355, *F.S.*), and cadavers over which a medical examiner has asserted authority §381.004(3)(h)1.c., without the consent of the test subject. This exception includes exempting pregnancy “opt out” testing from informed consent requirements discussed above.
- Criminal Acts: Victims of criminal offenses that involve transmission of body fluids may require the person charged with or convicted of the offenses to be tested for HIV infection by requesting a court to order the test, §960.003(2), *F.S.* Similarly, when a defendant, prosecuted for certain offenses in which transmission might have occurred, has been ordered to or has voluntarily given a blood sample, the victim may request the sample be tested for evidence of HIV without the consent of the defendant. §381.004(3)(h)6, *F.S.*
- Organ and Tissue Donations: Various statutory provisions permit testing without informed consent in specifically identified specialty areas: certain blood and tissue donations; corneal removals and eye enucleation that Florida allows by law to be done without consent; autopsies to which consent to perform the autopsy was obtained. §§381.004(3)(h)2, 5, and 9, *F.S.*
- Research: Established epidemiologic research methods that ensure test subject anonymity are exempted from informed consent requirements. §381.004(3)(h)8, *F.S.*

- Abandoned infants: When a licensed physician determines that it is medically indicated that a hospitalized infant have an HIV test, but the infant's parent(s) or legal guardian cannot be located after reasonable attempts, the test may be performed without consent. The reason why consent could not be obtained must be documented in the medical record, and the test result must be provided to the parent(s) or guardian once they are located. §381.004(3)(h)13, *F.S.*
- Significant Exposures: Under the limited circumstances discussed in Section VI. of this booklet, the blood of the source of a significant exposure to medical personnel or to others who render emergency medical assistance may be tested without informed consent. §381.004(3)(h)10-12, *F.S.*
- Repeat HIV testing: Renewed consents are not required for repeat HIV testing either to monitor the clinical progress of a previously diagnosed HIV-positive patient or for conversion from a significant exposure. §§381.004(3)(h)14 and 15, *F.S.*
- Judicial Authority: Finally, a court may order that an HIV test be performed without the individual's consent. §381.004(3)(h)7, *F.S.*

5. Consequences of Testing Without Informed Consent

Testing without informed consent subjects licensed health care providers to discipline by their licensing bodies, such as fines and license suspension or revocation. §381.004(6)(a), *F.S.* In addition, the provider may be sued civilly by the test subject in tort, such as for negligence, battery, and

invasion of privacy, for failing to secure informed consent in accordance with the law.

A separate statute designed to eliminate "unnecessary diagnostic testing" in general may make an HIV test illegal in some situations even when informed consent is obtained. This law prohibits diagnostic tests "which are not reasonably calculated to assist the health care provider in arriving at a diagnosis and treatment of a patient's condition." §766.111, *F.S.* Testing for general disease prevention purposes, which is the function of primary care physicians and health care clinics, should always be considered necessary. However, HIV testing in many elective surgical settings (most notably plastic surgery) risks violating this statute. In most of these settings, testing patients for evidence of HIV infection appears to be solely for the purpose of protecting health care workers from the risk of infection and therefore "unnecessary," absent special circumstances in which universal precautions would be ineffective. The statute authorizes a civil suit against the provider in which damages and attorney fees may be recovered.

Another provision in the Act outlaws, including criminal prosecution, forcing someone to consent to a test as a prerequisite for obtaining health care. It prohibits licensed health care professionals and facilities from requiring any person to take an HIV test as a condition of admission to the facility or to obtain any service covered by the provider's license, unless the appropriateness of the proposed treatment can only be determined by an HIV test. §381.004(11), *F.S.* Routinely testing for HIV infection in purely elective surgery, therefore, when the presence of HIV infection poses no differential outcome to the surgery, is subject to being found not only "unnecessary" and a civil violation, but also a criminal act under this statute.

B. PRELIMINARY AND CONFIRMATORY TESTS

The general rule governing release of HIV test results to test subjects or their legal representatives is that no HIV test result may be released unless a "preliminary" HIV test has been corroborated by a "confirmatory" test. §381.004(3)(d), *F.S.* The exceptions to this general rule are set forth below.

A "preliminary" HIV test is any test that "screens" for HIV antibodies, meaning the test has a high sensitivity to the presence of HIV antibodies but often only a moderate specificity as to whether in fact it is detecting only HIV antibodies. Because preliminary tests necessarily over-predict positive test results, a negative preliminary test result is considered definitive and no further testing is required. If such relatively inexpensive tests are positive, however, the general rule is that they must be followed by a more expensive but more accurate "confirmatory" test before the results may be released.

Preliminary HIV antibody testing usually is done in a lab, such as through an Enzyme Linked Immunosorbent Assay (ELISA or EIA) test. More recently, "rapid" HIV tests (discussed more below) have been developed, some of which yield results in 20 minutes or less. Such tests can be administered on site in accordance with U.S. Food and Drug Administration (FDA) approved guidelines. In any event, the Act requires a separate confirmatory test, commonly a "Western blot," be performed before the test result can be disclosed to the test subject except in the limited situations listed below, unless an exception applies.

The Act only allows preliminary results to be disclosed prior to receipt of confirmatory results in three situations:

- To medical and non-medical personnel when they incur a significant exposure. (These rules are discussed at some length in Section VI. of this booklet).
- To health care providers and test subjects "when decisions about medical care or treatment of, or recommendations to, the person tested cannot await the results of confirmatory testing." The Act expressly particularizes this language for pregnant women: preliminary test results may be disclosed when care, treatment, or recommendations regarding the mother or newborn cannot await confirmatory testing. Thus, for emergency deliveries of women without a history of prenatal care, the benefits to the newborn of aggressive drug treatments based on a positive antibody test can outweigh the risk that a confirmatory test may come back negative; the mother cannot intelligently make such a decision, however, without a preliminary positive HIV test result. Similarly, someone exhibiting clinical symptoms of AIDS should not have to await HIV confirmatory test results before initiating drug regimens. The exception specifies that disclosure in these circumstances may not be characterized as a diagnosis of HIV infection and the health care provider who ordered the test must document in the medical record the justification for disclosing the preliminary test result.
- Pursuant to "rapid" HIV testing results released in accordance with the manufacturer's instructions as approved by the FDA. Starting in 2002, the FDA approved several on-site HIV tests that could generate results in 20 minutes or less. Each manufacturer provides guidelines regarding not only quality assurance programs for its users (such as storage requirements, testing area temperature, test kit shelf-life, specimen collection, test performance, and results interpretation), but

also regarding whether and in what manner to advise a test subject of the rapid test results in the same session in which the rapid test is conducted.

This last exception for rapid testing highlights how well established legal requirements of the Act must confront issues arising from advances in medical technology, in this case, HIV testing technology. Until near the end of the millennium, preliminary test results (ELISA) often took days before results came back to providers, and it would frequently take almost another week for a provider to receive a confirmatory test result. Many providers, therefore, chose not to disclose any HIV test results until the time a confirmed positive result could be returned from the laboratory, thereby avoiding a procedure that effectively is a disclosure: the early report of test results means a negative result while later disclosure means positive results. With rapid HIV testing, however, test subjects often can know the test results in the same session in which the testing occurs. Although rapid HIV tests now approach 100% accuracy, errors can and do occur. Accordingly, counseling protocols in these situations need to be thought through carefully. The Florida Department of Health has not promulgated any rules regarding disclosure of positive preliminary test results from rapid testing kits; providers need follow only the recommendations of the manufacturers of the kits.

C. NOTIFICATION RESPONSIBILITIES

Starting in 1998, the Act eliminated the general requirement that all HIV tests be preceded by a mini-course on "measures for the prevention of, exposure to, and transmission of HIV infection," known as "pre-test" counseling. The 1998 amendments also eliminated providers' duties to disclose HIV test results to test subjects only in face-to-face meetings, called "post-test" counseling. §381.004(3)(c), *F.S.* The Act, however, retains these

requirements for local county health departments and registered HIV testing sites; they must continue providing the opportunity for pre- and post-test counseling as before. §§381.004(4) and (5), *F.S.*

Instead of conducting mandatory pre- and post-test counseling, persons ordering an HIV test must now "ensure that **all reasonable efforts** are made to notify the test subject of his or her test result" and then relate certain information to test subjects for both negative and positive test results. §381.004(3)(c), *F.S.* While under an unambiguous duty to notify test subjects of test results and provide HIV-positive patients with certain specified information, providers are left to their own judgments on the manner to discharge these responsibilities, much the same as they are in notifying their other patients of contagious diseases or serious illnesses. Consequently, providers must wrestle with three distinct notification compliance issues.

1. Confirming the Test Subject's Identity

Providers must determine a method for confirming the identity of the patient who will be told the HIV test result. This process is the most problematic aspect of existing notification duties because, as discussed in the next section, the fact of an HIV test, regardless of whether it is negative or positive, is "superconfidential."

Before the 1998 amendments, the post-test counseling requirements imposed a safe, albeit often burdensome, notification process. The provider, during pre-test counseling, scheduled an individual, private, face-to-face meeting (the post-test counseling session) at a time when confirmed positive test results would be available. This method ensured patient confidentiality (and additional test subject education) but also

possible patient inconvenience and expense for a return visit just to learn of a negative HIV test result.

Under existing law, providers may determine on their own how to notify their patients of their HIV test results, while still conforming to the Act's strict confidentiality requirements. For example, a provider could use a telephone call-in system in which each patient is given a unique code number that the patient must know as a condition for telephonic disclosure of the test results.

2. Post-Test Counseling Information

For patients with HIV negative test results, the amendment does not specify information that must be conveyed beyond stating that "notification shall include, as appropriate, information on preventing the transmission of HIV." Information that is "appropriate" for high-risk test subjects may not be for low-risk test subjects. Many providers may elect simply to convey this information as part of the informed consent process or simply continue pre-test counseling as before, even if no longer required by law.

For patients with HIV positive test results, the Act is more specific. The counseling must include information on the (a) availability of appropriate medical and support services, (b) the importance of notifying partners who may have been exposed, and (c) prevention of the transmission of HIV. These requirements existed in much the same language in the law prior to the 1998 amendments. This information is best conveyed in person by individuals knowledgeable about local HIV health and social services and trained to convey this information sensitively and completely.

3. "All Reasonable Efforts"

Providers are required to undertake "all reasonable efforts" to inform a test subject of their HIV test result through the provider's notification process. What constitutes "all reasonable efforts" for one provider with certain kinds and numbers of HIV test subjects may not be reasonable for a different provider with a different population. The amendment leaves some discretion to health care providers, based on the belief that one legislated method will not be appropriate in all settings.

For HIV-negative patients, the requirement could be satisfied if the patient has an opportunity to get the information but fails to exercise it, such as missing a scheduled return visit, or not calling in a coded number for learning test results. Because the patient had an opportunity to find out the test result and it is hard to conceive of any harmful consequences that can result from a negative HIV test result, the "all reasonable efforts" standard should be satisfied.

For HIV-positive test subjects, the legislation provides only one hard answer as to what constitutes "all reasonable efforts." For detention facilities (such as jails), mental health facilities, and hospital emergency departments, which are places from which a test subject is "released," if the test subject is released before being notified of the HIV positive test result, the provider need only inform the local county health department, which then assumes responsibility for fulfilling patient notification obligations. In all other settings, providers must do at least as much as they would for other patients who need to learn their diagnosis (anything less would be clearly unreasonable). The use of the word "all" implies that providers should exhaust every available but reasonable means of

contacting the individual without, of course, disclosing to anyone why there is a search for the patient.

After such efforts have been exhausted, the duty to notify HIV-positive patients can be passed to the local county health department through HIV infection reporting requirements (discussed in Section V. below). The Department will take steps to determine the need for follow-up once informed of the HIV-positive patient.

4. Model Protocols for Counseling and Testing

The Department of Health is obligated to provide guidance to health care providers on these notification compliance questions — the answers to which can vary from setting to setting, and sometimes among test subjects — through "protocols" on counseling and testing, which include criteria for evaluating a patient's risk of HIV infection and encouraging HIV testing on a voluntary basis. §381.004(8), *F.S.* The Department has developed several model protocols. One protocol addresses county health departments and registered testing programs that conduct or hold themselves out as conducting HIV testing in which testing is not incidental to medical diagnosis and treatment. A second suggests approaches for HIV testing by all other providers. Copies of the Model Protocols may be obtained from the Department of Health, Bureau of HIV/AIDS or through the website at www.floridaaids.org.

III. CONFIDENTIALITY

While all patient records are confidential under Florida and federal laws, Florida's Omnibus AIDS Act makes HIV test results "superconfidential" — health care providers who know a test subject's HIV test result have additional obligations to

the test subject to protect against further disclosure of records with such information.

A. "HIV TEST RESULTS"

Superconfidentiality does not attach to every piece of medical information pertaining to a person who has been tested for HIV or assessed for AIDS. Only the fact that an HIV test was performed on an identifiable individual and any "HIV test result" (negative as well as positive) are specially protected. §381.004(3)(e), *F.S.*

The statute defines "HIV test" and "HIV test result" narrowly. §381.004(2)(a) and (b), *F.S.* Only a laboratory report of an HIV test result entered in a medical record on or after July 6, 1988 (the effective date of the Omnibus AIDS Act), or any report or notation in a medical record of a laboratory report of an HIV test, falls within their scope. Explicitly excluded from the definition of an HIV test result are reports from patients of their HIV status to health care providers. Consequently, patient reports of their HIV test status from Department of Health anonymous testing sites, from home access HIV test kits, or from any other sources do not constitute "HIV test results" unless separately confirmed by the provider through a laboratory report or a medical record containing a laboratory report. Patient disclosures of an HIV test or infection to persons other than health care providers caring for the patient under the provisions of the Act also do not fall within the statute's special confidentiality protections.

Clinical observations of conditions typically associated with AIDS also are not superconfidential because they are not "HIV test results" — that is, they are not laboratory reports or medical record notes of such laboratory reports of an HIV test. Consequently, a medical chart with symptoms of AIDS and the

word AIDS appearing throughout it, but containing no HIV test result, is simply another medical record. A chart that says on one line, "Lab reports negative HIV test," however, is superconfidential. This superficially irrational outcome is explained by the policy goal of the statute to encourage voluntary testing. The Legislature apparently concluded that special protections are necessary to create the conditions under which people will agree to be tested for evidence of HIV but that these protections are not needed to give people incentives to seek treatment of symptoms.

B. SPECIAL HANDLING REQUIREMENTS

Although some other patient records also have special safeguards (for example, psychiatric and substance abuse records), the four following special handling requirements as a group are unique to HIV test results.

1. Legally Effective Releases

The Act allows providers to disclose HIV test results based on a test subject's "legally effective release." Two kinds of releases are legally effective. §381.004(3)(e)2, *F.S.*

One is a "specific release" where the test subject, in writing, specifically authorizes the release of his or her HIV test results. Signed by the test subject, this release explicitly gives the provider permission to send the HIV test results to a third party payer or a named person, such as a doctor or a hospital.

The other legally effective release involves "prior written authorization" to honor a "general release." A general release is a document directing disclosure to someone of an entire medical record or simply all of the

patient's records (including medical as well as payment and financial information). Under the Act, a general release will support disclosure of records containing an HIV test result only if the general release is preceded by the test subject's prior written permission allowing the provider to release the HIV test result with the rest of the record. A general release for a health care provider's records containing an HIV test result is not legally effective absent such prior written authorization.

A provider who receives a general release for a medical record containing protected HIV information without first having obtained the necessary prior written authorization confronts a "Catch 22" problem. To honor the general release violates the statute. But to decline to honor it and so advise the requestor may violate the statute by in effect disclosing that an HIV test result is in the record. Unless the provider's records include the very few other kinds of specially protected medical records, such as psychiatric or substance abuse care, no other basis usually exists than the Act for not complying with a properly executed general release. In addition, without a legally effective release the provider cannot bill a third party payer for the test or permit the third party payer to review the medical record to document other charges if that review would disclose the HIV test result.

To avoid these problems, providers can obtain, at the time the test is ordered, signed permission — "prior written authorization" — to honor any subsequently issued general release and to allow disclosure to any third party payer. Alternatively, the provider can refuse to honor any release unless the requestor uses the provider's own standard release form, which would require the patient's signature, and would specifically authorize disclosure of any HIV test result that may appear in the file.

Segregating HIV test results from the rest of the medical record is usually inadvisable because test results commonly are medically significant and must be readily accessible to the provider looking at the medical chart. Moreover, it is virtually impossible for the vast majority of providers to segregate successfully HIV test results in a medical file. More often than not, different parts of a medical record will refer to the HIV test results, and deletion of a part of any medical record is almost never appropriate.

In addition, absent a special procedure to flag files in which someone has entered protected HIV test information (assuming the flags themselves do not raise confidentiality concerns) patient records custodians will have to review each and every page of a requested record before responding to a general release to avoid inadvertently disclosing an HIV test result. A prior written authorization as discussed above eliminates this problem as well.

2. Court Orders

Most medical information may be released based upon a subpoena, which essentially is a document issued by a lawyer in the course of litigation directing the subpoenaed party to appear for questioning and/or produce some documents. Absent an exception to superconfidentiality requirements or a specifically allowed disclosure, discussed below, the Act prohibits releasing, in response to a subpoena, a medical record with an HIV test result in it. A court order — a document signed by a judge usually after a hearing — is required. §381.004(3)(e)9, *F.S.*

Like general releases, subpoenas also pose a "Catch 22" for providers who do not routinely have in their files other superconfidential information, such as psychiatric consults. To comply is illegal, but to refuse to comply

may effectively disclose the existence of protected HIV test information, also violating the Act. The best response to this dilemma is usually to contact the patient, if available, and ask for instructions (the party issuing the subpoena in most cases is required to notify the patient of the subpoena). Other less satisfactory responses include going to court to "quash" the subpoena and asking for instructions; and notifying the party that issued the subpoena that based on statutory requirements of confidentiality, a court order is required for release of the record. Judicious providers with HIV test results in their files establish a workable protocol through their counsel. Lacking such a protocol, a provider should do what the Department of Health advises its county health departments: contact legal counsel.

3. Warning Statements

Whenever protected HIV test information is disclosed, it must be accompanied by a statement warning of the existence of superconfidentiality requirements: "This information has been disclosed to you from records whose confidentiality is protected by state law. State law prohibits you from making any further disclosure of such information without the specific written consent of the person to whom such information pertains, or as otherwise permitted by state law. A general authorization for the release of medical or other information is not sufficient for this purpose." §381.004(3)(f), *F.S.* Oral disclosure must be accompanied by oral notice of this warning followed by written notice within ten days. Care must be taken that this warning statement, or any other flag placed on the exterior of a patient record, does not inadvertently act as a signal to persons simply seeing the file that it contains superconfidential HIV test information.

This oral and written notice requirement does not apply to disclosures, discussed further below, among employees and agents of a health care facility or provider with a "need to know" or among health care providers and facilities involved in the care or treatment of a test subject. Rule 64D-2.003(4), *F.A.C.*

4. "Need-to-Know" Limitations

The fact that a health care provider or facility is authorized to know a patient's HIV test result does not mean that all their employees and agents have the right to know this information. The Act limits access to HIV test results to those employees and agents who either provide care to the test subject, such as doctors, nurses, and social workers; conduct administrative tasks supportive of the patient's care, such as secretaries, billing clerks, and administrators; or handle body fluids or tissues of a test subject; and have a "need-to-know" the patient's HIV test status. §381.004(3)(e)3, *F.S.*

The Department of Health has defined the circumstances in which these employees or agents have a statutory need-to-know. Rule 64D-2.003(2)(d), *F.A.C.* In essence, if the employee or agent in order to perform properly his or her normal tasks (providing care, performing business operations, or participating in approved educational or research programs) would have access to the patient's medical background, a need-to-know exists, and knowledge of the patient's HIV test status is permitted.

The need-to-know restrictions have additional implications for in-house record keeping. They authorize computerization of HIV test results provided it is achieved "in accordance with sound practices of record-

keeping." In addition, the Department recommends that records not be marked, coded, or otherwise externally distinguished to allow identification of whether an HIV test was performed. Finally, it requires a "uniform procedure" for maintaining confidential records so that only persons authorized to review or receive HIV test results may do so. Rule 64D-2.003(3), *F.A.C.*

This "need to know" requirement for "HIV test results" resembles the "minimum necessary" standard adopted in rules passed in late 2000, known as the "Privacy Rule," under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA protects the privacy of all "protected health information" (PHI), which essentially is everything with information bearing on the diagnosis or treatment of a patient or payments for medical care. 45 CFR 164.502(b). This federal standard requires health care providers to implement reasonable "minimum necessary" policies and procedures to limit when and how much PHI is shared, such as restricting staff access to PHI based on job duties. Under HIPAA, more protective state laws, such as Florida's HIV superconfidentiality requirements, apply when the federal HIPAA protections are less stringent.

After 1990, the legislature significantly expanded and thereafter refined the rights of medical personnel and others to learn a patient's HIV test status when a "significant exposure" to the patient's body fluids or tissue occurs. Section VI. of this booklet examines this issue separately.

5. Exception for Hospitals

In 1989, the Legislature excused hospitals from the first three superconfidentiality requirements discussed above (the legally effective

release, court order, and warning statement), but only when the hospital obtains in writing the test subject's informed consent to the HIV test and to its results being placed in the hospital's records. In order to qualify for the exemption, the hospital must explain to the patient during its informed consent procedure the more limited rights to confidential treatment of the HIV test results that attach to hospital records. §381.004(3)(g), *F.S.*

Consequently, patients who agree in writing to an HIV test in a hospital after being properly informed have only the "need to know" superconfidentiality protection. The hospital can treat the patient's medical record containing an HIV test result just as it would any other hospital medical record, except for "need to know" disclosures among its staff and employees (which closely resembles HIPAA privacy requirements for all medical records in any event).

C. PERMITTED DISCLOSURES

The Omnibus AIDS Act and its rules list the situations in which HIV test results may be disclosed. §381.004(3)(e), *F.S.*, and Rule 64D-2.003, *F.A.C.* Any disclosure that does not fall within one of the following permitted situations is prohibited.

1. The test subject of course may be told. If the test subject is incapacitated, deceased, or an unemancipated minor too young to understand the procedure, the person authorized by law to make medical decisions for the test subject may be told. A variety of statutes spell out when someone can or may be a test subject's legal representative, such as legal guardians, persons with medical power of attorney, and health care surrogates and proxies.

2. As discussed above, employees and agents of health care providers and facilities may disclose to one another a patient's HIV test status if they have a "need to know."
3. Health care providers involved in the care or treatment of a test subject and consulting among themselves or with health care facilities to determine diagnosis or treatment of the test subject may divulge superconfidential HIV test information without the patient's knowledge or consent. This provision allows health care providers, such as doctors, osteopaths, and dentists, to share this information with other providers, even if not within the same facility, whenever deciding upon a diagnosis or course of treatment. It does not authorize, however, release for the purposes other than diagnosis and treatments (such as for notifying other providers to take unusual exposure precautions) and does not supersede compliance with requirements to obtain patient permission before transferring the patient's medical records from one consulting provider to another.
4. A health care provider involved in the delivery of a child may note the mother's HIV test status in the medical record of the newborn.
5. A number of specific situations in which disclosure without consent of the test subject is permitted are listed in various statutes:
 - a. the Department of Health in order to comply with laws and rules governing reporting and controlling the spread of HIV infection.
 - b. to appropriate authorities in the course of reporting child sexual abuse or neglect.

- c. by certain licensed providers notifying their patient's sex or needle-sharing partner of their exposure pursuant to the Department of Health's "Partner Notification Protocol for Practitioners," discussed further in Section IV. B. below.
 - d. among health care facilities and providers engaged in certain kinds of transfers of human body parts and tissues.
 - e. health facility staff committees who engage in activities such as peer review and health program monitoring and evaluation and service reviews.
 - f. authorized medical and epidemiologic researchers.
6. Separate statutes govern release of HIV test information within correctional facilities, for convicted prostitutes, and for disclosing test results to the victim of a criminal offense, involving the transmission of body fluids of persons charged with or convicted of certain offenses in which transmission might have occurred.
7. When a child is placed in foster care or for adoption, the adults responsible for the child (including governmental personnel overseeing the child's care) may be told the child's HIV test status provided they are directly involved in the placement, care, control, or custody of the child. In addition, if a child's parent or legal guardian cannot be found after a reasonable attempt to locate them, the adult relative, custodian, or person responsible for the child may be told his or her HIV test result. Of course, this does not apply to minors who are tested under §384.30, *F.S.*

8. Employees of residential facilities or community based care programs for developmentally disabled persons (under Chapter 393, *F.S.*) who are directly involved "in the care, control, or custody of the test subject, and who have a need to know such information," may have access to the test subject's HIV test status.
9. Health care providers may disclose to public health authorities without the test subject's consent that a patient is HIV positive in only very limited circumstances:
 - a. when the government is acting as a guardian for foster and adoptive children;
 - b. when reporting to the Department of Health HIV/AIDS cases as required by law; or
 - c. for notification if the person has been released from an emergency department, detention facility, or the like.
10. A court may order the release of HIV test results when certain procedural safeguards are followed. The Act requires the court to weigh any asserted need for disclosure against the privacy interests of the test subject and the public interests of promoting voluntary testing and protecting those who are tested from discrimination. A special exception for Workers' Compensation administrative law judges authorizes them to disclose HIV test results but only upon a finding that the person seeking the test results has demonstrated a "compelling need" that cannot be accommodated by some other means.

11. Medical examiners, who can test without informed consent, must report positive HIV test results to the Department of Health.
12. Finally, as explained in the next part (Section IV.) of this booklet, another provision allows certain providers in tightly defined circumstances to tell the sexual and needle-sharing partners of HIV-positive patients that they have been exposed to HIV.

D. CONSEQUENCES OF BREACHING CONFIDENTIALITY

Release of HIV test results other than in accordance with the situations the Act specifically permits can have serious repercussions. The health care professional, who violates any of the Act's requirements, including its informed consent or confidentiality provisions, is subject to disciplinary action by the provider's licensing body. It is a first-degree misdemeanor (subject to up to one year of imprisonment) for anyone, whether a licensed provider or not, to violate the Act's confidentiality requirements; the language does not require the violation to be intentional. §381.004(6)(b), *F.S.* Finally, a 1998 amendment makes it a third degree felony (which carries punishment of up to five years imprisonment) for any person maliciously or for monetary gain to disseminate information identifying an individual with a sexually transmissible disease, including HIV infection, other than to a physician or nurse employed by the Department of Health or a law enforcement agency, if the person knew or should have known "the nature of the information." §§381.004(6)(c) and 384.34(6), *F.S.* In addition, the Florida Supreme Court recently held that anyone may be sued for negligence and other causes of action based on violation of the Act's duty of confidentiality. *Department of Corrections v. Abril*, 969 So. 2d 201 (Fla. 2007).

IV. NOTIFICATION OF THIRD PARTIES

Difficult ethical and moral issues for health care providers arise when they learn that an HIV-infected patient is not informing past or present sexual or needle-sharing partners of exposure to HIV. What obligation does the practitioner have to these third parties when the patient refuses to disclose or give the provider or public health authorities permission to disclose the exposure? When should the practitioner's duty to maintain the patient's right to confidential medical treatment be overridden by risk of harm to known third parties?

A. NO DUTY TO WARN

While reporting to public health authorities of the fact an HIV positive test result is required by law, as discussed in Section V., Public Health Measures, the Act expressly eliminates any legal obligation that may have existed for providers to tell others of the danger posed by the behavior of an infected patient. The Act fully protects from civil or criminal liability health care practitioners regulated by the Division of Medical Quality Assurance of the Department of Health who choose to abide by a patient's wishes not to disclose to known sexual or needle-sharing partners information about their exposure. §456.061(2), *F.S.* These practitioners include doctors, nurses, social workers, mental health counselors, psychologists, dentists, and others. This exemption makes sense in light of the criminalization of breaches of superconfidentiality requirements: if it is a crime for these providers to violate a patient's right to confidential HIV testing, then providers who remain silent and comply with the Act's unambiguous policy favoring patient confidentiality should be free from obligations to third parties placed at risk by the patient.

B. VOLUNTARY PARTNER NOTIFICATION

The person ordering the HIV test (or that person's designee), although under no liability exposure to the sexual or needle-sharing partners of their HIV-positive patients, is required to advise their patients with HIV positive test results of the importance of notifying partners who may have been exposed. §381.004(3)(c), *F.S.* Practitioners are well advised also to tell the patient of the availability of voluntary partner notification services provided by the Department of Health.

Personal knowledge of HIV infection status is a cornerstone of HIV prevention and treatment. Effective control of the HIV/AIDS epidemic requires that persons exposed to HIV infection are notified of the exposure so they may learn their own infection status and make appropriate behavior changes. Under the authority provided in §384.26, *F.S.*, county health department staffs offer voluntary and confidential partner notification and referral services to persons infected with HIV. When notifying partners, county health department staffs are required not to reveal the identity of the original client. Notifying the partners of a person who is HIV infected provides substantial public health benefits. Partner notification makes persons aware of their exposure to HIV and provides them with referrals to testing, treatment, and other services. Notification services also benefit the community by leading to earlier identification and treatment of previously undiagnosed cases of HIV. Research suggests that individuals who are infected with HIV and in care are less likely to transmit the disease to others.

Federal legislation, passed in 1996 as part of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act (which provides funding for urban areas and states and localities to support prevention, care, and treatment of HIV infection and AIDS), requires states to take administrative steps to

ensure that good faith efforts are made to notify the spouse of persons who are HIV positive. 42 U.S.C. §300ff-27a. A "spouse" is defined to include current and prior (within 10 years prior to HIV infection diagnosis) marriage partners. To comply with this requirement, the Department of Health has notified hospitals and doctors of the importance of notifying sexual partners, particularly spouses. In addition, the Department has instructed its health care providers to discuss the need to notify such partners and to advise them of the availability of the Department's voluntary partner notification program.

C. PRIVILEGE TO WARN

Although not required to warn third parties, many practitioners feel ethically obliged to do so. Under certain circumstances, practitioners may disregard superconfidentiality mandates (and the patient's instruction) and divulge the patient's HIV infection to a sexual or needle-sharing partner the patient has identified. This privilege exists only when the patient discloses the identity of the partner at risk (the provider cannot independently establish the third party is a "partner"). To be protected, the practitioner must act in good faith, conform to the ethics of his or her profession, and adhere to a detailed protocol ("Partner Notification Protocol for Practitioners") prescribed by the Department of Health. §456.061(1), *F.S.*, and Rule 64D-2.003(2)(1), *F.A.C.*

If this protocol is followed, the practitioner is immune from civil and criminal liability. The protocol, however, is not simple. Because failure to follow the protocol might result in loss of immunity, it should be implemented only after careful review, including advice from counsel. The procedures include the following:

- Identification of the third party must come from the patient.

- The practitioner must recommend the patient notify the partner, or use the Department's notification program, and to refrain from activity likely to transmit the virus.
- Upon the patient's refusal, the practitioner must advise the patient of the practitioner's intent to notify the partner.
- The preceding must be documented, but documentation in the patient's record may not include the name of the third party.
- The practitioner takes full responsibility for notifying the third party in accordance with the protocol. These procedures include protecting, to the extent possible, the patient's name and privately counseling the third party about HIV infection and the availability of voluntary HIV testing.

It is sound practice for practitioners, before undertaking the protocol, to recommend more than once that the test subject disclose the information personally to the partner or utilize the Department of Health's voluntary partner notification services. In addition, the reasons offered by the patient for not disclosing to the partner need to be recorded. Because of superconfidentiality requirements, it is advisable to keep detailed notes on adherence to the protocol in a separate record.

V. PUBLIC HEALTH MEASURES

Absent the systematic ability to gather information on an epidemic, governmental efforts to address public health challenges are necessarily limited to case-by-case responses. Initially, Florida like most other states required doctors to report to public health authorities only diagnosed cases of AIDS.

While the Omnibus AIDS Act required HIV test subjects be informed about the availability of health department partner notification services, the law made reporting HIV infection purely voluntary, prohibited the state from maintaining lists of HIV-positive persons, and contained few involuntary ways in which health authorities could lawfully learn of a person's HIV test status. HIV infection data was collected voluntarily and non-systematically. This approach, nearly universal at first throughout the United States, was based on the belief that mandatory reporting would drive HIV-infected persons “underground,” away from all sources of care, and thus worsening the spread of the disease.

A. HIV INFECTION REPORTING

In 1996, Florida became one of the first states with a high incidence of AIDS to authorize regulatory procedures requiring physicians and laboratories to report to local health authorities HIV positive test results with patient identifiers. §384.25, *F.S.* Practitioners and clinical laboratories that fail to report HIV positive test results are subject to a \$500 fine and disciplinary action by their licensing boards. §384.25(4), *F.S.*

This change was spurred in part by the Ryan White CARE Act. Enacted in 1990, this federal legislation now provides funding to urban areas, states, and localities to improve the availability of care for low-income, uninsured, and under-insured AIDS and HIV-infected patients and their families. Its funding has increased from \$220 million to current levels exceeding \$2.1 billion. Its funding mechanism depends on the numbers of persons with HIV infection and AIDS in the area receiving funds.

Florida’s HIV infection-reporting requirements increases available Ryan White funding for persons with the illness and enables the Department of Health to link them to medical and support services earlier in the process of infection.

In addition, HIV infection reporting as implemented by the Department seeks to increase the use of voluntary partner notification services and other preventive efforts aimed at reducing the likelihood of additional transmission. The demographic data from HIV infection reporting also provides useful insights into the "front end" of the epidemic and facilitates future planning.

Under rules promulgated by the Department of Health, practitioners must report to their local county health department within two weeks, the HIV positive diagnosis of all persons, except infants born to HIV-positive women, which must be reported the next day. Rule 64D-3.029, *F.A.C.* and Rule 64D-3.030(5), *F.A.C.* The information that must be reported is extensive. In settings in which several practitioners may be involved in HIV diagnosis (such as teaching hospitals and physician group practices), the Department of Health will accept a single report from one provider on behalf of the institution or group. Clinical laboratories must report to the local health department HIV test results from blood specimens within three working days of diagnosis. Rule 64D-3.031, *F.A.C.* These laboratory reports are relatively simple, essentially calling only for minimal identification information.

The Department of Health further expanded its HIV infection reporting requirements in 2006 to include CD4 and viral load reporting, which are tests routinely performed on persons diagnosed with HIV infection to assist with treatment decisions. Rule 64D-3.029, *F.A.C.* This change keeps Florida in compliance with CDC national surveillance guidelines issued in 1999 and enables further capturing of data showing the rates of HIV infection and AIDS in Florida.

These reporting requirements are critical first steps towards the ultimate goal of "mainstreaming" HIV infection — treating it like other sexually transmissible diseases. Nonetheless, confidentiality protections continue

based on current assessments of the environment surrounding personal decisions regarding HIV testing. When establishing mandatory HIV infection reporting, the Act simultaneously affirmed its commitment to anonymous HIV testing. §381.004(4), *F.S.* Because under anonymous testing, the identity of the test subject is not known, it cannot be reported to local health departments, and in any event is forbidden. §384.25(3)(b), *F.S.* Bolstering this commitment, the Act requires, as part of the informed consent process, that all test subjects be told of the availability and location of nearby anonymous testing locations. See Section II. A. 1., above. Hence, all test subjects have the option to be tested in a manner that avoids HIV infection reporting to public health officials.

B. INVOLUNTARY MEASURES

The ground rules for taking action against someone with HIV infection who endangers the public health are the same as those that apply to someone with a sexually transmissible disease. See §§384.26 to 384.288, *F.S.* In addition to its independent authority to investigate the source of sexually transmitted diseases, the Department of Health also has the power, with the permission of a court, to take an individual into custody, perform an HIV test without consent, hospitalize, and even isolate the person. The law requires the Department to meet increasingly higher burdens of proof as the restrictions on a person's freedom increase. It also gives non-consenting individuals a variety of important due process protections. It bears emphasizing that it is a criminal act for an HIV-infected person to have sexual intercourse with another absent such person knowing about the disease and consenting to the sexual intercourse. §384.24(2), *F.S.*

Involuntary measures in the context of significant exposures are discussed below in Section VI., "Significant Exposures."

C. TESTING SERVICES

The Department of Health maintains a statewide network of voluntary HIV testing programs that provide confidential and anonymous HIV testing. §381.004(4), *F.S.* The Act gives confidentiality protections to these HIV test results and establishes penalties for any breach of the Act. It is a crime to use HIV test results generated under the auspices of the Department of Health (which includes all confidential and anonymous testing sites run through local county health departments) to determine eligibility for disability, health and life insurance, or to discharge the person from employment.

The Act also regulates certain programs that conduct HIV testing, principally those that advertise they perform HIV tests. §381.004(5), *F.S.* These “registered” testing programs must sign up annually with the Department of Health and abide by specified criteria. Various licensed practitioners and laboratories who do not advertise their HIV testing program to the public can avoid these registration requirements.

VI. SIGNIFICANT EXPOSURES

All medical authorities recommend that health care workers use appropriate standard protections known as “universal precautions” — such as latex or polyurethane gloves, gowns, and/or masks — when exposure to the body fluids of a patient might reasonably be expected to occur. Nevertheless, accidental exposures can happen. The Act defines “significant exposure” in some detail, but it can be summarized as whenever skin or mucous membranes are exposed to the blood or body fluids of a patient or if the health care worker experiences a needle stick or sharps accident. §381.004(2)(c), *F.S.*

A. "NEED-TO-KNOW"

Health care workers (including persons working for health care professionals and within various health care facilities, as well as paramedics and emergency medical technicians) and non-medical personnel who experience a significant exposure during the course of medical practice or in the performance of professional duties, or are exposed while providing emergency medical assistance during a medical emergency, have the right to know the source patient's HIV test status. §381.004(3)(e)(14), *F.S.* This right of access extends to the source's medical records wherever they can be located.

Prior to granting access to an employee whose "need to know" arises only from the occurrence of a significant exposure, the records custodian (commonly in an employee health office) needs to document the factual basis for allowing this exception to superconfidentiality requirements. Accordingly, for employees, the custodian should obtain evidence of the likelihood that a significant exposure has occurred during the course of employment or within the scope of professional practice. For non-medical personnel, the records custodian should confirm the exposure was significant and occurred either during a medical emergency or while assisting medical personnel in the performance of their professional duties. Documentation of these facts must be kept only in the record of the employee or some other record separate from any record of the source patient.

B. TESTING AVAILABLE BLOOD WITHOUT CONSENT

When medical or non-medical personnel experience a significant exposure generating a "need to know," the blood of the source of the significant exposure may be tested without consent in two limited situations: when a blood sample from the source has already been drawn voluntarily for other purposes or when the exposure occurs while emergency medical treatment is

being provided to the source. Phrased alternatively, a source of a significant exposure to medical personnel or to non-medical personnel may not be required to undergo involuntary HIV testing (absent a court order) if no blood sample was drawn prior to the exposure or during treatment for the medical emergency giving rise to the exposure. §381.004(3)(h)10-11, *F.S.* A separate provision in the Act supplements these “significant exposure” exceptions to informed consent requirements by authorizing the medical examiner or attending physician to test deceased individuals who are the source of a significant exposure to medical personnel or nonmedical personnel who provided emergency medical assistance if the individual expired or could not be resuscitated during the emergency treatment. §381.004(3)(h)12, *F.S.*

Various procedures must be followed before HIV testing without consent under these circumstances is lawful. First, the source must be given the opportunity to consent voluntarily to the test and to the disclosure of the test results to the exposed person. This requirement is met if the source is unable to consent, for example, because he or she is unconscious or cannot be located within sufficient time to perform testing and begin treatment despite reasonable attempts. If there is no time to test, prophylactic treatment of the exposed person may begin. Second, the exposed person either must be tested for HIV infection or have tested negative within the previous six months. It is insufficient for the exposed person simply to agree to be tested prior to testing the source involuntarily. Finally, a physician must document both that a significant exposure has occurred and that the test result is medically necessary in the physician's medical judgment to determine the course of treatment for the exposed party.

Documentation of all of the above may not appear in the medical record of the source of the exposure; it must be in the exposed party's medical record.

In addition, none of the costs of the initial testing of the source may be charged to the source or his or her third party payer. Of course, the exposed person must keep confidential the fact of the test of the source and the HIV test results. Finally, the Department of Health does not require any physician or laboratory to report HIV positive test results from either a source of a significant exposure or the exposed person.

Finally, the Act also has a special provision providing an exception to the general rule against release of unconfirmed (“preliminary”) positive test results. Positive ELISA or rapid testing results may be released to the exposed person if the above significant exposure procedures are followed.

In most cases, source patients readily submit to HIV testing. If the source or the source's legal representative denies consent and no blood sample is available, the medical personnel, his or her employer, and nonmedical personnel may seek a court order directing the source to submit to HIV testing. A court may find probable cause for issuing a court order based on a sworn statement by a doctor that a significant exposure has occurred and that testing, in the doctor's medical judgment, is medically necessary to determine the course of treatment.

Two kinds of proceedings govern situations where involuntary testing is not otherwise permitted (no blood sample was drawn prior to the exposure or during emergency medical treatment). First, under a general statute the Department of Health has authority to ask a court to order the source of any exposure to be tested after a judicial hearing in which the source may participate. §§384.27(3) and (4), *F.S.* Second, a special statute applies only to law enforcement and correctional officers and certain forensic specialists, paramedics, emergency medical service personnel, and fire fighters who are injured while acting in the scope of their employment in such a way as to

permit HIV infection (or other sexually transmitted disease) to occur. §384.287, *F.S.* Such persons can seek a court order to test the source of the exposure, provided the person seeking the court order is also screened for the same STD. Fortunately, when sources are given adequate explanations and assurances, they usually agree to be tested. In addition, the number of documented transmissions to health care workers from patients is extremely low, and nearly all of these cases involved transmission by persons with clinical AIDS.

It is important to point out that testing the source of a significant exposure does not provide definitive information. If the source tests HIV negative, the source may not be virus-free due to the "window period." If the source tests HIV positive, transmission may not have occurred.

CONCLUSION

The Omnibus AIDS Act has undergone several significant changes since its passage in 1988: requiring HIV infection reporting, "streamlining" HIV testing by eliminating mandatory counseling in most settings, providing for "rapid" HIV tests, and requiring "opt out" testing for pregnant women. For the most part, however, these changes have "fine-tuned" the Act, leaving its basic structure intact. More changes to Florida's HIV/AIDS laws will occur as scientific knowledge, medical diagnosis and treatment, and public perceptions evolve.

Health care providers should learn the information summarized in this booklet. Because HIV infection and AIDS are likely to be major health concerns for many years to come, providers will see more and more patients whose care is subject to the Act. Over time, compliance with the Omnibus AIDS Act, now in existence for more than two decades, increasingly has become a routine part of meeting the public's health needs.

FLORIDA AIDS HOTLINE

English: 1-800-FLA-AIDS

Spanish: 1-800-545-SIDA

Creole: 1-800-AIDS-101

TTY: 1-888-503-7118

For additional information, please contact:

**The Department of Health
Bureau of HIV/AIDS
Bin #A09
4052 Bald Cypress Way
Tallahassee, FL 32399-1715**

(850) 245-4334

