July 30, 2015

ILLINOIS HOSPITAL ASSOCIATION
MEMORANDUM

TO: Chief Medical Officers, Member Hospitals & Health Systems
    Chief Nurse Executives
    Emergency Department Directors

FROM: Barb Haller, Senior Director, Health Policy & Regulation


The Governor recently signed into law legislation Public Act 99-0054 (formerly HB1004), amending the Illinois AIDS Confidentiality Act (Act) to clarify and streamline procedural and documentation requirements for obtaining informed consent for HIV testing in health care facilities. This memo summarizes the new provisions of PA99-0054, which are effective January 1, 2016:

1. Clarifies definition of “health care 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; and
8. Treats civil union partners the same as spouses for purposes of disclosures.

1. “Health Care Professional.” Under the Act, Physician Assistants and Advanced Practice Nurses are considered “health care professionals” under the following circumstances: (1) they work under appropriate supervision pursuant to a written agreement with a physician or (2) they practice in a hospital or ambulatory surgical treatment center with appropriate clinical privileges.

2. Informed Consent for “Opt-in” and “Opt-out” Testing. Health care providers, at their discretion, may implement opt-in or opt-out approaches for obtaining informed consent to HIV testing.

- Opt-in testing means 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 health care provider, health care 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 health care provider, health care professional, or health care 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 health care 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 health care provider, health care 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 health care professional to obtain the informed consent. “Health facility” means a hospital, nursing home, blood bank, blood center, sperm bank or other health care institution.

6. Pretest Information. Health care 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:
(1) a reasonable explanation of the test, including its purpose, potential uses, limitation, and the meaning of its results; and

(2) 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 health care 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 health care 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 health care professional or as designated by a health care 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, PA99-0054 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 PA99-0054. Health care professionals
and facilities should begin complying with PA99-0054 on January 1, 2016. IHA will keep you informed about any rule changes that may be promulgated for this new law.

For a quick summary of PA99-0054, the following table illustrates the similarities and differences between opt-in and opt-out HIV testing:

**REQUIREMENTS FOR OPT-IN vs. OPT-OUT HIV TESTING**

<table>
<thead>
<tr>
<th>OPT-IN HIV TESTING</th>
<th>OPT-OUT HIV TESTING</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-test Information and Opportunity to Ask Questions</strong></td>
<td>Pre-test information must be provided. May be provided in writing, verbally, by video, electronic or other means, as designated by supervising health care professional or health care facility. Individual must have opportunity to ask questions.</td>
</tr>
<tr>
<td><strong>Who Is a Qualified Person to Answer Questions about HIV Testing?</strong></td>
<td>A health care professional (physician, physician assistant or advanced practice nurse) OR when acting under the direction of a health care professional, a registered nurse, a medical assistant or other person sufficiently knowledgeable about HIV testing.</td>
</tr>
<tr>
<td><strong>Opportunity to Decline</strong></td>
<td>Individual accepts or declines testing.</td>
</tr>
<tr>
<td><strong>Consent</strong></td>
<td>Individual has said yes to HIV testing without any element of force.</td>
</tr>
<tr>
<td><strong>Consent Related to HIE</strong></td>
<td>If professional or facility participates in a HIE, inform patient test results may be accessible through HIE; inform patient of right to opt out of such disclosure.</td>
</tr>
<tr>
<td><strong>Format for Providing Consent</strong></td>
<td>May consent verbally or in writing; may combine HIV consent form with form used to obtain consent for general medical care or other medical test or procedure, provided forms.</td>
</tr>
</tbody>
</table>
Changes to AIDS Confidentiality Act Informed Consent Provisions  
July 30, 2015  
Page 5

<table>
<thead>
<tr>
<th>Health Facility Staff</th>
<th>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.</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation</td>
<td>Document verbal or written consent in the general consent for medical care, a separate consent form, or elsewhere in the medical record.</td>
<td>Document the subject’s or the subject’s legal representative’s declination of the test in the medical record.</td>
</tr>
<tr>
<td>Written Procedure for Conducting Opt-out Testing</td>
<td>Not Applicable</td>
<td>Those conducting opt-out testing must establish and implement a written procedure for conducting opt-out testing that conforms to Section (q)(2) and for providing pre-test information as defined in (w-5).</td>
</tr>
</tbody>
</table>