areas, and therefore, this regulation does not require a rural area flexibility analysis.

Job Impact Statement

The Department of Environmental Conservation has determined that this rule-making will have no negative effects on jobs or employment opportunities and therefore does not require a job impact statement. There are no additional regulations being proposed; only administrative changes and minor season adjustments.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Ambient Water Quality Standards and Groundwater Effluent Limitations

I.D. No. ENV-51-98-00016-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: This is a consensus rule making to amend Parts 700, 702 and 703 of Title 6 NYCRR.

Statutory authority: Environmental Conservation Law, sections 3-0301.2.m, 15-0313 and 17-0301

Subject: Ambient water quality standards and groundwater effluent limitations.

Purpose: To correct and clarify aspects of Parts 700, 702 and 703 that result from the amendment of those Parts effective March 12, 1998.

Text of proposed rule: Existing paragraph 702.16(c)(1) is AMENDED to read as follows:

702.16(c)(1) Groundwater effluent limitations are provided in Table 3 of section 703.6(e) of this Title. For those substances not included in Table 3 of section 703.6(e) of this Title and for which a guidance value has been derived as provided in section 702.15(a) *or section 702.15(f)* of this Part, the groundwater effluent limitation shall be equal to the guidance value.

Existing paragraph 702.19(a)(1) is AMENDED to read as follows:

(a)(1) An applicant for a SPDES permit or a SPDES permittee may make written application for a modification of a groundwater effluent limitation *listed in Table 3 of section 703.6(e) of this Title or* established pursuant to section 702.16(c)(1) of this Part.

Existing subdivision 702.19(b) is AMENDED to read as follows:

Where a request for a [variance] *modification of a groundwater effluent limitation* satisfies the requirements of this section, the department shall authorize the [variance] *modification* through the SPDES permit. The [variance] *modification* request shall be available to the public for review during the public notice period for the permit. The permit shall contain all conditions needed to implement the [variance] *modification.*

The entry for "Cyanide" in Table 1 of 703.5 is AMENDED as follows:

The Basis Code for the H(WS) Type standards is "B" instead of "H."

In the entry for "Principal organic contaminant" in Table 1 of 703.5, the second paragraph under "Remarks" is AMENDED to read as follows:

For the convenience of the reader, the principal organic contaminant standard of 5 ug/L (Basis Code J) is listed in this Table for *some but not all* substances [that also have standards for surface water.] *regulated by this standard.*

The entry for "Chlorinated dibenzo-p-dioxins and Chlorinated dibenzofurans" in Table 3 of 703.6(e) is AMENDED as follows:

An asterisk is added to the effluent limitation and the following Remark is added:

*Remark: *Value is for the total of the chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans as equivalents of 2,3,7,8-tetrachlorodibenzo-p dioxin (2,3,7,8-TCDD) as specified by the Class GA H(WS) standard in Table 1 of section 703.5 of this Part.*

Footnote 3 of Table 3 of 703.6(e) is AMENDED to read as follows:

3. Refer to groundwater effluent [standard] *limitation for* "Phenolic compounds (total phenols)."

Text of proposed rule and any required statements and analyses may be obtained from: Scott Stoner, Department of Environmental Conservation, 50 Wolf Rd., Albany, NY 12233-3502, (518) 485-5824

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

This action was not under consideration at the time this agency's regulatory agenda was submitted.

Consensus Rule Making Determination

As described under "Purpose," the proposed revisions to sections 702.19, 703.5 Table 1 and 703.6 Table 3 merely clarify or correct existing regulations.

The proposed revision to section 702.16 does not create new authority to establish groundwater effluent limitations where Aesthetic Type groundwater guidance values exist, but restores the previously existing specification that the magnitude of such limitations be set equal to the guidance value.

As shown in the Combined Regulatory Impact and Draft Environmental Impact Statement for the March 1998 amendments, no regulatory impact is attributed to the provisions concerning the Great Lakes System, irrespective of the water bodies included.

Thus, with no regulatory impact nor impact upon jobs (see statement below), the Department concludes that no person is likely to object to the rule as written.

Job Impact Statement

As described under "Purpose," the proposed revisions to sections 702.19, 703.5 Table 1 and 703.6 Table 3 merely clarify or correct existing regulations.

The proposed revision to section 702.16 does not create new authority to establish groundwater effluent limitations where Aesthetic Type groundwater guidance values exist, but restores the previously existing specification that the magnitude of such limitations be set equal to the guidance value.

As shown in the Combined Regulatory Impact and Draft Environmental Impact Statement for the March 1998 amendments, no regulatory impact is attributed to the provisions concerning the Great Lakes System, irrespective of the water bodies included.

Because there is no regulatory impact from this amendment, the Department concludes that there will be no effect on jobs or employment opportunities. Thus, it is not necessary to submit a job impact statement (JIS) for this rule making.

Department of Health

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Expedited HIV Testing of Women and Newborns

I.D. No. HLT-51-98-00007-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of sections 58-8.1, 58-8.2, 58-8.3 and 69-1.3 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 576, 2500-a and 2500-f

Subject: Expedited HIV testing of women and newborns.

Purpose: To insure that women with unknown HIV status receive expedited HIV testing for themselves or on their newborns in order to identify persons at risk and provide appropriate care.

Text of proposed rule: Subdivision (l) of section 69-1.3 is amended by adding a new paragraph (2) and existing paragraphs (2) through (6) are renumbered (3) through (7) respectively as follows:

Section 69-1.3 Responsibilities of the chief executive officer.

*****

(l) In addition to all applicable preceding requirements for HIV testing the following specific procedures shall be carried out:

(1) obtain a history of HIV testing and treatment from the mother to enable counseling consistent with such history and knowledge of her own HIV status, and document such history in the medical record;

(2) if no HIV test result obtained during the current pregnancy is available for the mother not known to be HIV infected, arrange an immediate screening test of the mother with her consent or of her newborn for HIV antibody with results available as soon as practicable, but in no event longer than 48 hours;

[(2)] *(3)* the newborn HIV test result shall be maintained securely and confidentially in the medical record of the newborn in accordance with Public Health Law, Article 27-F;

[(3)] *(4)* the chief executive officer or his designee shall transmit to the responsible physician a copy of the newborn's HIV test result, and, at the request of the responsible physician, shall transmit the result to an HIV specialized care center;

[(4)] *(5)* make referrals as necessary for follow-up of HIV positive newborns who cannot be located;

[(5)] *(6)* ensure that data required by the department for program evaluation and, in the case of HIV positive newborns, for patient follow-up, is collected and provided to authorized staff at the department; and

[(6)] *(7)* submit to the department information on the prior HIV testing and treatment history of the mother for the purposes of medical audits; such information shall be kept confidential as required by Public Health Law, section 206(1)(j).

A new subdivision (i) is added to section 58-8.1 and existing subdivision (i) is relettered subdivision a, to read as follows:

Section 58-8.1 Definitions.

*****

(i) Preliminary finding of HIV infection means results of antibody screening that have been neither substantiated nor refuted by HIV confirmatory testing.

[(i)]*(j)* Repeatedly reactive means having an activity/reactivity at least equal to the minimum significant level of activity (cut-off) established by the laboratory for the procedure on two of two tests, or two of three tests.

Subdivision (d) of section 58-8.2 is amended to read as follows:

58-8.2 General requirements.

*****

(d) [In addition to manufacturer-recommended controls or calibrators used as controls, a] *A* weakly reactive control shall be included with each HIV test plate, tray or batch.

Subdivision (d) of section 58-8.3 is amended to read as follows:

58-8.3 HIV diagnostic testing.

*****

(d) No laboratory shall notify a physician or other authorized persons that a specimen is reactive or an HIV test result is positive prior to receiving the results of HIV confirmatory testing, *except for antibody screening tests where notification of a preliminary finding of HIV infection is requested by the physician or other authorized person as part of the written request for such testing. Confirmatory testing must be carried out in all cases where notification of a preliminary finding of HIV infection is made.*

Text of proposed rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, FAX: (518) 486-4834, E-mail: B0019b@health.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

This action was not under consideration at the time this agency's regulatory agenda was submitted.

Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) section 2500-f requires the commissioner to promulgate regulations to implement a comprehensive program for the testing of newborns for HIV and/or the presence of HIV antibodies. The proposed regulations amend the current comprehensive program in response to recent advances in medical knowledge. PHL section 576 authorizes the department to "adopt and amend rules and regulations to effectuate the provisions and proposals" of Article 5, Title 5 "Laboratory Services" which includes promoting public health.

Legislative Objectives:

In the memorandum accompanying the comprehensive newborn testing bill (A. 4113-c, S. 7725), the legislature indicated its purpose was "to ensure that newborns who are born exposed to HIV receive prompt and immediate care and treatment and counseling that can enhance, prolong and possibly save their lives." The proposed amendments to 10 NYCRR, Subparts 69-1 and 58-8 will ensure that the HIV exposure status is available for all newborns whose mothers have not been tested for HIV or for whom HIV test results are not available at delivery. This will provide medical providers and patients with critical information necessary for decisions concerning the clinically appropriate administration of zidovudine within 48 hours after birth thereby preventing HIV transmission in many cases.

Needs and Benefits:

Transmission of HIV from mother to newborn can be prevented in many cases by administration of zidovudine which is recommended to be given to the mother starting during the second trimester of pregnancy, continued during labor, and given to the newborn after birth. Despite efforts to encourage universal prenatal HIV counseling and testing, preliminary data available at the time of delivery and submitted by birth hospitals with the newborn HIV test specimen indicate that almost half of all mothers in the delivery setting, and 51% of HIV mothers ultimately found to be HIV positive, do not have an HIV test result from the current pregnancy. This represents a missed opportunity to prevent HIV transmission.

Several major advances in medical knowledge about perinatal HIV transmission, HIV testing and HIV treatment have occurred since the current newborn HIV testing program was begun in February 1997, reflecting the rapidly changing environment of HIV prevention and care. Key new findings of a recent Department of Health study indicate that mothers who began zidovudine during labor and delivery had almost the same reduction in HIV transmission as women who began in prenatal care, and newborns whose mothers had not taken zidovudine and who began therapy in the first 48 hours of life experienced a significant reduction in HIV transmission.

The U.S. Public Health Service has recommended that screening HIV test results be used, prior to confirmatory testing, in situations where tested persons would benefit from this knowledge of their HIV status. The labor and delivery setting is specifically mentioned as one setting where such testing might be appropriate. The proposed regulation requires hospitals, birthing centers and birth attendants to arrange immediate HIV testing of the mother, with her consent, or her newborn, with results as soon as practicable but in no event longer than 48 hours. There is precedent for requiring the immediate provision of test results in the delivery setting in the perinatal hepatitis B prevention program authorized by PHL section 2500-e. The proposed regulations make possible the identification of all newborns exposed to HIV at a time when therapy may prevent HIV transmission.

The amendments to Subpart 58-1 would allow licensed laboratories to provide preliminary HIV results to providers before such results are confirmed by subsequent testing. This is necessary due to technological and time constraints. The amendments also update the regulations with respect to use of control samples. Laboratories are required to include in every test run a control which monitors the sensitivity of the assay and the technical performance of the assay. Some manufacturers are now including such a control with the test kit. If a kit control is in the low-positive range of the assay and serves as a sensitivity monitor as well as a performance monitor, a laboratory does not need to include an additional control intended to monitor the same parameters.

Costs:

Costs to State and Local Governments:

Costs to the State are discussed in the Costs to the Department of Health, which are reduced by the savings to the State and local governments in the Medicaid program. Medicaid costs will be reduced due to fewer incidences of transmission of HIV to newborns. Local governments operating medical facilities will incur costs described in the section on Costs to Regulated Parties noted below.

Costs to Regulated Parties:

Components of the cost would include: (1) time spent by providers drafting protocol for expedited HIV testing in the labor and delivery setting; and (2) obtaining and submitting the blood specimen in cases where a prenatal HIV test was not done or the result is not available. Under the proposed regulation, staff at these locations would have to offer these mothers consented HIV testing, or submit a cord blood specimen from the newborn for screening HIV testing. Testing would occur either at hospital-based laboratories or at commercial laboratories. At current testing rates, approximately 120,000 women or their infants a year would be tested under this program. All hospital laboratories holding a Diagnostic Immunology permit will be able to add HIV testing through a "fast-track" mechanism outlined below, or obtain HIV testing through the same referral laboratories that they currently use for maternity hepatitis B testing. At an estimated cost of $52 per case for staff time and testing materials, total cost of the program would be $6.24 million per year statewide. This does not include start up costs for facilities instituting HIV testing laboratory services. Such services would generate revenue from third party billing and directly from the patients. Program costs will diminish as efforts to encourage prenatal HIV counseling and testing are successful. All current cost-saving initiatives will be continued under the new regulatory program. These initiatives include special Medicaid payment rates at 24

hospitals with high HIV incidence. The cost of confirmatory HIV (PCR) testing will also continue to be provided free of charge at the Wadsworth Laboratory.

Additional provider costs associated with testing are medically appropriate and must be considered part of labor and delivery costs. Preventing HIV transmission is cost effective because of the high treatment costs for HIV infected persons. Hospital laboratories with a Diagnostic Immunology permit will be able to add HIV testing via a "fast-track" application or obtain HIV testing through the same referral laboratories as maternity hepatitis B testing. Hospitals and birthing centers will realize savings as a result of this program by not having to employ outreach staff to find mothers after discharge since post test counseling can be done while the mother is still in the hospital.

PHL requires all sites performing HIV antibody screening to hold a permit in HIV testing. Of the 169 hospitals and birthing centers affected by this amendment, only 24 currently hold a permit which includes HIV testing. However, it is expected that any hospital or D&TC laboratory with a permit in Diagnostic Immunology can be approved to perform HIV screening with a minimum of cost and paperwork. There is no fee associated with addition of a test category to an existing permit. Approximately 240 hospitals currently hold a Diagnostic Immunology category on their NYS permit and could be "fast-tracked" for approval for HIV screening. Many of these same facilities now provide on-site testing for hepatitis B under the prevention program authorized by PHL section 2500-e, and most likely have procedures in place for perinatal testing, as well as qualified personnel and the necessary equipment to easily add HIV screening to their test menu. "Fast-tracking" of such laboratories with previous diagnostic serology experience, but without HIV testing, would require that the laboratory validate the HIV test method on a statistically significant number of known reactivity specimens and participate in proficiency testing. It is estimated that this could be accomplished in 2-3 months. Costs associated with initiating HIV testing in a facility without an existing laboratory infrastructure (*i.e.*, birthing center) would include a $1,100 permit fee and minimally $4,000 in start-up costs for laboratory operation in addition to new personnel costs. For these facilities, referral of specimens to an off-site permit laboratory is an alternative.

Costs to the Department of Health:

The department will incur expenses related to staff time needed to HIV testing applications which may be submitted by providers. No new staff will be required. However, the State would realize savings under the proposed program because less staff time will be required to assist in locating mothers who have been lost to follow-up to provide newborn HIV positive test results. In addition, the State will realize savings in the Medicaid program because fewer HIV positive infants and children will require care.

Local Government Mandates:

These regulations will not impose any new program services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district, except for those local governments operating hospitals with maternity services.

Paperwork:

HIV test requisition forms will need to be modified by adding one data element to permit a provider to request preliminary test results. Alternatively, the providers may annotate the laboratory order form to request preliminary test results or submit a cover letter. Some paperwork will be required of hospital laboratories if they choose to seek an HIV testing permit.

Duplication:

None.

Alternatives:

One alternative considered involved decreasing the time to provide newborn HIV test results from the Wadsworth Laboratory. Currently, the newborn blood specimen must be collected after 24 hours of age to maximize the chances of detecting other congenital abnormalities which are tested for using the same specimen. This 24-hour period plus additional time necessary for specimen transport and testing does not permit return HIV test results within the first 48 hours of life. A second alternative involved granting hospitals waivers from 48-hour testing if they demonstrated that in a high percentage of cases in the delivery setting relevant maternal HIV test results were accessible or if hospitals demonstrated a low rate of HIV prevalence in women delivering in their facility. However, either option would result in some HIV-exposed infants not being detected in time to administer therapy to prevent HIV transmission. Consequently, the department determined that the proposed regulation was the best approach to protect the public health.

Federal Standards:

There are currently no Federal regulations related to prenatal or n born testing. The Federal government has provided only recommendati and guidelines for these activities.

Compliance Schedule:

The proposed amendments are to take effect upon publication c Notice of Adoption in the New York *State Register*.

Regulatory Flexibility Analysis

Effect on Small Businesses and Local Governments:

The proposed rule will impact an estimated six hospitals and e birthing centers, which meet the definition of a small business (indep dently owned and employs 100 or fewer individuals). No new costs to lo governments are anticipated, except for those operating hospitals w maternity services.

Compliance Requirements:

The reporting, recordkeeping and other affirmative acts that impac small businesses or local governments would have to undertake to com with this proposed rule include counseling the mother about the need expedited HIV testing. Current regulations require hospital maternity s vices and freestanding birthing centers to ensure that all mothers provided HIV counseling and informed that their newborn will be tes for HIV by the State's newborn testing program. Facilities would also ha to obtain and submit a blood specimen in cases where a prenatal HIV t was not done or the result is not available. Under the proposed regulati staff at these locations would have to offer these mothers consented H testing, or submit a cord blood specimen from the newborn for HIV testu and arrange HIV testing with preliminary results available within 48 hou Testing would occur at hospital-based laboratories or at commercial lab ratories.

Professional Services:

Impacted small businesses and local governments would need the sa staff: health care providers (doctors, nurses, nurse practitioners, physicia assistants), counseling and support staff, and laboratory staff, if conducti laboratory testing, as they currently employ. No additional staff would needed.

Compliance Costs:

According to current data, fewer than 500 maternity patients newborns per year in any hospital or birthing center operated by sm businesses and fewer than 1,000 per year at hospitals operated by loc health departments would need to be provided 48-hour HIV testing. Th number will diminish as efforts to encourage prenatal HIV counseling a testing are successful. At an average cost of $52 per case requiring imm diate HIV testing, the total cost would be less than $26,000 per sma business owned facility and $52,000 per local government facility.

Economic and Technological Feasibility:

The proposed regulatory program is economically and technological feasible since it is not anticipated that additional staff would require and expedited testing is technologically available.

Minimizing Adverse Impact:

Additional provider costs associated with testing are medically appr priate and must be considered part of labor and delivery costs. Preventin HIV transmission is cost effective because of the high treatment costs f HIV infected persons. Hospital laboratories with a Diagnostic Immuno ogy permit will be able to add HIV testing via a "fast-track" application obtain HIV testing through the same referral laboratories as materni hepatitis B testing. Hospitals and birthing centers will realize savings as result of this program by not having to employ outreach staff to fi mothers after discharge since post test counseling can be done while t mother is still in the hospital.

Small Business and Local Government Participation:

In advance of publication, the proposed regulations were discuss with representatives of the NYS Association of County Health Official the Health Care Association of NYS, the Greater NY Hospitals Associ tion and the NYC Health and Hospital Corporation.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

Forty-four counties meet the definition of a rural area (population le than 200,000) and an additional 11 counties have towns that are classifi as rural (towns with populations densities of 200 persons or less per squa mile). The proposed regulation applies to hospitals and birthing cente statewide, and therefore, will impact those facilities located in rural are in 55 counties. These facilities currently implement the Newborn Scree ing Program, and the proposed regulation requires the expansion of t program to require HIV testing within 48 hours in some instances.

Reporting, Recordkeeping and Other Compliance Requirements:

The reporting, recordkeeping and other affirmative acts that will impact hospitals in rural areas would have to be undertaken to comply with this proposed rule. Current regulations require hospital maternity services and freestanding birthing centers to ensure that all mothers are provided HIV counseling and informed that their newborn will be tested for HIV by the State's newborn testing program. Facilities must also obtain and submit the blood specimen in cases where a prenatal HIV test was not done or the result is not available. Under the proposed regulation, staff at these locations would have to offer these mothers consented HIV testing, or submit a cord blood specimen from the newborn for HIV testing. HIV testing must be arranged with preliminary results available within 48 hours. Testing would occur at hospital-based laboratories or at commercial laboratories.

Professional Services:

Hospitals in rural areas would not need additional professional staff to provide this additional service for women without known HIV test results.

Costs:

According to current data fewer than 500 maternity patients or newborns in any hospital and birthing center operated in rural areas would need to be provided 48-hour HIV testing. This number will diminish as efforts to encourage prenatal HIV counseling and testing are successful. At an average cost of $52 per case requiring immediate HIV testing, the total cost would be less than $26,000.

Minimizing Adverse Impact:

Additional provider costs associated with testing are medically appropriate and must be considered part of labor and delivery costs. However, preventing HIV transmission is cost effective because of the high cost of treatment for HIV infection persons. Hospital laboratories with a Diagnostic Immunology permit will be able to add HIV testing via "fast-track" application or obtain HIV testing through the same referral laboratories as maternity hepatitis B testing. Hospitals and birthing centers will realize savings as a result of this program by not having to employ outreach staff to find mothers after discharge since post test counseling can be done while the mother is still in the hospital.

Rural Area Participation:

In addition, in advance of publication, the proposed regulations were discussed with representatives of the NYS Association of County Health Officials, the Health Care Association of NYS, the Greater NY Hospitals Association and the NYC Health and Hospital Corporation.

Job Impact Statement

A Job Impact Statement is not attached because this rule will not have a substantial adverse impact on jobs and employment opportunities as apparent from its nature and purpose.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Registration of Trade Secrets

I.D. No. HLT-51-98-00008-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: This is a consensus rule making to repeal Part 72 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 4802 and 4805

Subject: Registration of trade secrets.

Purpose: To repeal obsolete regulations.

Text of proposed rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, FAX: (518) 486-4834, E-mail: B0019b@health.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Consensus Rule Making Determination

Under the New York State Right to Know Law (PHL sections 4802 and 4805), effective in December of 1980, the Department of Health was required to promulgate regulations to provide for the registration of trade secrets. At that time, product information was rare and usually incomplete. The purpose of the regulations was to allow for a secure and objective review of proprietary formulations to ensure that sufficient health and safety information was provide to the users of a product claiming trade secret protection.

This regulation. Title 10, Part 72. Registration of Trade Secrets, provided a means of any manufacturer, producer, formulator or employer to request trade secret protection for a product or mixture. Those requesting trade secret protection were asked to submit detailed information on product components, which were evaluated by department staff. The product Material Safety Date Sheet (MSDS) was reviewed for completeness and accuracy and suggestions for improvements in language were provided where appropriate. The product would then be assigned a unique registration number that would be included in place of ingredients on the product MSDS. Trade secret information files are maintained in isolated, locked storage cabinets and included in the department's internal controls inventory.

To date, 75 companies have submitted 526 product formulations for trade secret registration.

10 NYCRR Part 72 is obsolete. Since the implementation and expansion of the Federal OSHA Hazard Communication Standard (29 CFR 1910.1200), trade secret registration by New York State has become unnecessary. Material Safety Data Sheets are dramatically improved and mechanisms are in place for employers, health professionals and worker representatives to request trade secret information from manufacturers and importers. Federal OSHA oversees both MSDS content and access to trade secret information.

The repeal of these regulations will free manufacturers and importers from duplicative registration and confidentiality procedures. Because Federal safeguards are in place, no opposition to the proposed rule is anticipated.

Job Impact Statement

It is apparent from the nature and purpose of this rule that it will not have a substantial adverse impact on jobs and employment opportunities. It repeals a little used reporting requirement.

Insurance Department

EMERGENCY RULE MAKING

Homeowners Insurance Disclosure Information

I.D. No. INS-51-98-00015-E
Filing No. 2257
Filing date: Dec. 7, 1998
Effective date: Dec. 7, 1998

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Addition of Part 74 (Regulation 159) to Title 11 NYCRR.

Statutory authority: Insurance Law, sections 201, 301 and 3445

Finding of necessity for emergency rule: Preservation of general welfare.

Specific reasons underlying the finding of necessity: Chapter 44 of the Laws of 1998 added a new section 3445 to the Insurance Law which mandated that insurers provide a disclosure notice to their insureds with respect to the operation of a deductible in the insured's homeowner's insurance policy or dwelling fire personal lines policy which applies as a result of a windstorm. That section also requires the superintendent to establish, by regulation, the form of such notice which shall include the amount of the deductible, the circumstances under which the deductible applies and any other matters which are deemed necessary or appropriate. Chapter 44 was effective April 30, 1998 and it is imperative that insurers receive necessary information and guideline so that implementation of the statute is instituted as quickly as possible and the operation of the windstorm/hurricane deductible be clarified. In this way, insureds will understand their obligations in the event of a loss due to windstorm or hurricane. Insurers must be made aware of the specific information which must be included in the disclosure notice so that they may file this notice with the department and order printing of the notice as soon as possible. Accordingly, this rule must be provided on an emergency basis for the preservation of the general welfare.

Subject: Homeowners insurance disclosure information.

in place for professional discipline purposes. The requirement is a prudent measure that is not overly burdensome.

Comment: The vice-president of a corporation that operates a mail order pharmacy in New York State wrote that a sentence in section 63.6(b)(8) of the regulation is redundant because it concerns the counseling requirement for off-premises delivery of prescriptions, which is dealt with in another subparagraph.

Response: The sentence merely points the reader to the subparagraph that deals with the counseling requirement for off-premises delivery of prescriptions and provides useful guidance to the reader.

Comment: The vice-president of a corporation that operates a mail order pharmacy in New York State states that, overall, the amendment constitutes a positive contribution to the practice of pharmacy in New York State but requests changes as stated in this comment and the comments that follow that are attributable to him. He agrees that the mechanism used to offer patient counseling should be appropriate to the practice setting but questions the fact that there are special requirements for off-premises delivery of prescriptions when there is a prescriber approved alternative drug or when there are potential drug therapy problems.

Response: The amendment permits a written offer of counseling when the prescription is delivered off the premises of the pharmacy, but establishes two exceptions when the pharmacist or pharmacy intern is required to do more. The comment references the two exceptions. In the case of a prescription that is a prescriber approved alternative drug, the pharmacist or pharmacy intern must make a reasonable effort to contact the patient or person authorized to act on behalf of the patient. In the case of potential drug therapy problems which could endanger the health of the patient, prior to dispensing the prescription, the pharmacist must personally contact the patient or person authorized to act on behalf of the patient. The commentator suggests that these provisions should be applicable to on-premises delivery situations as well. However, the amendment requires the pharmacist or pharmacy intern to personally offer counseling to every patient or person authorized to act on behalf of the patient, when the prescription is delivered on the premises of the pharmacy. Therefore, the exceptions are inapplicable to on-premises delivery situations.

Comment: The vice-president of a corporation that operates a mail order pharmacy in New York State states that section 63.6(a)(9) of the proposed regulation overly restricts access to common electronic prescription records. He states that the provision would prohibit access to aggregate data about patients which is critical to clinical and marketing research. The vice-president of an organization of mail-order pharmacies and managed care firms also was concerned that this provision could stifle valuable research, even when that access utilizes appropriate safeguards that either prevent access to or otherwise protect individually identifiable information.

Response: This provision is needed to protect the confidentiality of patient information. It requires that a pharmacy that accesses a common electronic file or data base used to maintain required dispensing information shall only access this information upon the express request of the patient or person authorized to act on behalf of the patient. The intent of the regulation is to protect personally identifiable information, not aggregate information that is not personally identifiable. Accordingly, a nonsubstantial change will be made by inserting the words "personally identifiable" in the regulation in order to make it clear that the regulation restricts access to "required personally identifiable dispensing information". The amendment does not restrict access to aggregate information that is not personally identifiable.

Comment: The vice-president of an organization of mail-order pharmacies and managed care firms questions "why therapeutic substitution (use of therapeutic alternatives) requires a telephone offer to counsel."

Response: In the case of off-premises delivery of prescriptions, the proposed regulation requires a written offer of counseling with each prescription. When the prescription is a prescriber approved alternative drug, the amendment also requires a special written notification and requires a pharmacist or pharmacy intern to make a reasonable effort to contact a patient or person authorized to act on behalf of the patient by telephone in order to personally offer counseling. This is a reasonable measure designed to provide the patient or person authorized to act on behalf the patient with counseling opportunities when there is a prescriber approved drug change.

Comment: The vice-president of an organization of mail-order pharmacies and managed care firms states that requiring the pharmacist to personally contact the patient when the pharmacist determines that there are potential drug therapy problems would create patient uncertainty that could discourage the patient from taking his or her medication. The commentator states that "pharmacists addressing potential drug therapy issues generally will contact the physician before seeking to contact the patient." The commentator states that the regulation rejects this practice and is counterproductive.

Response: The proposed amendment constitutes a reasonable measure to protect the health of patients. For off-premises delivery or prescriptions, it requires that, prior to dispensing a prescription, the pharmacist or pharmacy intern must personally contact the patient or person authorized to act on behalf of the patient to offer counseling, when the pharmacist or pharmacy intern determines that there are potential drug therapy problems which could endanger the health of the patient. The regulation requires that the contact be made prior to dispensing the prescription. The regulation does not prevent the pharmacist or pharmacy intern from contacting the prescribing physician to inquire about the prescription, as suggested by the commentator. If the prescribing physician provides the pharmacist or pharmacy intern with information that results in the pharmacist or pharmacy intern determining that there are no potential drug therapy problems which could endanger the health of the patient, the regulation does not require the pharmacist or pharmacy intern to contact the patient.

Department of Health

NOTICE OF ADOPTION

Expedited HIV Testing of Women and Newborns

I.D. No. HLT-51-98-00007-A
Filing No. 693
Filing date: April 29, 1999
Effective date: Aug. 1, 1999

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of sections 58-8.1—58-8.3 and 69-1.3 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 2500-a, 2500-f and 576

Subject: Expedited HIV testing of women and newborns.

Purpose: To insure that women with unknown HIV status receive expedited HIV testing for themselves or on their newborns in order to identify persons at risk and provide appropriate care.

Text was published in the notice of proposed rule making, I.D. No. HLT-51-98-00007-P, Issue of December 23, 1998.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, FAX: (518) 486-4834, E-mail: B0019b@health.state.ny.us

Assessment of Public Comment

Twenty-six letters of comment were received in response to a Notice of Proposed Rule Making in the December 23, 1998 State Register addressing expedited HIV testing of women and newborns, pursuant to the authority of Public Health Law, sections 576, 2500-a and 2500-f. Fifteen organizations and individuals submitted letters which included identical language. Two respondents wrote opposing the proposal; three wanted mandatory HIV testing for all pregnant women; twenty-one offered conditional support for the proposed rule. The proposal would amend Title 10 NYCRR sections 58-8.1, 58-8.2, 58-8.3 and 69-1.3 to ensure that the HIV exposure status is available for all newborns whose mothers have not been tested for HIV or for whom the HIV test results are not available at delivery; its purpose is to allow early access to prophylaxis to prevent perinatal HIV transmission. The specific comments received and the Department's position on these comments can be summarized as follows:

FINANCIAL IMPACT

Several writers, including the Healthcare Association of New York State (HANYS) and the Greater New York Hospital Association (GNYHA), believe that the implementation of this regulation will greatly increase the financial burden to hospitals. They comment that health facilities will incur added expenses related to (1) the cost of HIV testing for women not tested during pregnancy, (2) additional, intensive counseling sessions, (3) the time and effort needed to locate patients who were dis-

charged prior to receiving the expedited HIV test results and, (4) the cost of ZDV prophylaxis for the uninsured. These writers ask that the State (a) provide adequate financial resources to support the cost of pre and post-test counseling and on-site, expedited HIV testing, (b) compel managed care plans and other insurers to pay for this mandated testing and, (c) develop a mechanism for utilizing State ADAP monies to cover the costs of treating the uninsured.

Discussion

The proposed regulations require hospitals, birthing centers and birth attendants to arrange immediate HIV testing of the mother, with her consent, or her newborn, with results to be available as soon as possible, but in no event longer than 48 hours. It is the Department's intent that 48 hours is the outside limit of what is acceptable, not the program goal, and that results will be made available as soon as possible. The Department expects, based on the hepatitis B prevention program which imposed similar requirements, that the HIV test result can usually be returned in time to achieve the goal of optimal preventive therapy, which means initiation of prophylaxis in the intrapartum period, before the mother and newborn leave the hospital. With a short turnaround time, health facilities should realize savings by not having to employ outreach staff to find mothers after discharge since post-test counseling can be done while the mother is still in the hospital. Additional provider costs associated with actual performance of the expedited HIV tests are medically appropriate and must be considered part of labor and delivery costs.

The Department agrees that funding mechanisms should be explored to address the cost of in-hospital testing. The Department is examining various options involving temporary Medicaid reimbursement to help defray the cost of counseling and testing in the delivery setting until increases in prenatal testing occur and less expensive testing technologies become available. However, the best, most cost-effective approach is to increase the incidence of HIV testing during prenatal care.

Current regulations require that all delivering women receive an assessment of their HIV testing status and receive core counseling. If the assessment determines that the woman has not been HIV tested, the facility must provide expanded HIV counseling to the woman. Under the proposed regulation, additional costs for expanded counseling will be incurred for those women tested prior to the pregnancy who currently do not require such counseling. To limit their financial burden for in-hospital HIV counseling and testing, health care facilities should strongly encourage all practitioners whose patients deliver at their hospitals or birthing centers to actively promote prenatal testing and reduce the number of women who require counseling in the delivery setting.

LABORATORY ISSUES

Several comments concerned the laboratories that serve New York's health care facilities. Writers express doubt about laboratory capacity, question if participating labs would be able to guarantee a 48-hour turnaround time for HIV test results, and ask for clarification about testing methodologies (ELISA, SUDS, ORASURE) and specimen source (*i.e.*, heelstick *v.* cord blood). To limit the possibility of false-positive test results, numerous agencies and organizations, including the HIV Law Project, the Minority Task Force on AIDS, NOW NYC (National Organization for Women), and Voices of Women of Color Against HIV/AIDS (VOW), ask that the State assure that the 48-hour testing time frame allows for both initial and confirmatory testing.

Discussion

The Department of Health is informing the clinical laboratory community of the proposed regulations and is encouraging them to provide HIV testing within the required turnaround time. It is anticipated that laboratory capacity will be further increased by the Department's plan to fast-track the approval process for interested laboratories holding diagnostic immunology permits to perform HIV screening.

The purpose of expedited testing is the initiation of prophylaxis to prevent perinatal HIV transmission in the intrapartum period or to the newborn immediately after birth. Therefore, preliminary results will be reported with appropriate counseling regarding the meaning of the test results and the necessity for confirmatory testing. New York State will provide laboratories with recommendations to reduce false positive test results. Information regarding testing methodologies and specimen source will be distributed with the Department of Health Memorandum implementing the expedited testing program.

LEGAL LIABILITY

Many writers express concern about false positive test results and ask that the State insure that laboratories, health care providers, and facilities are not held legally liable for the consequences of providing preliminary false positive HIV test results.

Discussion

The Department has proposed an amendment to the regulation governing HIV testing (10 NYCRR, Subpart 58-8) to allow New York State-permitted laboratories to report the results of HIV screening tests without confirmation (*e.g.* Western Blot) when requested by a physician or other authorized person. This amendment is consistent with U.S. Public Health Service (USPHS) recommendations, issued earlier this year, that health providers report preliminary positive HIV test results before confirmatory results are available in situations where tested persons would benefit from knowledge of the test result (MMWR 1998; 47 (no. 11)). Expedited HIV testing and the reporting of preliminary results in the delivery setting was specifically mentioned as an example of such a situation since early identification allows access to ZDV prophylaxis to prevent perinatal transmission when the HIV-positive mother has not been tested in pregnancy or when her test result is not available. Preliminary test results will be returned with a notation to the attending physician explaining the preliminary nature of the results. The Department will provide guidance to the physician in interpreting preliminary test results. Ultimately, it will be the responsibility of the attending physician to discuss the preliminary positive test result with the mother and make a recommendation about ZDV treatment as with any other test and treatment recommendation. Specific immunity from liability would require a statutory change, not a regulatory revision, and is not essential to protect the providers given the clinical recommendations from both the USPHS and the New York State Department of Health.

PROVIDER COMPLIANCE - PRENATAL COUNSELING REQUIREMENTS

The majority of respondents, including the fifteen organizations that submitted similar or identical letters, believe that the Department must clearly define the duty of providers to provide prenatal HIV counseling and offer testing to their patients, and warn that failure to do so will subject the practitioner to discipline by the Office of Professional Medical Conduct (OPMC) and expose them to the possibility of civil liability. These writers also call for the Department to (1) provide women with a mechanism for filing complaints against non-compliant providers, (2) strengthen the requirements for prenatal testing for managed care and Medicaid-managed care enrollees and, (3) require health care workers to provide social and mental health services, create adolescent protocols, and screen their clients for domestic violence issues.

Discussion

The Department of Health, with the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP), have transmitted numerous communications to prenatal providers informing them that prenatal HIV counseling, with the recommendation of testing, is the standard of care for all practitioners in all prenatal care settings. The Department is also urging hospitals and HMOs to improve the performance of their prenatal care system on HIV testing during pregnancy.

The Department recognizes the importance of monitoring compliance with this standard. Currently, provider compliance in regulated facilities is monitored by means of quality of care reviews conducted by IPRO, the Department's professional review organization. Prenatal testing is also monitored as a required quality indicator for Medicaid Managed Care.

To address consumer grievances, the Department is revising brochures related to prenatal/newborn HIV testing to include the Department of Health number that women can call to file complaints against providers.

EDUCATIONAL EFFORTS

Many writers urged the Department to (1) develop educational materials for pregnant women to explain the new program and convey the medical benefits of testing, (2) produce a form that facilities could provide to mothers in case of preliminary positive HIV test results, (3) educate physicians about the importance of prenatal testing, (4) assure that the appropriate counseling message is provided to individuals who will receive a preliminary test result (e.g., discuss accuracy of test and importance of confirmatory testing) and, (5) undertake a multi-media public education campaign regarding the need for prenatal HIV testing and the benefits of ZDV prophylaxis.

Discussion

The Department of Health agrees with the need to educate mothers, providers and facilities of this new initiative, and is in the process of developing educational materials to meet these needs. Further, the Department will undertake a comprehensive educational campaign around the new regulations that will include materials for pregnant women and health facilities. Written materials that describe the meaning of preliminary positive test results will also be developed. Other materials, already developed

for the prenatal counseling and testing program, will remain available to providers and consumers.

OTHER ISSUES

Several writers strongly endorsed mandatory testing of all pregnant women. Others, concerned about legal liability, ask that the Department adopt a consent form to include information about unconfirmed HIV testing and provide a separate consent for receiving preliminary HIV test results.

Discussion

Since the implementation of routine newborn HIV testing in February 1997, a consent form for testing of newborns has not been required. The Department will revise the form, Informed Consent to Perform an HIV Test, used if a pregnant woman wishes to be tested, to include information about expedited HIV testing. There will be no separate consent for receiving preliminary results since an explanation of preliminary results will be part of the counseling component. Further, all preliminary results will be confirmed.

SUMMARY

In conclusion, the Department does not believe the comments merit a revision of the regulation for expedited testing. The Department is addressing financing issues through the reimbursement system, laboratory issues through expedited processing of applications and technical assistance, and provider compliance through education and complaint investigation.

NOTICE OF ADOPTION

Schedule II and Certain Other Substances/Pharmacists

I.D. No. HLT-05-99-00010-A
Filing No. 703
Filing date: May 4, 1999
Effective date: May 19, 1999

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of sections 80.67, 80.69, 80.73 and 80.74 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 3308(2)

Subject: Schedule II and certain other substances/pharmacists.

Purpose: To allow pharmacists to complete certain missing information on an official New York State prescription.

Text was published in the notice of proposed rule making, I.D. No. HLT-05-99-00010-P, Issue of February 3, 1999.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, FAX: (518) 486-4834, E-mail: B0019b@health.state.ny.us

Assessment of Public Comment

The department received three letters commenting on the proposed regulations. All three letters were in support of the changes.

The Pharmacists Society of the State of New York stated that the changes "will go a long way in helping pharmacists provide the necessary medications to patients".

One writer suggested that we include "quantity" in the new section which delineated what information on the prescriptions pharmacists could not change. The writer apparently felt that the omission of the word "quantity" was an oversight by the department. However, we purposely did not include "quantity" because the intent of the regulations is to allow pharmacists, with authorization of a practitioner, to change information such as directions for use or dosage form (tablet to liquid), which may result in the change of the quantity.

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Reportable Communicable Diseases

I.D. No. HLT-20-99-00001-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of Parts 2 and 23 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 225(4), (5)(a), (5)(g) and (5)(h)

Subject: Reportable communicable diseases.

Purpose: To update the list of communicable diseases including sexually transmissable and nosocomial, which must be reported to the Department of Health.

Text of proposed rule: Subdivision (a) of section 2.1 is amended to read as follows:

Section 2.1 Communicable diseases designated: cases, suspected cases and certain carriers to be reported to the State Department of Health.

(a) When used in the Public Health Law and in this Chapter, the term infectious, contagious or communicable disease, shall be held to include the following diseases:

Amebiasis
Anthrax
Babesiosis
Botulism
Brucellosis
Campylobacteriosis
Chancroid
Chlamydia trachomatis infection
Cholera
Crytosporidiosis
Cyclosporiasis
Diptheria
[Drug-resistant Streptococcus pneumoniae invasive disease]
E. coli 0157:H7 infections
Ehrlichiosis
Encephalitis
Giardiasis
Gonococcal infection
[Granuloma inguinale]
Group A Streptococcal invasive disease
Group B Streptococcal invasive disease
Hantavirus
Hemolytic uremic syndrome
Hempohilus influenza invasive disease
Hepatitis (A; B; C[; nonA, nonB])
[Histoplasmosis, new cases]
Hospital-associated infections (as defined in section 2.2 of this Part)
[Kawasaki syndrome]
Leginellosis
[Leprosy]
[Leptospirosis]
Listeriosis
Lyme disease
Lymphogranuloma venereum
Malaria
Measles
Meningitis
  [Aseptic]
  Hemophilus
  Meningococcal
  Other (specify type)
Meningococcemia
Mumps
Pertussis (whooping cough)
Plague
Poliomyelitis
Psittacosis
Rabies
[Reye's syndrome]
Rocky Mountain spotted fever
Rubella
Congenital rubella syndrome
Salmonellosis
Shigellosis
Streptococcus pneumoniae invasive disease
Syphilis, specify stage
Tetanus
Toxic Shock Syndrome
Trichinosis
Tuberculosis, current disease (specify site)
Tularemia
Typhoid
[Typhus]
Yellow Fever

debtor does not have sufficient income or other financial resources to pay the monthly principal and interest payments or when equity in a residential property is stripped by repeated re-financings, primarily by the charging of excessive points and fees, when the borrower realizes no economic benefit.

Since the Legislature established a number of different standards regarding disclosures and practices in the making of such residential mortgage loans by enactment of section 6-l of the Banking Law, it is necessary that the comparative standards in Part 41 be made consistent with section 6-l.

Further, it is also necessary that certain provisions of section 6-l be clarified by the amendments to Part 41 in order that lenders and brokers may be in compliance with the requirements section 6-l when making such loans, given that such provisions are not otherwise defined by section 6-l nor has the Legislature provided any other guidance which would clarify the intended meaning of those provisions. The clarifying provisions of the amendments to Part 41 address determining "corroboration by independent verification" of a borrower's repayment ability and "net tangible benefit" to a borrower, both of which are critical standards in assessing whether instances of predatory lending have occurred.

4. Costs:

The amendments to Part 41 should impose no additional cost upon mortgage lenders or brokers not otherwise imposed by the enactment of the comparative provisions of section 6-l of the Banking law to which the amendments conform Part 41. The amendments impose no additional cost upon the Banking Department or any other state agency, or any unit of local government.

5. Local government mandates:

The amendments to Part 41 do not impose any requirements or burdens upon any units of local government.

6. Paperwork:

The amendments to Part 41 do not impose any new paperwork requirements.

7. Duplication:

None.

8. Alternatives:

The Banking Department considered whether to forego amending Part 41 or to repeal Part 41 in light of the enactment of section 6-l of the Banking Law, given that section 6-l may be viewed legally as occupying the field of regulation of high cost home loans in the state of New York. It was determined that Part 41 provides a more extensive regulatory scheme than section 6-l for the making of such mortgage loans, and therefore it is appropriate to make the non-conforming provisions of Part 41 consistent with the comparative statutory provisions of section 6-l. In addition, the provisions of section 6-l that are clarified by the amendments will eliminate uncertainty among mortgage lenders and brokers in the making of such loans by articulating appropriate conditions, which such lenders and brokers must meet in order to be in compliance with certain non-defined statutory standards established by section 6-l.

9. Federal standards:

In the initial promulgation of Part 41, the Banking Department stated the regulations established thresholds that were lower than the thresholds set by the Home Ownership Equity Protection Act (HOEPA). Subsequently, federal regulators modified the annual percentage rate threshold for first mortgages under HOEPA by making it identical to the corresponding threshold in Part 41. Section 6-l of the Banking Law establishes modified points and fees thresholds in certain instances that are more lenient for brokers and lenders than the comparable threshold in HOEPA. The definition of points and fees, in part, established by section 6-l refers and therefore corresponds to the comparative definition in HOEPA. The amendments would adopt the thresholds and definitions established by section 6-l.

10. Compliance schedule:

None. Any modification of existing disclosures or practices by lenders or brokers in regard to any cost home loans made on or after April 1, 2003 are the result of standards established by section 6-l of the Banking Law. Chapter 626, which enacted section 6-l, was approved on October 3, 2002, and brokers and lenders have had sufficient time to familiarize themselves with these standards and subsequently modify their disclosures and practices, if necessary, in order to comply with the standards of 6-l and the proposed amendments to Part 41.

Regulatory Flexibility Analysis

A Regulatory Flexibility Analysis for Small Business and Local Government is not submitted, based on the Department's conclusion that the amendments to Part 41 will not impose any adverse economic or technological impact upon small business beyond any such effects that may be caused by the requirements established by section 6-l of the Banking Law, applicable to the making of high cost home loans, to which the amendments conform Part 41. The amendments will not impose any adverse economic or technological impact upon local governments. The proposed amendments will impose no adverse reporting, recordkeeping or compliance requirements on small businesses or local governments.

Rural Area Flexibility Analysis

A Rural Area Flexibility Analysis for Small Business and Local Government is not submitted, based on the Department's conclusion that the amendments to Part 41 will not impose any adverse economic impact upon private entities in rural areas beyond any such effects that may be caused by the requirements established by section 6-l of the Banking Law, applicable to the making of high cost home loans, to which the amendments conform Part 41. The amendments will not impose any adverse economic impact upon public entities in rural areas. The proposed amendments will impose no adverse reporting, recordkeeping or compliance requirements private on public entities in rural areas.

Job Impact Statement

A Job Impact Statement is not attached because the proposed amendments to Part 41 will not have any appreciable and/or substantial adverse impact on jobs and employment opportunities beyond any such effects that may be caused by the requirements established by section 6-l of the Banking Law, applicable to the making of high cost home loans, to which the amendments conform Part 41.

State Board of Elections

NOTICE OF EXPIRATION

The following notice has expired and can not be reconsidered unless the State Board of Elections publishes a new notice of proposed rule making in the NYS *Register*.

Campaign Finance Limits

I.D. No.	Proposed	Expiration Date
SBE-08-03-00003-P	February 26, 2003	August 25, 2003

Department of Health

EMERGENCY RULE MAKING

Expedite HIV Testing of Women and Newborns

I.D. No. HLT-36-03-00003-E
Filing No. 920
Filing date: Aug. 25, 2003
Effective date: Nov. 1, 2003

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 69-1.3(b) of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 576, 2500-a and 2500-f

Finding of necessity for emergency rule: Preservation of public health and general welfare.

Specific reasons underlying the finding of necessity: Immediate adoption of this amendment is necessary to protect the public health and welfare and to prevent harm to infants born in New York State. The New York State Department of Health is actively engaged in the prevention of mother-to-child HIV transmission. Recent advances in medical knowledge concerning the prevention of perinatal HIV transmission have demonstrated that antiretroviral therapy, given to prevent HIV transmission, is most efficacious when given prenatally, during labor, or within the first 12 hours of an infant's birth. Although approximately 94 percent of women are tested for HIV during prenatal care, the HIV status of six percent is

unknown at presentation for delivery. Women at high risk for HIV who have received no prenatal care are over-represented within this group. In 1999, the Department implemented expedited HIV testing in the labor and delivery setting so that providers can initiate partial antiretroviral regimens either to the mother in labor or to the infant immediately after birth. The turnaround time for reporting the result was 48 hours from the drawing of blood from the mother (with her consent) or from the newborn (no consent required).

Heretofore, the program has been limited by the lack of a point-of-care rapid HIV test. In cases of HIV-exposure in a newborn where prenatal and/or intrapartum antiretroviral therapy (ART) were not given, studies have shown that therapy must be started for the newborn within 12 hours of birth to be effective in reducing the risk of transmission. The current expedited HIV testing protocols in most New York State birth facilities do not meet this 12-hour timeline for initiating prophylactic newborn ART. In 2001 to 2002, over 1400 HIV-infected women gave birth in New York State. Of these, one hundred mother/infant pairs were first identified as HIV-infected/exposed through expedited HIV testing in the labor, delivery or in the immediate newborn period. In the vast majority of cases (98 of 100), the median time from the mother's admission to the collection of the specimen for expedited HIV testing was 2.5 hours. However, even when testing was performed on-site, results were not returned for at least 20 hours, and treatment was not initiated in the newborn until 22.5 hours after birth. Clearly, achieving timelier reporting of expedited HIV test results is hampered by the lack of a point-of-care rapid test.

In November 2002, the U.S. Food and Drug Administration approved the first of a new generation of point-of-care rapid HIV tests. The test is waived under the Clinical Laboratories Improvement Act (CLIA) and may be performed under the supervision of a licensed physician, nurse practitioner or physician assistant, provided the facility performing the test has obtained a CLIA number and is registered with the Clinical Laboratories Evaluation Program (CLEP).

The availability of point-of-care HIV testing offers providers the opportunity to intervene during this most critical time frame for perinatal HIV transmission: labor and delivery. The purpose of this emergency and proposed rule making, which amends 10 NYCRR, Subpart 69-1.3(l)(2), is to ensure that the HIV exposure status is available as soon as possible for all newborns whose mothers have not been tested for HIV during the current pregnancy or for whom HIV test results are not available at delivery. By requiring a maximum turnaround time of twelve hours from the time the mother consents to testing or from the time of the infant's birth to the receipt of the result of the expedited HIV test, medical providers and patients will have information that is critical for the administration of antiretroviral medication during labor and delivery and to the newborn immediately after birth.

As a result of the Expedited HIV Testing regulations (effective August 1999) and the consequent increase of prenatal and expedited HIV testing, along with the prompt initiation of treatment to HIV-infected mothers, the rates of perinatal HIV transmission in New York State have decreased: from 10.9% in 1997 to 3.9% in 2001. New, rapid, point-of-care HIV testing technology can provide test results within 20 to 40 minutes. In most cases, this technology will allow obstetricians to have preliminary HIV test results before the mother delivers, when the initiation of antiretroviral therapy can be of significant benefit. In light of the advances in testing technology, the Department is proposing a regulatory change to 10NYCRR 69-1.3(l)(2) that would apply in cases where a woman presents for delivery with no documentation of her HIV status. In these cases, the amended regulation would require the birth facility to arrange an immediate HIV screening test of the mother with her consent or of her newborn without consent with results available as soon as possible, but in no event longer than 12 hours after the mother provides consent for testing or, if she does not consent, 12 hours after the time of the infant's birth. Reducing the turnaround time for expedited HIV testing allows health care providers to provide antiretroviral therapy in time to reduce the risk of mother-to-child transmission of HIV.

The emergency rule will take effect on November 1, 2003.

Subject: Expedited HIV testing of women and newborns.

Purpose: To enhance protection of newborns.

Text of emergency rule: Paragraph (2) of Subdivision (l) of Section 69-1.3 of NYCRR is amended to read as follows:

(2) if no HIV test result obtained during the current pregnancy is available for the mother not known to be HIV-infected, arrange an immediate screening test of the mother with her consent or of her newborn for HIV antibody with results available as soon as practicable, but in no event longer than [48 hours] *12 hours after the mother provides consent for testing or, if she does not consent, 12 hours after the time of the infant's birth.*

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire November 22, 2003.

Text of emergency rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, fax: (518) 486-4834, e-mail: regsqna@health.state.ny.us

Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) section 2500-f requires the commissioner to promulgate regulations to implement a comprehensive program for the testing of newborns for HIV and/or the presence of HIV antibodies. The proposed revision to the regulation amends the current comprehensive program in response to recent advances in medical knowledge concerning the prevention of perinatal HIV transmission and the availability of rapid HIV testing technology, with at least one device suitable for "point-of-care" use.

Legislative Objectives:

In the memorandum accompanying the comprehensive newborn testing bill (Chapter 220 of the Laws of 1996), the legislature indicated its purpose was "to ensure that newborns who are born exposed to HIV receive prompt and immediate care and treatment and counseling that can enhance, prolong and possibly save their lives". Transmission of HIV from mother to newborn can be prevented in many cases by the administration of antiretroviral medications, which are recommended to be given to the mother starting during the second trimester of pregnancy, continued during labor, and given to the newborn after birth. The proposed amendment to 10 NYCRR, Subpart 69-1.3(2) will ensure that the HIV exposure status is available for all newborns whose mothers have not been tested for HIV during the current pregnancy or for whom HIV test results are not available at delivery. By requiring a maximum turnaround time of twelve hours from the time of the mother's consent to testing or of the time of the infant's birth to the receipt of the result of the expedited HIV test, medical providers and patients will have information that is critical for the timely and efficacious administration of antiretroviral medication.

Needs and Benefits:

Improvements in medical knowledge and major advances in medical technology have occurred since the current program for the Expedited HIV Testing of Women and Newborns was implemented in August 1999. To date, the success of New York State's efforts to reduce perinatal HIV transmission to the lowest possible level has resulted in a decrease in the rate of perinatal HIV transmission for all HIV-exposed infants born in New York from 10.9% in 1997 to 3.9% in 2001. However, transmission is still occurring in instances where the HIV exposure status of an infant was identified too late to provide effective intervention. In such infants therapy must begin within 12 hours of birth to be effective in reducing the risk of transmission. In an addendum to the NYSDOH PCR study, published in the New England Journal of Medicine on 4/1/99, it was demonstrated that when ARV was given to the newborn within 12 hours of birth there was a 5.9% rate of HIV transmission. There was no significant benefit if ARV was begun after 12 hours birth as the transmission rate increased to 25%. The ability to have results from expedited HIV testing as soon as possible in cases where there was no history of prenatal HIV testing, coupled with the administration of prophylactic antiretroviral therapy, ideally during labor but no later than 12 hours of birth, is of vital importance in further reducing perinatal HIV transmission. To reduce perinatal HIV transmission to the greatest extent possible, facilities are urged not to view the 12-hour turnaround time as the goal of testing, but as the outside limit for offering effective therapeutic interventions to prevent transmission of HIV from the mother to her newborn.

Costs:

Costs to State and Local Governments:

The cost to State Government is minimal and can be covered by existing programs and staff. There is no cost to local government except to the extent they own and operate maternity hospitals. Any cost to the State and local governments will be reduced by the savings to the Medicaid program by reducing the costs of care as fewer incidences of HIV transmission to newborns occur. Local governments that operate medical facilities will incur costs as described in the section on Costs to Regulated Parties noted below.

Costs to Regulated Parties:

The approved rapid test is CLIA- waived due to low complexity and may be done at the point-of-care either under the supervision of a licensed laboratory or under a limited license under the supervision of a clinician in the labor and delivery sitting.

The vast majority (138) of the 159 birthing facilities currently hold a clinical laboratory permit in HIV testing or are eligible for fast-track approval for a permit in HIV testing. These facilities already have or could readily develop the capability of generating HIV test results on-site within twelve hours without additional costs. This is especially true for facilities with around-the-clock centralized laboratory services. Reagent, equipment, personnel and overhead costs for testing a single specimen using a instrument-based method (*i.e.,* ELISA) are approximately $15 for routine testing, but up to ten times that amount for 'on demand' (STAT) testing. Birth facilities would incur costs directly related to this proposal whenever expedited testing needed to be performed in the laboratory outside normal testing, and qualified staff needs to be called in specifically to run one test. Facilities using such an on-call staffing approach to expedited newborn HIV testing would incur up to 1.5 times the usual hourly wage for a medical technologist, which is estimated to be $40 per hour (including benefits) or $50 per hour (including benefits) if the technologist is a supervisor.

Facilities without current capacity to consistently generate results in 12 hours or less are encouraged to consider bringing HIV testing in-house and/or locating HIV testing in the labor and delivery setting whenever possible. Costs of introducing in-house HIV testing into either a centralized laboratory or the labor and delivery suite includes costs of reagents, devices and human resources necessary to validate the test method and write protocols, at an estimated maximum one-time cost of $1000. Point-of-care testing on the labor and delivery floor may be performed under supervision of the facility's central laboratory director at no additional cost, or conducted without such linkage, *i.e.,* as a limited service laboratory. The latter option would require a fee of $100 to register the alternative testing site with the Department. Other minimal costs include costs of initial training and ongoing competency assessment of non-laboratory testing personnel, *i.e.,* labor and delivery nursing staff, although technologists may also travel to patient floors to lend their expertise in the performance of tests and interpretation of results. The cost of conducting initial training for a group of 8 or fewer nurses can be estimated by multiplying the hourly wage of a supervisor-qualified technologist by 8 hours of training in device use, troubleshooting, record keeping and quality assurance activities, and adding the cost of 25 test devices. The device designated for point-of-care testing has a list price of $10.00 -$15.00 for each test kit.

Overall, the Department estimates that the costs of performing tests at the point-of-care are likely to be less than, or equal to, the costs of expedited HIV tests currently performed in a centralized laboratory. This estimate is based on the fact that rapid HIV tests do not require the purchase or maintenance of expensive laboratory equipment and that the cost of testing devices (OraQuick®, SUDS®) and the salaries of personnel conducting the tests are comparable. The cost of expedited HIV testing done in a reference laboratory (cost at one commercial laboratory is $75.00/expedited test) may not change, but birth facilities using these laboratories will have to ensure that they will be able to report results within the 12-hour turnaround time. The cost to the birth facility in time spent to provide pre-test HIV counseling is not expected to differ from the current cost of expedited HIV testing, which includes reimbursement rates of $52 for testing and $44 for counseling ($96.00/expedited test).

In light of the advances in testing technology, and the benefits of early initiation of antiretroviral therapy to prevent mother-to-child transmission of HIV, many birth facilities will opt to use a rapid HIV test device that generates results in a half-hour or less. Facilities have two options when performing rapid HIV testing on-site. Under the first option, they may perform the test under the main laboratory's permit, either in the laboratory itself or at the point-of-care under the supervision of the laboratory. Under the second option, facilities may register the labor and delivery suite as a Limited Service Laboratory and perform the test at point-of-care. Laboratories with a comprehensive HIV testing permit may choose to conduct "stat" testing 24 hours a day, 7 days a week using standard enzyme immunosorbent assay (EIA) testing technology within the 12 hour time limit. However, testing using rapid testing devices is encouraged to obtain HIV tests results as soon as possible. While procedures such as immediate transport of specimens by courier to a near-by laboratory, may, in theory, be effective for meeting a 12-hour turn-around-time, the Department's experience with such complex arrangements shows them to usually be an unacceptable alternative for on-site expedited testing.

Option 1 for rapid HIV testing: on-site testing with oversight by a centralized laboratory. Current PHL requires facilities performing HIV antibody screening to hold a permit in HIV testing. Of the 159 regulated hospitals and birthing centers affected by this amendment, 138 hold laboratory permits that include HIV and/or diagnostic immunology testing, the latter of which would be allowed, in response to the adoption of this amendment, to add HIV testing through a fast-track mechanism. For any of these 138 facilities that choose to add a new test to an existing HIV or fast-tracked diagnostic immunology permit, costs for protocol development, staff training, test validation and implementation of quality assurance measures are expected to be approximately $1000. There are no additional costs associated with modifying an existing permit to add a category or test. The remaining 21 birth facilities would incur an additional cost if they seek to provide HIV testing on-site, either under a comprehensive permit at an initial cost of $1000 plus annual fees based on gross annual receipts, or, using option 2 below, under a limited service laboratory registration at an annual registration fee of $100.

Option 2. On-site testing at the point-of-care, *i.e.,* in the labor and delivery suite or midwifery clinic, regardless of whether or not the facility currently operates a comprehensive laboratory on-site. Facilities choosing this option would incur a cost of $100 annually for registration as a limited service laboratory. Point-of-care testing sites would also incur small costs for initial training and ongoing competency assessment of non-laboratorial testing personnel, *i.e.,* labor and delivery nurses. The cost of conducting initial training for a group of 8 or fewer nurses can be estimated by multiplying the hourly wage of a supervisor-qualified technologist by 8 hours of training (on average approximately $50.00/hour by 8 hours equating to $400.00) in device use, troubleshooting, record keeping and quality assurance activities, and adding the cost of 25 test devices ($15 per test by 25 = $375). Therefore, the total training costs would be approximately $775. Cost attributable to periodic competency assessments of one to two hours could be calculated using the same formula. A materials cost of approximately $10.00 - $15.00 a test would be attributable to one single-use device and control materials.

Under either option, costs would be offset by revenue generated from third party billing, including Medicaid. Costs of expedited HIV testing in labor, delivery and newborn nursery settings will continue to diminish as efforts to increase prenatal HIV counseling and testing succeed. Any other provider costs associated with rapid HIV testing in the labor and delivery settings are medically appropriate and must continue to be considered part of labor and delivery costs.

Costs to the Department of Health:

The Department will use existing staff to review and approve HIV testing applications, and to conduct on-site surveys of applicant facilities.

Local Government Mandates:

This amendment to the current regulation will not impose any new program services, duties or responsibilities upon any county, city, town, village, school district, fire district or any other special district, except for those local governments operating hospitals with maternity services.

Paperwork:

Paperwork related to point-of-care rapid HIV tests does not significantly differ from that currently required by expedited testing regulations. This paperwork includes the clinician's written order for testing, notation of the completion of pre- and post-test counseling, documentation of the acquisition of the test specimen and recording the test result in the medical record. Some paperwork will be required of hospitals that apply for a limited permit to perform CLIA-waived testing, for laboratories that seek an addition to an existing permit, and for those hospital laboratories that choose to seek a new HIV testing permit.

Duplication:

None.

Alternatives:

There are no alternatives to the 12-hour time limit proposed by this amendment because a longer time period would result in some HIV-exposed infants not being detected in time to administer therapy to prevent HIV transmission. Because advances in scientific knowledge and medical technology allow for rapid HIV testing, the Department determined that the proposed revision to the regulation is the best approach to protect the public health.

Federal Standards:

There are currently no Federal regulations related to prenatal or newborn testing. The Federal government has provided only recommendations and guidelines for these activities. The proposed regulatory change is consistent with current federal recommendations.

Compliance Schedule:

The Department has already advised regulated parties that this amendment will be going into place. The Department understands that many facilities are already undertaking activities to implement rapid HIV testing. The Department expects that facilities will be in compliance by the emergency regulation's November 1, 2003 effective date.

Regulatory Flexibility Analysis

Effect on Small Businesses:

The proposed rule will impact an estimated three birth hospitals and four birthing centers that meet the definition of a small business (independently owned and employs 100 or fewer individuals). No real impact on small businesses is expected, since regulations requiring expedited HIV testing are already in place. No new costs to local governments are anticipated, except for those operating hospitals with maternity services.

Compliance Requirements:

The reporting, recordkeeping and other affirmative acts that impact small businesses or local governments would not change with this proposed amendment. Current regulations require hospitals and birthing centers to ensure that all mothers who present for delivery have a negative HIV test result from the current pregnancy or a positive HIV test result during or prior to the pregnancy. If no test result is documented, the mother is offered consented expedited HIV testing. If she declines, an expedited HIV test is performed on her infant, without consent. Current regulations require a turnaround time for preliminary HIV test results of no more than 48 hours from the time the specimen is collected. The proposed rule change would decrease the turnaround time to within 12 hours after the mother's consent for testing, or if she does not consent, within 12 hours of the infant's birth.

Professional Services:

Impacted small businesses and local governments would need the same staff of health care providers (doctors, nurses, nurse practitioners, physicians assistants), counseling and support staff as they currently employ. No additional staff would be needed.

Compliance Costs:

The percentage of women receiving prenatal counseling and testing is steadily increasing, and the need for expedited HIV testing in the intrapartum period is decreasing. As of December 2002, hospital data indicate that approximately 94% of all women giving birth have documentation of their HIV status before delivery. This rate was 62% in July 1999, one month before expedited testing in delivery settings was implemented. Using these data, the need for expedited HIV testing has clearly decreased through the years, from an estimated 120,000 mothers/infants in 1999 to less than 15,000 in 2002. At $52 per test, the total statewide testing cost in 1999, estimated to be $6.24 million per year, has decreased to $780,000 per year. This number is expected to continue to decline as more women accept prenatal HIV testing. The cost for expedited HIV testing using rapid, point-of-care testing kits is not expected to exceed the cost of expedited testing as currently performed and would be considerably less if facilities choose to take advantage of point-of-care rapid testing.

Economic and Technological Feasibility:

The proposed amendment to the regulatory program is economically and technologically feasible since it is not anticipated that additional staff would be required and rapid, point-of-care testing technology is readily available.

Minimizing Adverse Impact:

Provider costs associated with rapid, point-of-care expedited HIV testing are medically appropriate and must be considered part of labor and delivery costs. Current reimbursement rates for expedited HIV testing subsidize the costs incurred by the delivery facility ($44 for counseling and $52 for testing), and will continue. Since preventing HIV transmission saves the high treatment costs for HIV-infected persons, expedited HIV testing in the labor and delivery setting is actually cost effective. Hospitals and birthing centers also realize savings as a result of this program by not having to employ outreach staff to find mothers after discharge since post-test counseling can be done while the mother is still in the hospital.

Small Businesses and Local Government Participation:

In advance of publication, the proposed amendment to the regulation was discussed at a two hour meeting held on March 23, 2003 by the Greater New York Hospital Association with representatives from 31 birthing facilities and the Health and Hospitals Corporation attending, and on April 30, 2003 at a video conference hosted by the Hospital Association of New York State and broadcast to birthing facilities statewide.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

Forty-four counties meet the definition of a rural area (population less than 200,000) and an additional 11 counties have towns that are classified as rural (towns with population densities of 200 persons or less per square mile). The proposed amendment to the current regulation applies to hospitals and birthing facilities in 55 counties. These facilities already follow the Expedited HIV Testing regulation; significant program expansion is not expected.

Reporting, Recordkeeping and Other Compliance Requirements:

The reporting, recordkeeping and other affirmative acts that will impact hospitals in rural areas have already been undertaken to comply with the Expedited HIV Testing regulation. Current regulations require maternity hospitals and freestanding birthing centers to ensure that all women who present for delivery with no documentation of HIV status are counseled about expedited HIV testing, and, arrange that an immediate HIV screening test of the mother with her consent or of her newborn without consent is performed. Technological advances mean that rapid HIV screening tests can now be performed at the point-of-care. Birth facilities can choose to use the new technology for rapid HIV testing, or to continue with the expedited HIV testing program already in place at their facilities. If the new technology is not chosen, the decreased turnaround time for the return of preliminary test results will have to be negotiated with either the hospital-based or the commercial laboratories that perform expedited HIV testing.

Professional Services:

Hospitals in rural areas would not need additional professional staff to provide this service for women without known HIV test results.

Costs:

According to current annualized data, fewer than 50 maternity patients or newborns in any hospital or birthing center operated in rural areas require expedited HIV testing. This number will continue to diminish as efforts to promote prenatal HIV testing succeed. If an average of $52 (the total per test average cost of ELISA or SUDS testing, exclusive of counseling) for each expedited HIV test is used to estimate the total cost of expedited testing (test device, equipment and personnel), the total annual cost for rapid expedited HIV testing in each rural birth facility will be approximately $2,600, or less, depending on the number of maternity patients or newborns needing rapid testing.

Minimizing Adverse Impact:

Additional provider costs associated with testing are medically appropriate and must be considered part of labor and delivery costs. However, preventing HIV transmission is cost effective because of the high cost of treatment for HIV-infected persons. Hospitals and birthing centers will realize savings as a result of this program by not having to employ outreach staff to find mothers after discharge since post-test counseling can be done while the mother is still in the hospital.

Rural Area Participation:

In advance of publication, the proposed amendment to the regulation was discussed at a two hour meeting held on March 23, 2003 by the Greater New York Hospital Association with representatives from 31 birthing facilities and the Health and Hospitals Corporation attending, and on April 30, 2003 at a video conference hosted by the Hospital Association of New York State and broadcast to birthing facilities statewide.

Job Impact Statement

A Job Impact Statement is not attached because this amended rule will not have a substantial adverse impact on jobs and employment opportunities as apparent from its nature and purpose.

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Newborn Screening

I.D. No. HLT-36-03-00008-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of section 69-1.2(b) of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2500-a

Subject: Newborn screening.

Purpose: To add three conditions to the current eight that comprise the New York State newborn screening panel.

Text of proposed rule: Section 69-1.2 Diseases and conditions tested.

(a) Unless a specific exemption is granted by the State Commissioner of Health, the testing required by sections 2500-a and 2500-f of the Public Health Law shall be done by the testing laboratory according to recognized clinical laboratory procedures.

(b) Diseases and conditions to be tested shall include: phenylketonuria, branched-chain ketonuria, homocystinuria, galactosemia, homozygous

sickle cell disease, hypothyroidism, biotinidase deficiency [and], human immunodeficiency virus (HIV) exposure and infection, *cystic fibrosis, congenital adrenal hyperplasia, and medium-chain acyl-CoA dehydrogenase deficiency (MCADD).*

Text of proposed rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, fax: (518) 486-4834, e-mail: regsqna@health.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) Section 2500-a requires institutions caring for infants 28 days or under of age, as well as persons required to register the birth of a child, to cause newborns to be tested for phenylketonuria, branched-chain ketonuria, homocystinuria, galactosemia, homozygous sickle cell disease, hypothyroidism, and other diseases and conditions to be designated by the Commissioner of Health. Specifically, PHL Section 2500-a (a) provides statutory authority for the Commissioner of Health to designate in regulation other diseases or conditions that would require newborn testing in accordance to the Department's mandate to prevent infant and child mortality, morbidity, and diseases and defects of childhood. Pursuant to this authority, biotinidase deficiency and human immunodeficiency virus (HIV) have been added to the newborn testing panel by regulatory amendment since the enactment of Section 2500-a.

Legislative Objectives:

In enacting PHL Section 2500-a, the Legislature intended to promote public health through mandatory screening of New York State newborns to detect those with serious but treatable neonatal conditions and to ensure their referral for medical intervention. This proposal, which would add three disorders to the list of seven genetic/congenital disorders and one infectious disease currently in regulation, is in keeping with the Legislature's public health aims of early identification and timely medical intervention for all the State's youngest citizens. The Legislature recently affirmed its objective for a healthy young citizenry by enacting a State budget with dedicated funding for expansion of the State's Newborn Screening Program's testing panel, applying new technologies for the most accurate and timely identification of affected infants. The Department anticipates this express commitment to maintaining a premier program to continue in the form of annual appropriations to ensure funding for staffing and non-personal services.

Needs and Benefits:

Following legislative enactment of PHL Section 2500-a, the New York State Newborn Screening Program began as a statewide mandatory initiative to detect infants with serious but treatable neonatal conditions, and refer those infants for immediate medical intervention and follow-up. Regulations promulgated by the Commissioner of Health in 10 NYCRR Subpart 69-1 set forth requirements for specimen collection, testing, result reporting and case follow-up. Data compiled from New York State's Newborn Screening Program and other states' programs have shown that timely intervention and treatment can drastically improve affected infants' survival chances and quality of life. Advancing technology, emerging novel medical treatments and rising public expectations for this critical public health program demand that the panel of screening conditions be expanded at this time through amendment of Subpart 69-1.2.

This amendment would add three disorders—cystic fibrosis (CF), congenital adrenal hyperplasia (CAH) and medium-chain acyl-CoA dehydrogenase deficiency (MCADD)—to the scope of newborn screening services already provided by the Department. The three new disorders meet established criteria applied worldwide for newborn screening program test panels. These criteria are: the conditions must be medically significant; their incidence and prevalence must represent a matter of public health concern, or they must affect a substantial number of newborns, so that the resulting cost to society for health care and lost productivity is significant; reliable assays for diagnosis of the conditions, suitable for large-scale population screening, must be available; and early detection of the disorders during the neonatal period must allow for medical intervention effective in amelioration, or prevention of medical complications and other consequences.

An American Academy of Pediatrics task force reviewing newborn screening has suggested that state newborn screening programs consider testing for CF—one of the most common serious inherited disorders. Chronic illness and even death can result from alterations in the viscosity (thickness) of body secretions, especially in the lungs, pancreas and gastrointestinal tract, caused by CF. Such alterations lead to impaired absorption of nutrients in the gastrointestinal tract, and eventual malnutrition and failure to thrive; as well as impaired lung function resulting in increased chronic bacterial bronchitis and abundant inflammation in the airways, respiratory failure, and even death. Early detection and intervention ensures improved infant nutritional status and linear growth, as well as more stable lung function. In New York State's birth population, CF has a combined incidence of one in 3,700 births, resulting in an expected annual incidence of 86 CF cases.

CAH is the third most common condition that can be detected by newborn screening and the most immediately lethal. This inherited endocrine disorder may cause sexual misassignment of female infants as male at birth, with eventual accelerated skeletal maturation and short stature in both sexes. Treatment with supplements slows precocious maturation, and surgery can correct genital malformations. CAH affects one in 5,000 newborns in the State, yielding an expected annual incidence of 50 cases. Testing for CAH is now a part of many states' screening profiles, including the neighboring states of Massachusetts, Rhode Island, Pennsylvania and New Jersey. In 1999, the Department received 25 unsolicited letters from physicians, endocrinology experts and families of affected infants, urging addition of CAH testing for New York's newborns.

MCADD is one of several abnormalities in the body's ability to metabolize fats, resulting in toxic build-up of fatty acids. Although the disorder's presentation is variable, it may cause hypoglycemia, lethargy, vomiting, seizures and coma. One-third of infants die during the first clinical episode, and MCADD is thought to be the cause of one to two percent of sudden infant deaths. Survivors of severe clinical episodes may experience muscle weakness, failure to thrive and cerebral palsy, as well as learning difficulties. However, the disorder is effectively treated when detected early, primarily through avoidance of fasting. MCADD has an estimated incidence of one in 18,000 births in the State, an expected annual incidence of 14 cases of the condition.

Costs:

Costs to Private Regulated Parties:

Regulated parties include the approximately 170 hospitals, and diagnostic and treatment centers providing birthing services in the State, their chief executive officers, and birth attendants who assist with at-home births (*i.e.,* licensed midwives). These entities will incur no new costs related to collection and submission of blood specimens to the State's Newborn Screening Program, since the dried blood spot specimens now collected and mailed to the program for other currently available testing would also be used for the additional tests proposed by this amendment. However, birthing facilities and, to a lesser extent, at-home birth attendants would likely incur minimal additional costs related to fulfilling their responsibilities for ensuring referral of infants who screen positive for CF, CAH or MCADD, specifically, human resources costs of approximately 1.0 person/hour (for nursing and counseling staff with clerical support) for communicating the need of and/or arranging referral for medical evaluation of the additional identified infants. Overall, for 95 percent of the State's birthing facilities (*i.e.,* 156 of 163), the number of infants requiring referral would increase from seven or fewer to no more than ten per week; therefore, no additional staff would be required at these institutions.

Facilities and practitioners receiving referrals, including: hospitals; specialized care centers; clinical specialists (*i.e.,* medical geneticists); and primary and ancillary care providers (*i.e.,* pediatricians, nutritionists and physical therapists), would incur costs for medical evaluation, including confirmatory testing in some cases, ongoing care, and treatment supplies such as antibiotics and dietary supplements. Specifically, such parties would incur human resources costs of approximately $300 for an initial comprehensive medical evaluation of an infant with an abnormal screening test result. However, given the low specificity of screening tests to ensure no false negative results, the Department anticipates that as many as 98 percent of referred infants will ultimately be found not to be afflicted with the target condition, using clinical assessment and relatively simply confirmatory tests.

Hospitals, specialized care centers and independent providers will incur additional costs for providing post-evaluation and ongoing medical management services to the approximately two percent of identified infants whose disorders are confirmed. Human resources costs for post-confirmation services of two to five person/hours, involving medical geneticists, genetic counselors and nutritionists, have been estimated at $450 per affected infant, including $300 for a comprehensive office visit and $150 for a genetic or nutritional counseling session.

The proposed regulations do not impose additional reporting requirements upon the regulated public (trappers and hunters).

7. Duplication

There are no other local, state or federal regulations concerning the possession, transporting, or disposal of coyote and marten. The Department is the only governmental entity with the legal authority to regulate the managed harvest of coyote and marten in New York.

8. Alternatives

An alternative to making the proposed changes is to leave the regulations intact. However, this would perpetuate the unnecessary requirement to pelt seal coyotes, and reduce the Department's ability to manage marten.

9. Federal Standards

There are no federal government standards for the possession, transportation, and disposal of coyote and marten.

10. Compliance Schedule

Trappers and hunters will be expected to comply with the new regulations as soon as they take effect.

Regulatory Flexibility Analysis

This proposed rule making will revise regulations concerning the possession, transportation, and disposal of coyotes taken by hunters and trappers, and marten taken by trappers. The Department has determined that this rule making will not impose an adverse economic impact on small businesses or local governments. The proposed revisions are not expected to significantly change the number of participants or the frequency of participation in the regulated activities.

The Department has also determined that these amendments will not impose any reporting, recordkeeping, or other compliance requirements on small businesses or local governments. All reporting or recordkeeping requirements associated with trapping are administered by the Department.

Therefore, the Department has concluded that a regulatory flexibility analysis is not required.

Rural Area Flexibility Analysis

This proposed rule making will revise regulations concerning the possession, transportation, and disposal of coyotes taken by hunters and trappers, and marten taken by trappers. The Department has determined that this rule making will not impose an adverse economic impact on rural areas. The proposed revisions are not expected to significantly change the number of participants or the frequency of participation in the regulated activities.

The Department has also determined that these amendments will not impose any reporting, recordkeeping, or other compliance requirements on public or private entities in rural areas. All reporting or recordkeeping requirements associated with trapping and hunting are administered by the Department.

Therefore, the Department has concluded that a rural area flexibility analysis is not required.

Job Impact Statement

The purpose of this rule making is to amend the requirements for the possession, transportation, and disposal of coyotes taken by hunters and trappers, and marten by trappers. Based on the Department's past experience in implementing similar regulations to those herein proposed, and based on the professional judgement of staff in the New York State Department of Environmental Conservation (DEC), the proposed regulatory changes included in this rule making are not expected to have any adverse impacts on jobs or employment opportunities in New York State. This rule making will remove the pelt seal requirements for coyote, which should have a positive impact on those engaged in trapping or hunting coyotes by making reporting easier and less time-consuming. The proposal to require submission of the entire marten carcass should not have any effect on or cause the loss of any jobs or employment opportunities. Therefore, DEC has concluded that a Job Impact Statement is not required.

Department of Health

EMERGENCY RULE MAKING

Expedited HIV Testing of Women and Newborns

I.D. No. HLT-12-04-00012-E
Filing No. 798
Filing date: July 9, 2004
Effective date: July 9, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 69-1.3 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 576, 2500-a and 2500-f

Finding of necessity for emergency rule: Preservation of public health.

Specific reasons underlying the finding of necessity: Immediate adoption of this amendment is necessary to protect the public health and welfare and to prevent harm to infants born in New York State. The New York State Department of Health is actively engaged in the prevention of mother-to-child HIV transmission. Recent advances in medical knowledge concerning the prevention of perinatal HIV transmission have demonstrated that antiretroviral therapy, given to prevent HIV transmission, is most efficacious when given prenatally, during labor, or within the first 12 hours of an infant's birth. Although approximately 94 percent of women are tested for HIV during prenatal care, the HIV status of six percent is unknown at presentation for delivery. Women at high risk for HIV who have received no prenatal care are over-represented within this group. In 1999, the Department implemented expedited HIV testing in the labor and delivery setting so that providers can initiate partial antiretroviral regimens either to the mother in labor or to the infant immediately after birth. The turn-around-time for reporting the result was 48 hours from the drawing of blood from the mother (with her consent) or from the newborn (no consent required).

Heretofore, the program has been limited by the lack of a point-of-care rapid HIV test. In cases of HIV-exposure in a newborn where prenatal and/or intrapartum antiretroviral therapy (ART) were not given, studies have shown that therapy must be started for the newborn within 12 hours of birth to be effective in reducing the risk of transmission. The expedited HIV testing protocols in most New York State birth facilities did not meet this 12-hour timeline for initiating prophylactic newborn ART. In 2001 to 2002, over 1400 HIV-infected women gave birth in New York State. Of these, one hundred mother/infant pairs were first identified as HIV-infected/exposed through expedited HIV testing in the labor, delivery or in the immediate newborn period. In the vast majority of cases (98 of 100), the median time from the mother's admission to the collection of the specimen for expedited HIV testing was 2.5 hours. However, even when testing was performed on-site, results were not returned for at least 20 hours, and treatment was not initiated in the newborn until 22.5 hours after birth. Clearly, achieving timelier reporting of expedited HIV test results is hampered by the lack of a point-of-care rapid test.

In November 2002, the U.S. Food and Drug Administration approved the first of a new generation of point-of-care rapid HIV tests. The test is waived under the Clinical Laboratories Improvement Act (CLIA) and may be performed under the supervision of a licensed physician, nurse practitioner or physician assistant, provided the facility performing the test has obtained a CLIA number and is registered with the Clinical Laboratories Evaluation Program (CLEP).

The availability of point-of-care HIV testing offers providers the opportunity to intervene during this most critical time frame for perinatal HIV transmission: labor and delivery. The purpose of this emergency and proposed rule making, which amends 10 NYCRR, Subpart 69-1.3(l)(2), is to ensure that the HIV exposure status is available as soon as possible for all newborns whose mothers have not been tested for HIV during the current pregnancy or for whom HIV test results are not available at delivery. By requiring a maximum turn-around-time of twelve hours from the time the mother consents to testing or from the time of the infant's birth to the receipt of the result of the expedited HIV test, medical providers and patients will have information that is critical for the administration of antiretroviral medication during labor and delivery and to the newborn immediately after birth.

As a result of the Expedited HIV Testing regulations (effective August 1999) and the consequent increase of prenatal and expedited HIV testing, along with the prompt initiation of treatment to HIV-infected mothers, the rates of perinatal HIV transmission in New York State have decreased: from 10.9% in 1997 to 3.9% in 2001. New, rapid, point-of-care HIV testing technology can provide test results within 20 to 40 minutes. In most cases, this technology will allow obstetricians to have preliminary HIV test results before the mother delivers, when the initiation of antiretroviral therapy can be of significant benefit. In light of the advances in testing technology, the Department is proposing a regulatory change to 10NYCRR 69-1.3 (l)(2) that would apply in cases where a woman presents for delivery with no documentation of her HIV status. In these cases, the amended regulation would require the birth facility to arrange an immediate HIV screening test of the mother with her consent or of her newborn without consent with results available as soon as possible, but in no event longer than 12 hours after the mother provides consent for testing or, if she does not consent, 12 hours after the time of the infant's birth. Reducing the turn-around-time for expedited HIV testing allows health care providers to provide antiretroviral therapy in time to reduce the risk of mother-to-child transmission of HIV.

The emergency rule will take effect upon filing with the Secretary of State.

Subject: Expedited HIV testing of women and children.

Purpose: To amend the current comprehensive program in response to recent advances in medical knowledge and the rapid HIV testing technology to enhance protection of newborns.

Text of emergency rule: Paragraph (2) of Subdivision (l) of Section 69-1.3 of NYCRR is amended to read as follows:

(2) if no HIV test result obtained during the current pregnancy is available for the mother not known to be HIV-infected, arrange an immediate screening test of the mother with her consent or of her newborn for HIV antibody with results available as soon as practicable, but in no event longer than [48 hours] *12 hours after the mother provides consent for testing or, if she does not consent, 12 hours after the time of the infant's birth.*

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously published a notice of proposed rule making, I.D. No. HLT-12-04-00012-P, Issue of March 24, 2004. The emergency rule will expire September 6, 2004.

Text of emergency rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, fax: (518) 486-4834, e-mail: regsqna@health.state.ny.us

Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) section 2500-f requires the commissioner to promulgate regulations to implement a comprehensive program for the testing of newborns for HIV and/or the presence of HIV antibodies. The proposed revision to the regulation amends the current comprehensive program in response to recent advances in medical knowledge concerning the prevention of perinatal HIV transmission and the availability of rapid HIV testing technology, with at least one device suitable for "point-of-care use.

Legislative Objectives:

In the memorandum accompanying the comprehensive newborn testing bill (Chapter 220 of the Laws of 1996), the legislature indicated its purpose was "to ensure that newborns who are born exposed to HIV receive prompt and immediate care and treatment and counseling that can enhance, prolong and possibly save their lives. Transmission of HIV from mother to newborn can be prevented in many cases by the administration of antiretroviral medications, which are recommended to be given to the mother starting during the second trimester of pregnancy, continued during labor, and given to the newborn after birth. The proposed amendment to 10 NYCRR, Subpart 69-1.3(2) will ensure that the HIV exposure status is available for all newborns whose mothers have not been tested for HIV during the current pregnancy or for whom HIV test results are not available at delivery. By requiring that HIV test results be available as soon as is practicable but in no case later than twelve hours from the time of the mother's consent to testing or the time of the infant's birth, the Department intends to ensure that medical providers and patients have the information they need to make decisions about preventive treatment in a timely manner.

Needs and Benefits:

Improvements in medical knowledge and major advances in medical technology have occurred since the current program for the Expedited HIV Testing of Women and Newborns was implemented in August 1999. To date, the success of New York State's efforts to reduce perinatal HIV transmission to the lowest possible level has resulted in a decrease in the rate of perinatal HIV transmission for all HIV-exposed infants born in New York from 10.9% in 1997 to 3.9% in 2001. However, transmission is still occurring in instances where the HIV exposure status of an infant was identified too late to provide effective intervention. In such infants therapy must begin within 12 hours of birth to be effective in reducing the risk of transmission. In an addendum to the NYSDOH PCR study, published in the New England Journal of Medicine on 4/1/99, it was demonstrated that when ARV was given to the newborn within 12 hours of birth there was a 5.9% rate of HIV transmission. There was no significant benefit if ARV was begun after 12 hours birth as the transmission rate increased to 25%. The ability to have results from expedited HIV testing as soon as possible in cases where there was no history of prenatal HIV testing, coupled with the administration of prophylactic antiretroviral therapy, ideally during labor but no later than 12 hours of birth, is of vital importance in further reducing perinatal HIV transmission. To reduce perinatal HIV transmission to the greatest extent possible, facilities are urged not to view the 12-hour turn-around-time as the goal of testing, but as the outside limit for offering effective therapeutic interventions to prevent transmission of HIV from the mother to her newborn.

Costs:

Costs to State and Local Governments:

The cost to State Government is minimal and can be covered by existing programs and staff. There is no cost to local government except to the extent they own and operate maternity hospitals. Any cost to the State and local governments will be reduced by the savings to the Medicaid program by reducing the costs of care as fewer incidences of HIV transmission to newborns occur. Local governments that operate medical facilities will incur costs as described in the section on Costs to Regulated Parties noted below.

Costs to Regulated Parties:

The approved rapid test is CLIA- waived due to low complexity and may be performed either in the centralized laboratory or at the point-of-care, subject to appropriate NYSDOH approvals. The Department will work closely with facilities to assist them in meeting the turn-around-time requirements of this proposal.

The vast majority (141) of the 159 birthing facilities currently hold a clinical laboratory permit in HIV testing or are eligible for fast-track approval for a permit in HIV testing. These facilities already have or could readily develop the capability of generating HIV test results on-site within twelve hours without additional costs. This is especially true for facilities with around-the-clock centralized laboratory services. Reagent, equipment, personnel and overhead costs for testing a single specimen using an instrument-based method (i.e., EIA) are approximately $15 for routine testing, but up to ten times that amount for'on demand' (STAT) testing. Birth facilities would incur costs directly related to this proposal whenever expedited testing needed to be performed in the laboratory outside normal testing hours, and qualified staff needed to be called in specifically to run one test. Facilities using such an on-call staffing approach to expedited newborn HIV testing would incur up to 1.5 times the usual hourly wage for a medical technologist, which is estimated to be $40 per hour (including benefits) or $50 per hour (including benefits) if the technologist is a supervisor.

The Department will work closely with facilities that do not have current capacity to consistently generate results in 12 hours or less, and assist them in meeting regulatory requirements. Costs of introducing in-house HIV testing include costs of reagents, devices and human resources necessary to validate the test method and write protocols, at an estimated maximum one-time cost of $1000. Facilities that conduct testing at point of care, i.e., in the labor and delivery department, would also incur minimal costs associated with initial training and ongoing competency assessment of non-laboratory testing personnel, i.e., labor and delivery nursing staff, although technologists may also travel to patient floors to lend their expertise in the performance of tests and interpretation of results. The cost of conducting initial training for a group of 8 or fewer nurses can be estimated by multiplying the hourly wage of a supervisor-qualified technologist by 8 hours of training in device use, troubleshooting, recordkeeping and quality assurance activities, and adding the cost of 25 test devices. The device designated for point-of-care testing has a list price of $10.00 -$15.00 for each test kit.

Overall, the Department estimates that the costs of performing tests at the point-of-care are likely to be less than, or equal to, the costs of expedited HIV tests currently performed in a centralized laboratory. This estimate is based on the fact that rapid HIV tests do not require the purchase or maintenance of expensive laboratory equipment and that the cost of testing devices (OraQuick®, SUDS®) and the salaries of personnel conducting the tests are comparable. The cost of expedited HIV testing done in a reference laboratory (cost at one commercial laboratory is $75.00/ expedited test) may not change, but birth facilities using these laboratories will have to ensure that they will be able to report results within the 12-hour turn-around-time. The cost to the birth facility in time spent to provide pre-test HIV counseling is not expected to differ from the current cost of expedited HIV testing, which includes reimbursement rates of $52 for testing and $44 for counseling ($96.00/expedited test).

In light of the advances in testing technology, and the benefits of early initiation of antiretroviral therapy to prevent mother-to-child transmission of HIV, many birth facilities will opt to use a rapid HIV test device that generates results in a half-hour or less. Facilities may perform rapid HIV testing either in the laboratory itself or at the point-of-care subject to appropriate NYSDOH approval. Laboratories with an HIV testing permit may choose to conduct "stat testing 24 hours a day, 7 days a week using a standard instrument-based (e.g., EIA) testing technology within the 12 hour time limit. However, testing using rapid testing devices is encouraged to obtain HIV tests results as soon as possible. While procedures such as immediate transport of specimens by courier to a near-by laboratory, may, in theory, be effective for meeting a 12-hour turn-around-time, the Department's experience with such complex arrangements shows them to usually be an unacceptable alternative for on-site expedited testing.

Of the 159 regulated hospitals and birthing centers affected by this amendment, 141 hold laboratory permits that include HIV and/or diagnostic immunology testing, the latter of which would be allowed, in response to the adoption of this amendment, to add HIV testing through a fast-track mechanism. For any of these 141 facilities that choose to add a new test to an existing HIV or fast-tracked diagnostic immunology permit, costs for protocol development, staff training, test validation and implementation of quality assurance measures are expected to be approximately $1000. There are no additional costs associated with modifying an existing permit to add a category or test. The remaining 18 birth facilities would incur an additional cost if they seek to provide HIV testing on-site, including an initial cost of $1000 plus annual fees based on gross annual receipts.

Facilities offering on-site testing at the point-of-care, i.e., in the labor and delivery suite under the auspices of an existing permitted laboratory, would incur minimal costs for initial training and ongoing competency assessment of non-laboratory testing personnel, i.e., labor and delivery nurses. The cost of conducting initial training for a group of 8 or fewer nurses can be estimated by multiplying the hourly wage of a supervisor-qualified technologist by 8 hours of training (on average approximately $50.00/hour by 8 hours equating to $400.00) in device use, troubleshooting, recordkeeping and quality assurance activities, and adding the cost of 25 test devices ($15 per test by 25 = $375). Therefore, the total training costs would be approximately $775. Cost attributable to periodic competency assessments of one to two hours could be calculated using the same formula. A materials cost of approximately $10.00 - $15.00 a test would be attributable to one single-use device and control materials.

Costs would be offset by revenue generated from third party billing, including Medicaid. Costs of expedited HIV testing in labor, delivery and newborn nursery settings will continue to diminish as efforts to increase prenatal HIV counseling and testing succeed. Any other provider costs associated with rapid HIV testing in the labor and delivery settings are medically appropriate and must continue to be considered part of labor and delivery costs.

Costs to the Department of Health:

The Department will use existing staff to review and approve HIV testing applications, and to conduct on-site surveys of applicant facilities.

Local Government Mandates:

This amendment to the current regulation will not impose any new program services, duties or responsibilities upon any county, city, town, village, school district, fire district or any other special district, except for those local governments operating hospitals with maternity services.

Paperwork:

Paperwork related to point-of-care rapid HIV tests does not significantly differ from that currently required by expedited testing regulations. This paperwork includes the clinician's written order for testing, notation of the completion of pre- and post-test counseling, documentation of the acquisition of the test specimen and recording the test result in the medical record. Some paperwork will be required of birth facilities that seek an addition to an existing permit, and for those that choose to seek a new HIV testing permit.

Duplication:

None.

Alternatives:

There are no alternatives to the 12-hour time limit proposed by this amendment because a longer time period would result in some HIV-exposed infants not being detected in time to administer therapy to prevent HIV transmission. Because advances in scientific knowledge and medical technology allow for rapid HIV testing, the Department determined that the proposed revision to the regulation is the best approach to protect the public health.

Federal Standards:

There are currently no Federal regulations related to prenatal or newborn testing. The Federal government has provided only recommendations and guidelines for these activities. The proposed regulatory change is consistent with current federal recommendations.

Compliance Schedule:

The Department has already advised regulated parties that this emergency amendment is in place. The Department understands that many facilities previously initiated activities to implement rapid HIV testing. The Department understands that facilities have been in compliance since the first emergency regulation's November 2003 effective date.

Regulatory Flexibility Analysis

Effect on Small Businesses:

The proposed rule will impact an estimated three birth hospitals and four birthing centers that meet the definition of a small business (independently owned and employs 100 or fewer individuals). No real impact on small businesses is expected, since regulations requiring expedited HIV testing are already in place. No new costs to local governments are anticipated, except for those operating hospitals with maternity services.

Compliance Requirements:

The reporting, recordkeeping and other affirmative acts that impact small businesses or local governments would not change with this proposed amendment. Current regulations require hospitals and birthing centers to assess whether mothers who present for delivery have a negative HIV test result from the current pregnancy or a positive HIV test result during or prior to the pregnancy. If no test result is documented, the mother is offered consented expedited HIV testing. If she declines, an expedited HIV test is performed on her infant, without consent. Current regulations require a turn-around-time for preliminary HIV test results of no more than 48 hours from the time the specimen is collected. The proposed rule change would decrease the turn-around-time to within 12 hours after the mother's consent for testing, or if she does not consent, within 12 hours of the infant's birth.

Professional Services:

Impacted small businesses and local governments would need the same staff of health care providers (doctors, nurses, nurse practitioners, physicians assistants), counseling and support staff as they currently employ. No additional staff would be needed.

Compliance Costs:

The percentage of women receiving prenatal counseling and testing is steadily increasing, and the need for expedited HIV testing in the intrapartum period is decreasing. As of December 2002, hospital data indicate that approximately 94% of all women giving birth have documentation of their HIV status before delivery. This rate was 62% in July 1999, one month before expedited testing in delivery settings was implemented. Using these data, the need for expedited HIV testing has clearly decreased through the years, from an estimated 120,000 mothers/infants in 1999 to less than 15,000 in 2002. At $52 per test, the total statewide testing cost in 1999, estimated to be $6.24 million per year, has decreased to $780,000 per year. This number is expected to continue to decline as more women accept prenatal HIV testing. The cost for expedited HIV testing using rapid, point-of-care testing kits is not expected to exceed the cost of expedited testing as currently performed and would be considerably less if facilities choose to take advantage of point-of-care rapid testing.

Economic and Technological Feasibility:

The proposed amendment to the regulatory program is economically and technologically feasible since it is not anticipated that additional staff would be required and rapid, point-of-care testing technology is readily available.

Minimizing Adverse Impact:

Provider costs associated with rapid, point-of-care expedited HIV testing are medically appropriate and must be considered part of labor and

delivery costs. Current reimbursement rates for expedited HIV testing subsidize the costs incurred by the delivery facility ($44 for counseling and $52 for testing), and will continue. Since preventing HIV transmission saves the high treatment costs for HIV-infected persons, expedited HIV testing in the labor and delivery setting is actually cost effective. Hospitals and birthing centers also realize savings as a result of this program by not having to employ outreach staff to find mothers after discharge since post-test counseling can be done while the mother is still in the hospital.

Small Businesses and Local Government Participation:

In advance of publication, the proposed amendment to the regulation was discussed at a two hour meeting held on March 23, 2003 by the Greater New York Hospital Association with representatives from 31 birthing facilities and the Health and Hospitals Corporation attending, and on April 30, 2003 at a videoconference hosted by the Hospital Association of New York State and broadcast to birthing facilities statewide.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

Forty-four counties meet the definition of a rural area (population less than 200,000) and an additional 11 counties have towns that are classified as rural (towns with population densities of 200 persons or less per square mile). The proposed amendment to the current regulation applies to hospitals and birthing facilities in 55 counties. These facilities already follow the Expedited HIV Testing regulation; significant program expansion is not expected. There are no birth facilities in the remaining seven counties.

Reporting, Recordkeeping and Other Compliance Requirements:

The reporting, recordkeeping and other affirmative acts that will impact hospitals in rural areas have already been undertaken to comply with the Expedited HIV Testing regulation. Current regulations require maternity hospitals and freestanding birthing centers to ensure that all women who present for delivery with no documentation of HIV status are counseled about expedited HIV testing, and, arrange that an immediate HIV screening test of the mother with her consent or of her newborn without consent is performed. Technological advances mean that rapid HIV screening tests can now be performed at the point-of-care. Birth facilities can choose to use the new technology for rapid HIV testing, or to continue with the expedited HIV testing program already in place at their facilities. If the new technology is not chosen, the decreased turn-around-time for the return of preliminary test results will have to be negotiated with either the hospital-based or the commercial laboratories that perform expedited HIV testing.

Professional Services:

Hospitals in rural areas would not need additional professional staff to provide this service for women without known HIV test results.

Costs:

According to current annualized data, fewer than 50 maternity patients or newborns in any hospital or birthing center operated in rural areas require expedited HIV testing. This number will continue to diminish as efforts to promote prenatal HIV testing succeed. If an average of $52 (the total per test average cost of ELISA or SUDS testing, exclusive of counseling) for each expedited HIV test is used to estimate the total cost of expedited testing (test device, equipment and personnel), the total annual cost for rapid expedited HIV testing in each rural birth facility will be approximately $2,600, or less, depending on the number of maternity patients or newborns needing rapid testing.

Minimizing Adverse Impact:

Additional provider costs associated with testing are medically appropriate and must be considered part of labor and delivery costs. However, preventing HIV transmission is cost effective because of the high cost of treatment for HIV-infected persons. Hospitals and birthing centers will realize savings as a result of this program by not having to employ outreach staff to find mothers after discharge since post-test counseling can be done while the mother is still in the hospital.

Rural Area Participation:

In advance of publication, the proposed amendment to the regulation was discussed at a two hour meeting held on March 23, 2003 by the Greater New York Hospital Association with representatives from 31 birthing facilities and the Health and Hospitals Corporation attending, and on April 30, 2003 at a video conference hosted by the Hospital Association of New York State and broadcast to birthing facilities statewide.

Job Impact Statement

A Job Impact Statement is not attached because this amended rule will not have a substantial adverse impact on jobs and employment opportunities as apparent from its nature and purpose.

Assessment of Public Comment

Two individuals sent in comments regarding the proposed regulatory change.

Comment:

One commentor focused on perceived inaccuracies and inconsistencies in the regulatory impact statement (RIS) and regulatory flexibility analysis (RFA) that were filed concurrent with this amendment's express terms on September 10, 2003 and March 24, 2004, further suggesting that the RIS and RFA be revised and republished.

Response:

No revisions were made to the published regulation's expressed terms, RIS or RFA as a result of this commentor's suggestions as noted in this assessment.

Comment:

The commentor stated that the Department does not have the statutory authority to sanction point-of-care expedited maternal/newborn HIV testing at sites not holding clinical laboratory permits. The commentor further suggested that adoption of this proposed amendment be postponed until such time as regulations are adopted to establish standards for laboratories that limit their test menus to simple, CLIA-waived tests.

Response:

The concerns raised by the commenter have become moot and, accordingly, no revisions to the regulation or its supporting documentation are deemed necessary at this time. As of the date of this assessment, all birthing facilities that perform expedited maternal/newborn HIV testing on-site do so pursuant to a valid clinical laboratory permit issued by the Department, in full compliance with Public Health Law Article V Title 5. Postponing enactment of this regulation is therefore unnecessary and not in the interest of the public health.

Comment:

The same commentor noted that there are differences between costs and compliance requirements filed in September 2003 and March 2004, specifically that costs and compliance requirements specific to point-of-care testing were filed with the initial emergency adoption in September 2003, but were omitted from subsequent filings.

Response:

This difference is attributable to the Department's evolving approach to oversight of point-of-care testing. In 2003, the laboratory-licensing program anticipated statutory amendment to PHL that would have excepted from existing permit requirements any laboratory that limited its testing to simple, CLIA-waived tests, and would have required such facilities to register with the Department. That proposal for registration was subsequently abandoned. The impact statement accompanying the 2004 filing for the subject amendment was modified accordingly in order to provide an up-to-date assessment of expected costs. Other costs, such as those incurred for training and on-going competency assessment of testing personnel are detailed in both the RIS published on September 10, 2003 and the RIS published on March 24, 2004.

Comment:

The commentor stated that there is no justification in the amendment's impact statement or the flexibility analyses for the extensive requirements for laboratories that currently have permits.

Response:

The Department believes that no such justification is necessary. The issue at hand is to minimize the time in which HIV test results are made available to medical personnel attending the delivery and caring for the newborn, not whether Subpart 58-1 requirements for a permit are justified.

Comment:

The same commentor stated that there are no compliance requirements detailed for birthing facility's laboratories that do not have permits.

Response:

The Department has determined that birthing facilities that had not made an affirmative decision to bring HIV testing in-house by the time this rule's second emergency filing was published had no intention of doing so. Such facilities have expressed to the Department that they can and will use alternative means to meet the proposed 12-hour turn around time for HIV test results. Given that the Department's primary concern is the timely availability of HIV test results, it is evident that no purpose would be served by outlining permit requirements for twenty or fewer laboratories, none of which intend to apply for an initial permit.

Comment:

The second commentor, from an HIV-related community advisory group, stated that this advisory group realized the importance of this amendment and were in full support of the proposed changes. She stated that having expedited test results available within 12 hours would ensure that medical providers and patients had the information needed to make

decisions in a timely manner regarding treatment to prevent transmission of HIV to the infant.

Response:

Since this commentor strongly supports the proposed changes, no revisions were needed to the published regulation's terms, RIS or RFA.

EMERGENCY RULE MAKING

Arboviral Infection Reporting

I.D. No. HLT-18-04-00002-E
Filing No. 795
Filing date: July 7, 2004
Effective date: July 7, 2004

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 2.1 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 225(4), (5)(a), (h), (i), 206(1)(d) and (e)

Finding of necessity for emergency rule: Preservation of public health.

Specific reasons underlying the finding of necessity: Immediate adoption of this rule is necessary to monitor the magnitude and scope of illness caused by arthropod-borne viruses, and enable timely case reporting and investigation, as well as the implementation of control interventions, as needed.

Arboviral infections are usually transmitted to people by arthropod vectors (primarily mosquitoes and ticks), and include viruses capable of causing symptoms ranging from asymptomatic or mildly symptomatic infection, to encephalitis, coma and death. Current communicable disease reporting requirements specify the reporting of encephalitis and meningitis but do not require the reporting of specific arboviral infections. Arboviral infections are of increasing importance to public health officials as evidenced by the ongoing West Nile virus outbreak.

West Nile virus was introduced to the metropolitan New York City area in 1999. The virus has rapidly dispersed across the United States and now only four states currently remain free of evidence of West Nile virus in various surveillance systems. This untreatable, potentially fatal mosquito-borne virus has affected every county in New York State. Late August through November is the time of year when the virus is most likely to be transmitted from mosquitoes to humans. A significant and further alarming discovery was made in 2002 when public health investigations determined that West Nile virus can be transmitted from person to person through blood transfusion. During the 2002 West Nile virus outbreak in the United States, a total of 23 persons were reported to have acquired West Nile virus infection after receiving blood components.

Because of the possibility of recurrent West Nile virus epidemics, some blood collection agencies across the country now voluntarily screen for the presence of West Nile virus and may identify individuals with asymptomatic or mild West Nile viral infection. Through the end of August 2003, the CDC is aware of over 150 presumptive West Nile virus-viremic blood donors reported from 11 states. Reporting of these viremic donors to State and local health departments will provide critical information about the presence and spread of West Nile virus in the State, and will allow timely implementation of prevention efforts.

In addition to West Nile virus, several arboviruses, such as Eastern equine encephalitis virus, Jamestown Canyon encephalitis virus, LaCrosse encephalitis virus, and Powassan encephalitis virus, have been found in various locations across New York State. Other mosquito-borne arboviruses, such as St. Louis encephalitis virus, have been introduced into New York State as a result of significant dispersal of native United States strains through major geographic expansion of infected mosquito populations that started along the Mississippi River valley. These viruses are currently known to be transmitted to people only through the bite of an infected mosquito and usually cause severe neurological symptoms in symptomatic individuals. Health care providers who suspect arboviral infection in these symptomatic patients can submit serum or cerebrospinal fluid specimens for arboviral laboratory diagnostic tests.

The rule change will enable the New York State Department of Health to identify potential mosquito- and tick-borne virus- associated infections in blood donors and other individuals who may not have encephalitis or meningitis symptoms. Requiring the reporting of these individuals will prevent further serious human infection through the earliest possible recognition of a problem, assist in defining the incidence and clinical spectrum of illness, and instituting recommendations for disease prevention on a timely basis.

Subject: Arboviral infection reporting.

Purpose: To add arboviral infection to the list of communicable diseases.

Text of emergency rule: Subdivision (a) of Section 2.1 is amended to read as follows:

2.1 Communicable diseases designated: cases, suspected cases and certain carriers to be reported to the State Department of Health.

(a) When used in the Public Health Law and in this Chapter, the term infectious, contagious or communicable disease, shall be held to include the following diseases and any other disease which the commissioner, in the reasonable exercise of his or her medical judgment, determines to be communicable, rapidly emergent or a significant threat to public health, provided that the disease which is added to this list solely by the commissioner's authority shall remain on the list only if confirmed by the Public Health Council at its next scheduled meeting:

Amebiasis
Anthrax
Arboviral infection
Babesiosis
Botulism
Brucellosis
Campylobacteriosis
Chancroid
Chlamydia trachomatis infection
Cholera
Cryptosporidiosis
Cyclosporiasis
Diphtheria
E. coli 0157:H7 infections
Ehrlichiosis
Encephalitis
Giardiasis
Glanders
Gonococcal infection
Group A Streptococcal invasive disease
Group B Streptococcal invasive disease
Hantavirus disease
Hemolytic uremic syndrome
Hemophilus influenzae (invasive disease)
Hepatitis (A; B; C)
Hospital-associated infections (as defined in section 2.2 of this Part)
Legionellosis
Listeriosis
Lyme disease
Lymphogranuloma venereum
Malaria
Measles
Melioidosis
Meningitis
  Aseptic
  Hemophilus
  Meningococcal
  Other (specify type)
Meningococcemia
Mumps
Pertussis (whooping cough)
Plague
Poliomyelitis
Psittacosis
Q Fever
Rabies
Rocky Mountain spotted fever
Rubella
Congenital rubella syndrome
Salmonellosis
Severe Acute Respiratory Syndrome (SARS)
Shigellosis
Smallpox
Staphylococcal enterotoxin B poisoning
Streptococcus pneumoniae invasive disease
Syphilis, specify stage
Tetanus
Toxic Shock Syndrome
Trichinosis

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Antonia C. Novello, M.D., M.P.H. Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

January 2004

Dear Colleague:

This letter provides important information related to the Maternal-Pediatric HIV Prevention and Care Program and the ongoing efforts in New York State to reduce perinatal HIV transmission to the lowest possible level. It serves to underscore the importance of the midwife's role and transmits new information related to advances in rapid HIV testing technology and emergency legislation targeted to promote prevention efforts.

IMPORTANCE OF PRENATAL HIV TESTING

HIV counseling with a strong clinical recommendation for voluntary testing is a standard of prenatal care recognized by the New York State Department of Health, the American College of Obstetrics and Gynecology (ACOG), the American Academy of Pediatrics (AAP), and the United States Public Health Service. The prenatal provider should counsel the mother about the benefits of knowing her HIV status, including her ability to make informed decisions about breastfeeding and, if she is HIV-infected, about medical interventions for her own health and for reducing the risk of HIV transmission to her baby. In New York State, counseling should also include information on the legal requirement that all newborns be tested for HIV and the fact that, if she declines to be tested during the prenatal period, she will receive additional HIV counseling and a recommendation for expedited testing during labor and delivery. If she declines testing for herself in both the prenatal and delivery settings, her newborn will be tested immediately after birth.

HIV counseling should be provided as early as possible in prenatal care. However, the Department has identified a small but significant number of cases where the mother tested negative early in pregnancy and became infected after testing. In these cases, the mother's infection and her infant's exposure were not identified until several weeks after the infant's birth, too late for therapy to prevent perinatal HIV transmission. For this reason, the Department encourages prenatal providers in areas of New York State where HIV seroprevalence is high to recommend repeat HIV testing in the third trimester of pregnancy.

EXPEDITED HIV TESTING IN LABOR AND DELIVERY

In 2003, over 94 percent of women presenting for delivery at hospitals in New York State had been HIV tested during their current pregnancies. Expedited HIV testing in the labor and delivery setting served as a safety net for the remaining six percent. Those who tested positive in labor and delivery had the opportunity to receive abbreviated antiretroviral regimens, which have been shown to be effective in reducing perinatal HIV transmission when initiated intrapartum or within the first twelve hours of life.

In light of the availability of a new generation of rapid HIV-1 antibody tests, which can be conducted at point of care, the Department has implemented an emergency amendment to the newborn HIV testing regulations [10NYCRR 69-1.3 (2)]. The amendment, which was effective on November 1, 2003, requires that the results of expedited HIV testing in labor and delivery be available as soon as possible, but no later than 12 hours after the mother consents to testing or after the birth of the child. The purpose of the amendment is to ensure that information on the mother's HIV status is available as soon as possible so that therapy to prevent perinatal HIV transmission can be initiated intrapartum or immediately after the birth of the child. (A copy of the New York State Register dated December 3, 2003 is enclosed as Attachment A.)

Protocol for Rapid Maternal/Newborn HIV Antibody Testing

w York State regulations [10NYCRR 69-1] require all birth facilities and birth attendants to provide expedited HIV testing of either mother (with consent) or infant (without consent) when the mother's prenatal HIV status is unknown or undocumented at the time of presentation for delivery. Effective November 1, 2003, the results of the expedited test be available as soon as possible, but in no event longer than 12 hours after the mother consents to testing of herself or 12 hours after the birth of the infant if the infant is tested [10NYCRR 69-1.3 (2)]. Please refer to Attachment C for detailed information.

The shortened turnaround time for test results is now feasible with the availability of a new generation of rapid HIV-1 antibody tests which can be conducted at point-of-care. For information about obtaining a CLIA number to provide rapid testing, please see the enclosed letter from the Wadsworth Center for meeting laboratory requirements. Currently, OraQuick is the only point-of-care rapid HIV test that has been CLIA-waived and may be performed outside of a laboratory setting. For information on rapid HIV testing, see the Centers for Disease Control (CDC) website at www.cdc.gov

Preliminary rapid HIV test results are available in 20-30 minutes. In the case of a negative rapid test result, no further confirmatory testing is required. The negative result should be reported to the mother as a final HIV test result in the context of post-test counseling.

A positive rapid HIV antibody screening test result is a preliminary result and should be reported to the mother as HIV-positive, unconfirmed. The midwife should counsel the mother regarding the meaning of a preliminary positive result, assess her risk to determine the likelihood that the result is true positive, discuss the risks and benefits of antiretroviral therapy (ARV) with the mother, and initiate ARV as soon as possible. The birth attendant is required to collect and process a specimen for confirmatory testing and to provide the mother with post-test counseling appropriate to the result of the confirmatory test, which must be available within four days. The birth attendant should ·'-o collect the first DNA PCR test specimen from the HIV-exposed infant within the first 48 hours and send it to dsworth Laboratory (see instructions included in Attachment E) for processing. These tests are free of charge for all HIV-exposed infants.

Maternal/ Newborn Management in the Absence of Antenatal ARV Therapy

The Department of Health has published clinical care guidelines for the management of HIV-infected pregnant women and the prevention of perinatal transmission. The guidelines, which were developed by a committee of experts convened by the AIDS Institute, include four options for the prevention of perinatal transmission when the mother has not received prenatal ARV therapy. These options are summarized in Attachment D. Please ensure the ready availability of prophylactic ARV at the delivery site for administration to the mother and/or the newborn as appropriate upon (the unlikely) finding of a preliminary positive HIV test result.

Thank you for your ongoing efforts to reduce the transmission of HIV infection to New York's infants to the lowest possible level. Should you or staff at your facility have questions regarding the implementation of this emergency regulation, please contact Sheila Hackel, R.N., or Ellen Kowalski, R.N., in the AIDS Institute's Regulatory Unit, Bureau of HIV Ambulatory Care, at (518) 486-6048.

Sincerely,

Guthrie Birkhead, M.D., M.P.H.
Director, AIDS Institute

Attachments

ATTACHMENTS:

The following materials are attached for your information:

Attachment A is a copy of the New York State Register with the revised emergency regulation announced and dated December 3, 2003. The original emergency regulation was dated September 10, 2003.

Attachment B "Informed Consent to Perform an Expedited HIV Test in the Delivery Setting" is a revised form (DOH-4158) for use with expedited testing in the delivery setting. The revisions to the consent form are minimal, and relate to two places where 48 hours was changed to 12 hours on page one of the form.

Attachment C Subpart 69-1 "Testing for Phenylketonuria and Other Diseases and Conditions", which outlines the Newborn Screening Program guidelines, definitions and responsibilities.

Attachment D "Recommendations for Prophylaxis to Reduce Mother-to-child Transmission When Mother Has Not Received Prenatal Antiretroviral Therapy" from Prevention of Perinatal HIV Transmission Clinical Guidelines, New York State Department of Health, AIDS Institute, March 2000. These recommendations are periodically updated and may be accessed at the website for the clinical guidelines: http://hivguidelines.org

Attachment E contains information on the Pediatric HIV PCR Testing Service at Wadsworth Center and how to obtain the test kits. PCR diagnostic testing is free of charge for all HIV-exposed infants.