- Recordkeeping requirements specifically applicable to whole body acquisition services and whole body users are included to supplement existing requirements for all nontransplant anatomic banks found in Section 52-2.9(i).
- Disposition and transfer requirements for whole bodies, body segments and other nontransplant anatomic parts are described.
- A requirement for reporting nontransplant anatomic banking activities to the Department is specified.

Costs

Currently, staff members of all New York State medical schools that would be whole body acquisition services, meet all stipulated educational requirements. If a whole body acquisition service does not meet this proposal's staffing requirements, it may incur expenses associated with employing: (1) a nontransplant anatomic bank director who holds a graduate degree in anatomy or the health sciences; and (2) an appropriately trained morgue attendant, diener, or licensed funeral director responsible for preparation, care and maintenance of whole bodies and body segments. Full-time salaries for properly trained morgue attendants or dieners range from $24,000 to $46,200. Salaries for a director with the appropriate graduate degree would depend upon whether the director is full-time or part-time and other responsibilities within the institution. Full-time salaries for occupations requiring similar credentials range from $38,000 to $101,390. (See NYS Education Department website workforce wages.)

A whole body user may incur expenses associated with recruiting a staff member with a graduate degree in the health sciences, and training in human dissection or in the activity to be performed. Based upon information submitted in the application process, nontransplant anatomic banks currently licensed to use whole bodies and body segments in research and/or education are already likely to employ such an individual.

A whole body acquisition service not already in compliance with the proposal's new facilities requirements could incur additional expenses, as follows:

(1) a working sink and adequate counter space for preparation of whole bodies and body segments (costs range from $5,000 to more than $10,000, depending on size and specifications);

(2) counters, tables, and cabinetry made of material easily disinfected and cleaned (modular-unit base cabinets cost from $800 to $1,400 each);

(3) a refrigerated storage room dedicated solely to storage of whole bodies or body segments, with lockable access doors and alarms to signal intrusion or unacceptable temperature deviation (cost varies depending on size and type, e.g., four-body crypt versus walk-in, or portable versus fixed-room, but ranges from $12,000 to $140,000);

(4) a U.S. Occupational Safety and Health Administration (OSHA)-approved device for handling, lifting and internal transportation of whole bodies or body segments (a cadaver lift assembly costs approximately $4,000); and

(5) an OSHA-approved eye wash station (a fixed, plumbed station costs from $300 to $500).

A whole body user not already in compliance with the proposal's facilities requirements could incur additional expenses, as follows:

(1) a dedicated room with lockable access doors and isolation from public view to ensure safe and respectful handling of whole bodies and body segments (costs associated with providing locks and a means to obscure the public's view are minimal);

(2) dissection tables commercially designed for that purpose (commercial dissection tables cost $2,800 for a standard table and $4,400 for a hinged-hood table);

(3) a working sink and adequate counter space (costs range from $5,000 to more than $10,000, depending on size and specifications); and

(4) an OSHA-approved eye wash station (a fixed, plumbed station costs from $300 to $500).

Other nontransplant anatomic banks not already in compliance with the proposal's facilities requirements could incur additional expenses, as follows:

(1) a room of sufficient size and construction with lockable doors to restrict access to individuals directly associated with the education or research conducted, and ensure isolation from public view (costs associated with providing locks and a means to obscure the public's view are minimal); and

(2) a working sink and adequate counters constructed of nonporous materials (costs range from several hundred dollars to more than $1,000, depending on size and specifications).

Unless otherwise stated, cost estimates provided above are based upon information generally available in medical and laboratory supply catalogs and cost estimates provided by medical schools that would be required to comply with these standards.

Nontransplant anatomic banks could incur some minimal additional costs to revise written procedures, and forms/logs for recording specific information to document the donation process, informed consent, and storage and disposition of nontransplant anatomic parts. It is not possible to provide an estimate of the costs of implementing this amendment's record keeping provisions, since costs would vary depending upon the volume of the nontransplant anatomic parts recovered and the amount of record keeping already in place. Most research and education facilities currently identify, track and dispose of nontransplant anatomic parts in a manner consistent with these requirements as part of good research techniques and inventory procedures. Moreover, it is expected that existing staff would be able to implement these requirements, thereby avoiding added labor costs.

The above-described costs would be easily offset by the benefits to be derived from assurance of safe, appropriate and respectful handling of human bodies, body segments, organs, and tissues used in research and/or education.

Minimizing Adverse Impact

The proposed amendments would have no significant adverse impact on rural facilities presently in compliance with established industry standards. The need to codify standards for appropriate handling of whole bodies and body segments outweighs any added costs some facilities located in rural areas may incur in implementing these changes fully. These amendments have been developed with an emphasis on minimizing burdens on regulated parties to the greatest extent possible, while maintaining adequate standards to ensure safe and respectful handling of whole bodies and body segments.

Rural Area Participation

The Department notified all regulated parties directly regarding the proposed regulation in order to solicit comments. Changes have been incorporated, as appropriate, based on comments and suggestions received as a result. No adverse comments were received from affected parties that operate a tissue bank in an area designated as rural.

More recently, the Department distributed copies of the modified proposal at the January 20, 2006 meeting of the Anatomical Committee of the Associated Medical Schools of New York State, and participated in discussion of specific changes made in response to informal comments. No adverse comments and no written comments were received as a result of this meeting.

Job Impact Statement

A Job Impact Statement is not attached, because it is apparent, from the nature and purpose of the proposed rule, that it will not have a substantial adverse impact on jobs and employment opportunities.

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Language Assistance and Patient Rights

I.D. No. HLT-20-06-00004-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 405.7 and 751.9 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2803

Subject: Language assistance and patient rights.

Purpose: To strengthen communications provisions for persons who do not speak English or do not speak it well; and add two rights to the Patient's Bill of Rights to be consistent with the Public Health Law.

Text of proposed rule: Paragraph (7) of subdivision (a) is repealed in its entirety and a new paragraph (7) of Section 405.7 is added to read as follows:

(7) the hospital shall develop a Language Assistance Program to ensure meaningful access to the hospital's services and reasonable accommodation for all patients who require language assistance. Program requirements shall include:

(i) the designation of a Language Assistance Coordinator who shall report to the hospital administration and who shall provide oversight for the provision of language assistance services;

(ii) policies and procedures that assure timely identification and ongoing access for patients in need of language assistance services;

(iii) the development of materials that will be made available for patients and potential patients that summarize the process and method to access free language assistance services;

(iv) ongoing education and training for administrative, clinical and other employees with direct patient care contact regarding the importance of culturally and linguistically competent service delivery and how to access the hospital's language assistance services on behalf of patients;

(v) signage, as designated by the Department of Health, regarding the availability of free language assistance services in public entry locations and other public locations;

(vi) identification of language of preference and language needs of each patient upon initial visit to the hospital;

(vii) documentation in the medical record of the patient's language of preference, language needs, and the acceptance or refusal of language assistance services;

(viii) a provision that family members, friends, or non-hospital personnel may not act as interpreters, unless:

(a) the patient agrees to their use;

(b) free interpreter services have been offered by the hospital and refused; and

(c) in the event the family members, friends, or non-hospital personnel are younger than 16 years of age; issues of competency, confidentiality or conflicts of interest are taken into account. The use of individuals younger than 16 years of age should be used only in emergent circumstances and their use documented in the medical record;

(ix) management of a resource of skilled limited english proficiency interpreters and/or persons skilled in communicating with vision and hearing impaired individuals;

(a) limited English proficiency interpreters and persons skilled in communicating with vision and/or hearing impaired individuals shall be available to patients in the inpatient and outpatient setting within 20 minutes and to patients in the emergency service within 10 minutes of a request to the hospital administration by the patient, the patient's family or representative or the provider of medical care. The Commissioner of Health may approve time limited alternatives to the provisions of this subparagraph regarding limited english proficiency interpreters and persons skilled in communicating with vision and/or hearing impaired individuals for patients of rural hospitals; which:

(1) demonstrate that they have taken and are continuing to take all reasonable steps to fulfill these requirements but are not able to fulfill such requirements immediately for reasons beyond the hospital's control; and

(2) have developed and implemented effective interim plans addressing the communications needs of individuals in the hospital service area.

(x) an annual needs assessment utilizing demographic information available from the United State Bureau of the Census, hospital administrative data, school system, data, or other sources, that will identify limited English speaking groups comprising more than one percent of the total hospital service area population. Translations/transcriptions of significant hospital forms and instructions shall be regularly available for the languages identified by the needs assessment; and

(xi) reasonable accommodation for a family member or patient's representative to be present to assist with the communication assistance needs for patients with mental and developmental disabilities.

New paragraphs (18) and (19) are added to subdivision (c) of Section 405.7 to read as follows:

(18) Authorize those family members and other adults who will be given priority to visit consistent with your ability to receive visitors.

(19) Make known your wishes in regard to anatomical gifts. You may document your wishes in your health care proxy or on a donor card, available from the hospital.

Subdivisions (n) and (o) are amended and new subdivisions (p) and (q) are added to Section 751.9 to read as follows:

(n) approve or refuse the release or disclosure of the contents of his/her medical record to any health-care practitioner and/or health care facility except as required by law or third-party payment contract; [and]

(o) access his/her medical record pursuant to the provisions of section 18 of the Public Health Law, and Subpart 50-3 of this Title[.] ;

(p) authorize those family members and other adults who will be given priority to visit consistent with your ability to receive visitors; and

(q) make known your wishes in regard to anatomical gifts. You may document your wishes in your health care proxy or on a donor card, available from the center.

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:

The authority for the promulgation of this regulation is contained in Public Health Law (PHL) Sections 2803 and 2805-r. PHL Section 2803 outlines the powers and duties of the Commissioner. It also authorizes the State Hospital Review and Planning Council (SHRPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities. PHL Section 2805-r specifically authorizes the promulgation of regulations in relation to the right of patients who are unable to speak to have certain people present at all times during their stay at a hospital.

Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost.

Needs and Benefits:

Provision of quality health care to individuals who have difficulty with the English language or are hearing and/or vision impaired is a major problem as clinicians are often unable to obtain information to make accurate diagnoses and because patients often do not understand the treatment regimens prescribed for them. Language barriers make it difficult to obtain information about medical services, to make appointments, understand how to obtain medical insurance and navigate the health care system in general. Non-English speaking patients are less likely to use preventive and primary care services and poor communication due to language difficulties deters individuals from receiving timely treatment and can result in increased costs and inefficiencies overall.

The number of languages spoken in the United States is increasing significantly. Approximately 11 million people, (4.2% of the U.S. population) do not speak English, or do not speak it well, while over 21 million people (8.1% of the U.S. population) speak English less than very well. Almost two-thirds of New York City's residents are immigrants. These immigrants and their children come from over 200 different countries and speak more than 140 languages. While the majority of these individuals are in New York City, other areas of the State are impacted as well.

To address the increased need for language services in the hospital setting, the Department is strengthening its regulation regarding communication services. This proposal will require hospitals to develop a Language Assistance Program to ensure meaningful access to the hospital's services and reasonable accommodation for all patients who require language assistance. They are minimum standards that all hospitals are required to provide. More services could be provided if a hospital chooses to do so.

This proposal also makes technical amendments to the hospital and diagnostic and treatment center patients' rights provisions to include two rights that are in statute and in the Department's Your Rights as a Hospital Patient booklet, but were never added to the regulation.

COSTS:

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

The new provisions of Section 405.7 should not increase costs for the regulated entities with the exception of the development of guidance materials that will summarize available language programs and how patients can access this free service. Many hospitals may already have such materials in place The current provisions in Section 405.7 already require hospitals to manage a resource of skilled interpreters and persons skilled in communicating with vision and/or hearing impaired individuals. They also require hospitals to provide translations/transcriptions of significant hospital forms, instructions and information in order to provide effective visual, oral and written communication with all persons receiving treatment in the hospital.

The new provisions will require regulated entities to designate a Language Assistance Coordinator to provide oversight for the provision of language assistance services. Such coordinator may be designated from within the current hospital staff. Regulated entities will need to provide training, manage skilled limited English proficiency interpreters and/or

persons skilled in communicating with vision and hearing impaired individuals in a timely manner. Again they may designate such individuals from within current hospital staff or current volunteers.

Regulated entities must also develop an annual needs assessment that will identify limited English speaking groups comprising more than one percent of the total hospital service area population. They must also make readily available for languages identified by the needs assessment, translations/transcriptions of significant hospital forms and instructions. Hospitals are already required to do this.

Costs to Local and State Government:

Municipally owned hospitals will be required to adhere to these regulations the same as all other regulated entities. They are not expected to incur any increased costs other than for the development of the same guidance materials as noted above.

Costs to the Department of Health:

This proposal requires the Department to designate signage for use by the hospitals regarding the availability of free language assistance services in key entry locations and other public locations. While this can be done utilizing existing staff, some costs will be incurred for translation of standard signs for all languages utilized by New York State residents.

The Department currently has a translating and interpreting services contract to provide language assistance services on a needed basis. The current contract has a translation of documents cost ranging from $.22/word to $.35/word depending on the contract vendor and the language being translated. For the Your Rights as a Hospital Patient booklet it would cost between $3,214.20 and $5,113.50. This booklet already exists in Spanish and can be found on the Department's website at www.health.state.ny.us. The current contract costs between $1.98 - $2.00/minute for over the phone interpreters.

Local Government Mandates:

None.

Paperwork:

Program requirements required by hospitals will include the development of materials that will be made available for the patients and potential patients that summarize the process and method to access free language assistance services. Such requirements will also require documentation in the medical record of the patient's language of preference, language needs and the acceptance or refusal of language assistance service.

Duplication:

Title VI of the Civil Rights Act prohibits discrimination that has been interpreted by the federal government to include protection of minorities who do not speak English or speak it well. Recipients of federal funding must take reasonable steps to ensure that people with limited English proficiency have meaningful access to their programs and services. This provision parallels the Civil Rights Act. Title VI is a law that is general in nature with respect to discrimination. This regulation contains specific requirements with respect to hospital Language Assistance Programs. It will not conflict with or duplicate the federal statute.

Alternative Approaches:

The current regulation could be left in place, however it is not as comprehensive as the new provisions. Current provisions have not always resulted in the Department's assurance that all patients have meaningful access to hospital services for all patients who require language assistance.

Federal Requirements:

Title VI of the Civil Rights Act prohibits discrimination. Its purpose is to ensure that federal money is not used to support health care providers who discriminate on the basis of race, color, or national origin. The federal Department of Health and Human Services (HHS) and the courts have applied this statute to protect minorities who do not speak English well. This provision parallels the Civil Rights Act. Title VI is a law that is general in nature with respect to discrimination. This regulation contains specific requirements with respect to hospital Language Assistance Programs. It will not conflict with or duplicate the federal statute.

Compliance Schedule:

This regulation will take effect upon publication of a Notice of Adoption in the New York State Register.

Regulatory Flexibility Analysis

Effect of Rule:

Section 405.7 of 10 NYCRR provisions of this regulation will apply to general hospitals; of which 5 are small businesses, (defined as 100 employees or less). Section 751.9 provisions will apply to diagnostic and treatment centers; 237 are considered small businesses.

Compliance Requirements:

In order to comply with the Section 405.7 requirements, hospitals must develop a Language Assistance Program that will reasonably accommodate the needs of all patients who require language assistance. The Section 751.9 requirements do not impose any additional compliance requirements. They simply put into regulation two patients' rights provisions that are in the Public Health Law and in the Department's Your Rights as a Hospital Patient booklet.

Professional Services:

Hospitals will be required to designate a Language Assistance Coordinator and provide ongoing training and education for administrative, clinical and direct patient care staff in culturally and linguistically competent service delivery. This can be done from existing staff.

Compliance Costs:

Compliance can be done with existing staff therefore the compliance costs should be none with the possible exception of those hospitals that have not identified the availability of languages in printed materials.

Economic and Technological Feasibility:

It should be economically and technologically feasible for small businesses to comply with these regulations. There should be no increased costs to implement this regulation with the possible exception of those hospitals that have not identified the availability of languages in printed materials. Existing staff can be utilized.

Minimizing Adverse Impact:

These provisions authorize the Commissioner to approve time limited alternatives regarding limited English proficiency interpreters and persons skilled in communicating with vision/and or hearing impaired individuals of rural hospitals which: (1) demonstrate that they are taking all reasonable steps to fulfill these requirements; and (2) have developed and implemented effective interim plans addressing the communications needs of individuals in the hospital service area.

Small Business and Local Government Participation:

Outreach to the affected parties, is being conducted. Organizations who represent the affected parties are given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the State Hospital Review and Planning Council. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

During the September 22, 2005 Codes and Regulations Committee meeting several speakers from the Immigrant Health Care Access and Advocacy Collaborative, comprised of associations serving those in need of language assistance, as well as the Greater New York Hospital Association, spoke in favor of the proposal and urged its passage. There were extensive discussions with these groups as well as with the Health Care Association of New York State who worked together to develop regulations that would provide quality health care to hospital patients with limited English proficiency or disabilities.

Rural Area Flexibility Analysis

Types and Estimated Number of Rural Areas

The proposed amendment will apply Statewide, including the 43 rural counties with less than 200,000 inhabitants, and the 10 urban counties with a population density of 150 per square mile or less. There are 51 rural hospitals in New York State.

Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services

Hospitals, including rural hospitals, will be required to develop Language Assistance Programs that will reasonably accommodate the needs of all patients who require language assistance. They will also be required to designate a Language Assistance Coordinator and provide ongoing training and education for administrative, clinical and direct patient care staff in culturally and linguistically competent service delivery. This can be done from existing staff. Guidance materials will need to be developed that will summarize available language programs and how patients can access this free service. Many hospitals may already have such materials in place. An annual needs assessment must be developed that will identify limited English speaking comprising more than one percent of the total hospital service area population. They must also make readily available for languages identified by the needs assessment, translations/transcriptions of significant hospital forms and instructions. Hospitals are already required to do this. Documentation in the medical record of the patient's language of preference, language needs and the acceptance or refusal of language assistance service will also be required.

Costs

These provisions should not increase costs for the regulated entities with the exception of the development of guidance materials that will summarize available language programs and how patients access this free service. Many hospitals may already have such materials in place.

Minimizing Adverse Impact

These provisions authorize the Commissioner to approve time limited alternatives regarding limited English proficiency interpreters and persons skilled in communicating with vision and/or hearing impaired individuals of rural hospitals which: (1) demonstrate that they are taking all reasonable steps to fulfill these requirements; and (2) have developed and implemented effective interim plans addressing the communications needs of individuals in the hospital service area.

Rural Area Participation

Outreach to the affected parties, including those in rural areas is being conducted. Organizations who represent the affected parties have been given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the State Hospital Review and Planning Council. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

Job Impact Statement

A Job Impact is not included because these provisions will not have a substantial adverse impact on jobs and employment activities.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Cytotechnologists Work Standard

I.D. No. HLT-20-06-00005-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 58-1.12(b)(7) of Title 10 NYCRR.

Statutory authority: Public Health Law, section 576-a

Subject: Cytotechnologiests work standard.

Purpose: To provide flexibility to the department is establishing work standards that consider new technologies for pap smear screening.

Text of proposed rule: Pursuant to the authority vested in the Commissioner of Health by Section 576-a of the Public Health Law, existing paragraph (7) of Section 58-1.12(b) of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is amended, and new subparagraph (iv) is added, to be effective upon publication of a Notice of Adoption in the State Register, as follows:

58-1.12(b)(7) Exceptions. (i) Each laboratory [must]*shall* evaluate the performance of each cytotechnologist *in its employ*, and establish an appropriate examination volume limitation based on *the cytotechnologist's* experience, documented accuracy[,] and performance in proficiency testing, or [for]*on* other reasons, including false-negative *or false-positive interpretations* [reports]. Under no circumstances [should]*shall* this volume be exceeded, even if it is [less]*lower* than the maximum work standard.

(ii) A cytotechnologist may exceed the work standard by [10]*twenty (20)* percent, with the written approval of the department. The laboratory director may request such approval based on each cytotechnologist's experience, documented accuracy, including false-negative or *false*-positive [reports]*interpretations*, and *a* performance *score* in proficiency testing of not more than two *(2)* errors. Documentation of [this]*department* approval [must]*shall* be available in the laboratory, and may be revoked by the department with prior notice to the laboratory, based on a cytotechnologist's performance in proficiency testing or other evidence that the cytotechnologist's accuracy is [less]*other* than acceptable. The laboratory director [must]*shall* monitor the performance of each cytotechnologist and advise the department [when the]*whenever the* approval is to be revoked based on on-the-job performance.

(iii) Cytotechnologists who qualify as supervisors under section 58-1.4 of this Subpart may re-examine up to [20] *twenty (20)* slides per day [separate from]*in addition to* the workload standard, *provided the combined total number of slides does not exceed one-hundred (100),* as part of the [quality control-]quality assurance program of the laboratory, with the prior approval of the department, based on documented accuracy, including [false negative or positive reports]*false-negative and false-positive interpretations*, and performance in proficiency testing. Such approval may be revoked, with prior notice to the laboratory, based on proficiency testing performance or other evidence that the cytotechnologist's accuracy is [less]*other* than acceptable. Records [must]*shall* be maintained to document the *examination* volume and hours worked *by each cytotechnologist.*

(iv) The department may increase the cytotechnologist work standard beyond the level already authorized elsewhere in this section for cytotechnologists using a federal Food and Drug Administration (FDA)-approved device in the preparation or examination of cytology slides:

(a) in determining whether to increase the cytotechnologist work standard with respect to a particular device, the department shall consider the following: the FDA's approved use of the device; studies of the accuracy, reliability and appropriate use of the device; input from clinical laboratories using the device; recommendations of experts in the field of cytology and/or cytotechnology; and other relevant information as appropriate;

(b) (1) the department may require a clinical laboratory wishing to exceed the cytotechnologist work standard set forth elsewhere in this section to request in writing the department's approval. The department may also require the applicant laboratory to provide, in a form acceptable to the department, some or all of the following information regarding the device in use at the laboratory: the device manufacturer's recommendations, if any, regarding the quantity (i.e., slide volume), speed or manner of slide examination, and the basis for such recommendations; documentation of training for each cytotechnologist using the device; each cytotechnologist's experience using the device, including false-negative and false-positive interpretations, workload, and number of hours spent examining slides; each cytotechnologist's performance on proficiency testing; as well as any other information as determined appropriate by the department to assess device capacity and user capability; and

(2) the department shall provide written notice of the authorized work standard established pursuant to this subparagraph. The department may set a work standard in writing that applies to one or more cytotechnologists.

(c) laboratories shall maintain documentation of approval pursuant to this subparagraph for a minimum of two (2) years after use of the device is discontinued;

(d) if the department determines that a cytotechnologist work standard authorized pursuant to this subparagraph increases the rate of errors or compromises the reliability of results, the department shall adjust the standard as it deems appropriate and shall notify the affected clinical laboratories in writing of such change. Clinical laboratories that find the adjustment unacceptable may request only in writing that the department reconsider its determination; and

(e) notwithstanding the foregoing, any cytotechnologist work standard authorized by the department pursuant to this subparagraph shall be at least as stringent as the federal standards promulgated under the federal clinical laboratory improvement amendments of nineteen hundred and eighty-eight (1988) and/or other applicable law(s).

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 Section 576-a was enacted as Chapter 539 of the Laws of 1988. The statute established standards for cytotechnologists' workload, a registration requirement for individuals engaged in initial examination of slides, and quality standards for preparing and examining the slides. Regulations adopted as 10 N.Y.C.R.R. Sections 58-1.12 and 58-1.13 pursuant to that legislation have been in effect since 1989. Public Health Law, Article 5, Title V was amended by Chapter 436 of the Laws of 1993. Section 576-a of that legislation modified the state's cytotechnologist work standard, (i.e., a numeric limitation on the cytology slides, including Pap smears, that a cytotechnologist may examine during a work day) to effect parity with federal standards in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). Section 576-a also includes a provision authorizing the Department to increase the cytotechnologist work standard in response to technological advances in instrumentation and devices for assisted examination of cytology slides.

Legislative Objectives:

In 1988, media reports made the public aware of problems associated with inordinate cytotechnologist workloads in clinical laboratories examining gynecologic slides (Pap smears) for evidence of cervical cancer. At that time, New York was the only state with a comprehensive program of oversight of these laboratories, including review of cytotechnologist qualifications, and on-site assessment of laboratory operations and proficiency testing. While excessive testing volumes had not been reported in New York State, the Legislature determined that additional steps were required to protect women residents of the State, and Public Health Law Section