PL 2007 c 218 An Act Concerning Testing of Pregnant Women and Newborns for HIV: The Regulations

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The Process

- Legislation signed into law
- Legislation requires regulations
- Regulations published in NJ Register for public comment
- 60 day public comment period
- Publication of final regulation with response to comments

- Effective 6/08
- Follow current CDC recommendations
- Give information
- Opt-out HIV Testing 1\textsuperscript{st} & 3\textsuperscript{rd} Trimesters
- Opt-out Rapid HIV Testing L&D
- All newborns if mother’s status unknown – unless written parental religious objection
9/06 CDC Revised Recommendations

Pregnant Women - I

- Universal opt-out HIV screening
  - Include HIV in routine panel of prenatal screening tests
  - Consent for prenatal care includes HIV testing
  - Notification and option to decline
  - Note: NJ Law Consent or Declination No Longer Required Effective 6/08!
• Second test in 3rd trimester for pregnant women:
  – Known to be at risk for HIV
  – In jurisdictions with elevated HIV incidence including NJ
  – In high HIV prevalence health care facilities
Opt-out rapid testing with option to decline for women with undocumented HIV status in L&D
  – Initiate ARV prophylaxis on basis of rapid test result
  – Note: NJ Law Consent or Declination No Longer Required Effective 6/08!

Rapid testing of newborn recommended if mother’s status unknown at delivery
  – Initiate ARV prophylaxis within 12 hours of birth on basis of rapid test result
Estimated Number of Perinatally Acquired AIDS Cases, by Year of Diagnosis, 1985-2004 – United States

- PACTG 076 & USPHS ZDV Recs
- CDC HIV screening Recs
- ~95% reduction

Number of cases

Year of Diagnosis

New Jersey Born
Pediatric HIV/AIDS Cases & Exposures
1993-2008 By Category
As of June 30, 2008

<table>
<thead>
<tr>
<th>Birth Year</th>
<th>Infected</th>
<th>Indeterminate</th>
<th>Seroreverter</th>
<th>Total Reports</th>
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<tr>
<td></td>
<td>#</td>
<td>%</td>
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<td>46</td>
<td>28</td>
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<tr>
<td>2007</td>
<td>2</td>
<td>2</td>
<td>57</td>
<td>43</td>
</tr>
<tr>
<td>2008</td>
<td>0</td>
<td>0</td>
<td>33</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td>348</td>
<td>9</td>
<td>1098</td>
<td>29</td>
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</table>
Prevalence of Diseases Screened for in Newborns

- Tyrosemia 1 in > 300,000
- Maple-syrup urine disease 1 in 175,000
- Homocystinuria 1 in 100,000
- Galactosemia 1 in 60,000
- Phenylketonuria 1 in 14,000
- Hypothonoidism 1 in 4,000
- Perinatal HIV (US) 1 in 1,500
To Whom do the Regulations for PL 2007 c 218 Apply?

- Clinical practitioners
- Hospitals
- Ambulatory care facility birth centers that provide prenatal care, newborn care, screening and order diagnostic tests for HIV or AIDS, diagnose individuals with HIV or AIDS, or provide treatment for individuals diagnosed with HIV or AIDS
“Clinical Practitioner” shall mean any of the following acting within his or her scope of practice:

- physician,
- advanced practice nurse,
- physician assistant,
- registered professional nurse or
- certified nurse midwife
Definitions - Continued

• “Perinatally exposed” means that an infant is born to a woman who is known to be HIV infected at the time of delivery, either through HIV testing prior to or during her pregnancy, or diagnosed by a medical practitioner.

• “Birthing facility” means a hospital or ambulatory care facility birth center licensed by NJDHSS that provide birthing and newborn care services.
Definitions - Continued

• "Hospital" means an institution, whether operated for profit or not, whether maintained, supervised or controlled by an agency of the government of the State or any county or municipality or not, which maintains and operates facilities for the diagnosis, treatment or care of two or more non-related individuals suffering from illness, injury or deformity and where emergency, out-patient, surgical, obstetrical, convalescent or other medical and nursing care is rendered for periods exceeding 24 hours.
Information Referenced in the Regulation

- CDC September 2006 MMWR (www.cdc.gov)
- CDC practical guide and model protocol on rapid HIV antibody testing during labor and delivery for women of unknown HIV status (www.cdc.gov)
Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings
Information Referenced in the Regulation

Rapid HIV Antibody Testing During Labor and Delivery for Women of Unknown HIV Status
A Practical Guide and Model Protocol

Available at:
U.S. Public Health Service
Perinatal Guidelines

Recommendations for the Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and to Reduce Perinatal HIV-1 Transmission in the United States

April 2009
N.J.A.C. 8:61- 4.4 HIV screening procedures for pregnant women

• Opt-out testing ASAP & 3rd trimester
  – Woman may decline verbally or in writing
  – No need to test if woman is already documented to be HIV positive

• Document each HIV test date and result in the medical record

• If testing refused document refusal to test in the medical record
Provision of Information (at Least, but not Limited to)

- Routine HIV testing is part of PNC unless declined
- How HIV is transmitted
- The meaning of the test and the results
- Possible need for additional testing
- Benefit of knowing HIV status as early in pregnancy as possible
Provision of Information (at Least, but not Limited to)

• Benefits of HIV testing of newborns, including interventions to prevent transmission
• Medical treatment available for HIV
• Reduced rate of HIV transmission to the fetus if treated
• Protection and confidentiality provisions for HIV
Provision of Information (at Least, but not Limited to)

• Right to refuse testing without prejudice or fear of denial of care
How to Provide the Information

- Verbally,
- Brochures,
- Video, or
- Other type of media
- Opportunity to ask questions
- Document receipt of the information
- Note: counseling no longer required
One Test. Two Lives. 2007

- Campaign promoting prenatal HIV screening to providers & patients
- www.cdc.gov/1test2lives
One Test. Two Lives.

Provider Materials

HIV Resources for Obstetric Providers and Their Patients

For Providers

CDC One Test Two Lives
Web: www.cdc.gov/eid/0209

This site offers resources and information for health care providers and patients about HIV and its impact. The site includes guidelines, educational materials, and resources for preventing, diagnosing, and treating HIV.

The American College of Obstetricians and Gynecologists (ACOG)
Web: www.acog.org
Phone: 202-639-3600

ACOG offers resources and educational materials for obstetricians and gynecologists, including guidelines and recommendations for HIV testing and prevention.

American College of Physicians (ACP)
Web: www.acponline.org

ACP provides resources and educational materials for physicians, including guidelines and recommendations for the prevention and treatment of HIV.

National Institute of Allergy and Infectious Diseases (NIAID)
Web: www.niaid.nih.gov

NIAID conducts and supports research on the causes, treatment, and prevention of HIV and other infectious diseases.

American College of Obstetricians and Gynecologists (ACOG)
Web: www.acog.org

ACOG is an organization that advocates for the prevention and treatment of HIV and other sexually transmitted infections.

The Kaiser Permanente Health Plan
Web: www.kaiserpermanente.org

Kaiser Permanente provides resources and educational materials for patients and healthcare providers, including guidelines for HIV testing and prevention.

American College of Physicians (ACP)
Web: www.acponline.org

ACP provides resources and educational materials for physicians, including guidelines and recommendations for the prevention and treatment of HIV.

National Institute of Allergy and Infectious Diseases (NIAID)
Web: www.niaid.nih.gov

NIAID conducts and supports research on the causes, treatment, and prevention of HIV and other infectious diseases.

The Children's Hospital of Philadelphia
Web: www.chop.edu

Children's Hospital of Philadelphia provides resources and educational materials for parents and healthcare providers, including guidelines for HIV testing and prevention.
One Test. Two Lives.

Patient Materials-English/Spanish

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**Helpful Tests For You And Your Baby**

Because you're pregnant, you want to take good care of yourself and the baby growing inside of you. That includes getting health tests early in your pregnancy, perhaps as soon as your first visit. Here are some of the blood tests that doctors, midwives and nurses recommend for all pregnant women:

**Test**

**What is it? What is it important for?**

<table>
<thead>
<tr>
<th>Test</th>
<th>What is it?</th>
<th>Why is it important?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Type and Rh Factor</td>
<td>A person's blood type is either A, B, AB, or O. Every pregnant woman should know her blood type in case she needs blood when she has her baby.</td>
<td>Helps in blood transfusions at delivery.</td>
</tr>
<tr>
<td>CBC</td>
<td>Counts the number of red blood cells, white blood cells, and platelets.</td>
<td>Helps to determine a person's blood cell count.</td>
</tr>
<tr>
<td>Hepatitis</td>
<td>Hepatitis is a virus that causes liver disease.</td>
<td>Helps to identify those at risk for developing liver disease.</td>
</tr>
<tr>
<td>HIV</td>
<td>HIV (Human Immunodeficiency Virus) is a virus that affects the immune system.</td>
<td>Helps to determine if a woman is infected with HIV.</td>
</tr>
<tr>
<td>Rubella (German Measles)</td>
<td>Rubella is a viral disease that can cause severe complications if contracted during pregnancy.</td>
<td>Helps to identify those at risk for developing rubella.</td>
</tr>
<tr>
<td>Syphilis (Treponema pallidum)</td>
<td>Syphilis is a bacterial disease that can cause major health problems in both the mother and baby.</td>
<td>Helps to identify those at risk for developing syphilis.</td>
</tr>
</tbody>
</table>

Your doctor, midwife, or nurse may also suggest other tests based on your family history and the results of earlier tests.

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**To LEARN MORE**

If you would like to learn more about HIV testing, visit the National HIV Testing Resources Web site at http://www.hivtest.org

You can also contact CDCINFO by e-mail at cdcinfo@cdc.gov or by phone at 1-800-CDC-INFO (232-4636) in English, or 1-888-287-6777 in Spanish.

The number for callers with TTY equipment is 1-866-222-6645.

Your call is free and private.
Who can Provide the Information?

- Primary care practitioner
- Delegate to another clinical practitioner
- Delegate to unlicensed assistive personnel
- If delegated must assure
  - Information is provided
  - Provision of the information is within the scope of practice of the person to whom it is delegated or within the capabilities of the unlicensed assistive personnel
A Clinical Practitioner Shall NOT:

- Deny appropriate PNC or other medical care to a woman who refuses HIV testing
- Offer an HIV test if the woman is already documented in her medical record to be HIV positive
- Deny HIV testing of pregnant woman or newborn based on economic status
Facility written procedures for HIV testing and screening in L&D

- On admission HIV status documented in medical record and medical record transferred to L&D
- If HIV status unknown, undocumented or not retested in 3rd trimester rapid testing unless woman objects
- Rapid HIV test results explained to the woman
Currently Available Tests

Rapid Tests

Uni-Gold Recombigen

Multispot HIV-1/HIV-2

Reveal G3

OraQuick Advance

Clearview Complete HIV 1/2

Clearview HIV 1/2 Stat Pak
Facility written procedures for HIV testing and screening in L&D

• If the woman refuses HIV testing the refusal must be documented in the medical record
A Clinical Practitioner in a Birthing Facility

• A clinical practitioner in a birthing facility who cannot follow through with providing HIV information in accordance with N.J.A.C. 8:61-4.4(c), or who cannot provide care for a woman with a positive HIV test or a perinatally exposed newborn, shall initiate a referral to another clinical practitioner who, within the scope of practice of the clinical practitioner, is able and willing to provide information on HIV and care for the woman and newborn.
A Clinical Practitioner in a Birthing Facility Shall NOT:

• Deny appropriate care and treatment to a pregnant woman who refuses to be tested for HIV during labor and delivery

• Deny a pregnant woman or newborn an HIV test on the basis of the pregnant woman’s or newborn’s economic status
Facility shall inform parents or legal guardian that the newborn shall be given a rapid HIV test when mother’s HIV status is undocumented or untested in 3rd trimester

- Exception: parents or legal guardian object in writing based upon religious tenets and practices
- “Parents” both parents when available, or a legally responsible parent when only one parent is available
N.J.A.C. 8:61-4.6 HIV Screening & RT Procedures Newborn Infant Post-Delivery

- The birthing facility shall obtain a written statement signed by the parents or legal guardian that HIV testing conflicts with their religious tenets or practices.

- The birthing facility shall document the objection and include the written statement in the newborn’s medical record.
N.J.A.C. 8:61-4.6 HIV Screening & RT Procedures Newborn Infant Post-Delivery

• When a newborn receives a rapid HIV test, the birthing facility shall provide the parents or legal guardian with the following:
  – 1. Explanation of the recommended ARV preventive treatment for the infant;
  – 2. Appropriate medical care & treatment for the woman and newborn;
  – 3. Availability of appropriate referrals for her & newborn to physicians or health care facilities with experience and expertise in providing medical care and services to women with HIV and other social services as necessary
A birthing facility shall:

- 1. Perform an HIV test on a newborn infant ASAP after birth, unless the parents or legal guardian object;
- 2. Document the date of a positive HIV test on the newborn in the medical record; and
Clinical practitioner or birthing facility that orders an HIV test or receives the results of a positive HIV test shall advise a pregnant woman who tests HIV positive on:

1. Recommended treatment to reduce the risk MTCT
2. The appropriateness of & need for further testing;
3. Methods to prevent HIV transmission;
4. Appropriate medical care & treatment for the woman;
5. Availability of appropriate referrals for her & newborn to prevention services, physicians or facilities with experience and training in providing services and treatment to women with HIV and other social services as necessary.
N.J.A.C. 8:61-4.7 Confidentiality

• A clinical practitioner or birth birthing facility shall maintain the confidentiality of HIV information and test results in accordance with the requirements of N.J.S.A. 26:5C-5 through 26:5C-14, and N.J.A.C. 8:57-1.12, but shall release information and results as follows:
  – A woman’s test results may be provided to the clinical practitioner caring for the woman’s infant
N.J.A.C. 8:61- 4.7 Reporting

- HIV positive test results and perinatal exposure shall be reported to NJDHSS in accordance with N.J.A.C. 8:57-2;
- The medical records of a perinatally exposed newborn and the newborn’s mother shall be made available to the NJDHSS for audit for epidemiologic purposes.
N.J.A.C. 8:61- 4.7 Reporting

• In accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996, NJDHSS or its designee may contact an infant’s health care provider to follow-up on the HIV status and HIV related care of the infant.
In addition to the written procedures required by N.J.A.C. 8:61-4.5

- Shall adopt and implement written policies and procedures on HIV screening and testing of pregnant women and newborns,
- Shall be reviewed at least once every three years, and
- Revised more frequently as needed, and which shall include at least the following:
• 1. Procedures for communicating rapid HIV test results to the labor and delivery site;
• 2. Designation of a staff member to be responsible for receiving verbal and written positive HIV screening test results and documenting the results in the newborn infant’s medical record; and
• 3. Procedures on prenatal, newborn and labor and delivery HIV screening, which shall include a protocol for rapid HIV testing
• Birthing facilities shall provide training and education for labor and delivery staff on providing the information required by N.J.A.C. 8:61-4.4(c) and on HIV testing, including manufacturer’s instructions on using HIV test kits.

• The most recent CDC guidelines on HIV screening and testing of Adults, Adolescents, and Pregnant Women and these guidelines shall be used for establishing policies and procedures.
Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings
N.J.A.C. 8:61-4.9 QI Rapid Testing Pregnant Women & Newborns

• A birthing facility shall develop a plan by which to
  – collect and analyze HIV data
  – evaluate outcomes
  – focus on corrective action and improving performance.

• Birthing facility shall have a QA plan for rapid HIV testing.
Current Status of Regulations

• 9/21/09: Publication in New Jersey Register for public comment

• 11/20/09: Comment period ends
  – Postmarked on or before November 20, 2009
  – In writing to Ruth Charbonneau, Director, Office of Legal and Regulatory Affairs, New Jersey Department of Health and Senior Services, PO Box 360, Trenton, NJ 08625-0360.
How to Comply with the Regulations? Help is Available!

- Best practices being developed with an Advisory Committee and FXBC
- Technical assistance available
- Plenary and breakout sessions today on best practices and their implementation
- The goal is the maximal reduction of perinatal HIV transmission