AIDS Confidentiality Act Changes

July 30, 2015

Memorandum

The Governor recently signed into law legislation Public Act 99-0054 (formerly HB 1004), amending the Illinois AIDS Confidentiality Act (Act) to clarify and streamline procedural and documentation requirements for obtaining informed consent for HIV testing in healthcare facilities. This memo summarizes the new provisions of PA 99-0054, which are effective January 1, 2016:

1. Clarifies definition of "healthcare professional"
2. Defines "informed consent" in terms of "opt-in" or "opt-out" testing
3. Changes documentation requirements
4. Requires a written policy for conducting opt-out testing in lieu of certain documentation requirements
5. Allows health facility clerical staff to obtain consent via a general consent form
6. Defines pre-test information
7. Defines a person qualified to answer questions related to pre-test information
8. Treats civil union partners the same as spouses for purposes of disclosures

1. "Healthcare Professional": Under the Act, Physician Assistants and Advanced Practice Nurses are considered "health care professionals" under the following circumstances:
   - They work under appropriate supervision pursuant to a written agreement with a physician; or
   - They practice in a hospital or ambulatory surgical treatment center with appropriate clinical privileges.

2. Informed Consent for "Opt-In" and "Opt-Out" Testing: Healthcare providers, at their discretion, may implement opt-in or opt-out approaches for obtaining informed consent to HIV testing.
   - Opt-in testing is an approach where an HIV test is offered and the patient accepts or declines testing. It is a process by which an individual or their legal representative receives pre-test information, has an opportunity to ask questions, is offered the test, and consents or declines verbally or in writing to the test without undue inducement or any element of force.
   - Opt-out testing is an approach where a patient is notified that HIV testing may occur unless the patient declines. It is a process by which the individual or their legal representative has been notified verbally or in writing that the test is planned, has received pre-test information, has been given the opportunity to ask questions and the opportunity to decline testing, and has not declined testing. Where such notice is provided, consent for HIV testing may be incorporated into the patient’s general consent for medical care on the same basis as are other screening or diagnostic tests; a separate consent for opt-out HIV testing is not required.

Health Information Exchange (HIE): In addition, where the healthcare provider, healthcare professional or health facility participates in an HIE, informed consent requires a fair explanation to the patient that the results of the HIV test will be accessible through an HIE and meaningful disclosure of the patient’s right to opt out of disclosure of the patient’s health information through the HIE. This applies to both opt-in and opt-out testing.

3. Documentation: A form used to obtain informed consent for HIV testing may be combined with forms used to obtain written consent for general medical care or any other medical test or procedure, provided that the forms make it clear that the subject may consent to general medical care, tests or procedures without being required to consent to HIV testing, and clearly explain
how the subject may decline HIV testing.

A healthcare provider, healthcare professional or healthcare facility conducting opt-in testing shall document verbal or written consent in the general consent for medical care, a separate consent form or elsewhere in the medical record.

A healthcare provider, professional or facility conducting opt-out testing shall document the subject’s or the subject’s legally authorized representative’s declination of the test in the medical record. It is not required to document in each patient’s medical record that the individual was provided the pre-test information. Note: The law does not require such individual documentation for opt-in testing either.

4. Written Procedure for Conducting Opt-Out Testing: Instead of individual documentation that pre-test information was provided to the patient, a healthcare provider, healthcare professional or health facility conducting opt-out testing shall establish and implement a written procedure for conducting opt-out testing pursuant to the opt-out provision of the Act (subsection (q)(2) of Section 3) and for providing pre-test information, as that term is defined under subsection (w-5) of the Act. It may be helpful for the written procedure to include a process for communicating to the appropriate personnel when an individual has opted out of HIV testing.

This one-time policy development requirement is in lieu of the more burdensome individual documentation that pre-test information was provided.

5. Potential New Role for Health Facility Clerical Staff: PA99-0054 provides that health facility clerical staff or other staff responsible for the consent form for general medical care may obtain consent for HIV testing through a general consent form. This replaces the requirement for a healthcare professional to obtain the informed consent. “Health facility” means a hospital, nursing home, blood bank, blood center, sperm bank or other healthcare institution.

6. Pretest Information: Healthcare professionals and facilities should note that the definition of “pre-test information” in PA99-0054 includes “the availability of a qualified person to answer questions” about HIV testing, and defines who is a “qualified person.”

Pre-test information means:

- A reasonable explanation of the test, including its purpose, potential uses, limitation, and the meaning of its results; and
- A reasonable explanation of the procedures to be followed, including the voluntary nature of the test, the availability of a qualified person to answer questions, the right to withdraw consent to the testing process at any time, the right to anonymity to the extent provided by law with respect to participation in the test and disclosure of test results, and the right to confidential treatment of the information identifying the subject of the test and the test results, to the extent provided by law.

Pre-test information may be provided in writing, verbally or by video, electronic or other means, and may be provided as designated by the supervising healthcare professional or the health facility.

7. “Qualified Person” to Answer Questions: For purposes of pre-test information, a “qualified person to answer questions” is a healthcare professional or, when acting under the supervision of a health care professional, a registered nurse, a medical assistant or other person determined to be sufficiently knowledgeable about HIV testing, its purpose, potential uses, limitations, the meaning of the test results and the testing procedures in the professional judgment of a supervising healthcare professional or as designated by a healthcare facility.

8. Civil Union Partners: For purposes of Section 9 of the Act, where a physician is permitted to notify a spouse of a subject’s positive HIV test result, the physician may notify a civil union partner.

Finally, PA 99-0054 also amends the State Finance Act to extend the African-American HIV/AIDS Response Fund to July 1, 2026, in order for the Department of Public Health to continue to provide grants to reduce the disparity of HIV and AIDS between African-Americans and other population groups that may be impacted by the disease.
The changes described in this memo are effective January 1, 2016, despite the fact that the corresponding Administrative Rules (77 Illinois Administrative Code 697) may also require changes to comport with the provisions of PA 99-0054. Healthcare professionals and facilities should begin complying with PA 99-0054 on January 1, 2016. IHA will keep you informed about any rule changes that may be promulgated for this new law.