utilized by regulated parties. The approaches suggested in State Administrative Procedure Act Section 202-b(2) were rejected as inconsistent with the purpose of the regulation.

Rural Area Input:

The New York State Association of County Health Officers (NYSACHO), including representatives of rural counties, has been informed about this change and has voiced no objections.

Job Impact Statement

This regulation adds neonatal herpes to the list of diseases that clinical laboratories, clinicians, and hospitals must report to public health authorities and for which clinicians must submit laboratory specimens. The staff who are involved in reporting neonatal herpes at the local and State health departments are the same as those currently involved with reporting, monitoring and investigating other communicable diseases. Implementation should not significantly increase the demands on existing staff nor increase the need to hire additional staff for laboratories, hospitals, and providers. The NYSDOH has determined that this regulatory change will not have a substantial adverse impact on jobs and employment.

NOTICE OF ADOPTION

Language Assistance and Patient Rights

I.D. No. HLT-20-06-00004-A

Filing No. 1040

Filing date: Aug. 28, 2006 Effective date: Sept. 13, 2006

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

Action taken: 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 addition of two rights to the Patient's Bill of Rights to be consistent with the Public Health Law.

Text of final rule: Paragraph (7) of subdivision (a) is repealed in its entirety and a new paragraph (7) of Section 405.7 is added to read as follows: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) issues of age, competency, confidentiality, or conflicts of interest are taken into account. Any individual acting as an interpreter should be 16 years of age or older; individuals younger than 16 years of age should only be used in emergent circumstances and their use documented in the medical record.

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

Final rule as compared with last published rule: Nonsubstantial changes were made in section 405.7(a)(7)(viii)(c), (ix), (ix), (a), (x).

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: regsqna@health.state.ny.us

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Although the regulation has been changed since it was published in the *State Register* on May 17, 2006, the changes do not necessitate any changes to the Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis or Job Impact Statement.

Assessment of Public Comment

The Department received 16 letters with comments during the official comment period. They came primarily from associations and individuals involved with issues concerning immigrants, access to health care, translation services, legal assistance and health and hospitals. One comment with approximately 198 signatures came from a senior citizens center.

In general, the comments supported the proposed regulatory changes and many strongly supported the proposal. While there was overwhelming support, there were suggested changes recommended. They are as follows:

Comment:

In subparagraph (ix) of paragraph (7) "and/or" should be changed to "and". Communication services should be offered to limited English proficient individuals as well as to those who are vision and/or hearing impaired. Skilled language interpreters and persons skilled in communicating with hearing and vision impaired individuals are not interchangeable.

Response:

Several of the letters received contained this comment. The Department agrees and the change has been made.

Comment:

Subparagraph (viii) of paragraph (7) specifies that 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. Several comments suggested that these considerations should be made whenever interpreter services are provided by family, friends, or non-hospital personnel of any age.

Response:

The Department agrees that this standard was the intent in the proposed regulation and this change has been made.

Comment:

Sixteen year olds should not miss school to serve as interpreters for their families.

Response:

While the Department agrees that a 16 year old should not miss school to serve as an interpreter, it has no way to regulate the action of a parent in this situation. The age limit was discussed as part of the deliberations. The consensus reached was age 16.

Comment:

The proposed regulations should permit public inspection of the entire hospital language assistance plan, rather than access to a summary only.

Response:

This concept was discussed as part of the deliberations on the regulation. While some members of the review group continued to seek this public disclosure, the consensus of the group was to maintain the requirement as written. No change to the regulation will be made.

Comment

The proposed regulations should include better monitoring requirements to ensure full compliance with these important provisions.

Response:

Compliance with the regulations will be monitored by Department of Health staff in response to complaints or through focused surveillance. This approach is consistent with ensuring compliance with all other parts of the State Hospital Code.

Comment:

One comment asked for clarification of acceptable interpretation services. A concern is the lack of any explicit mention in the proposed regulation of interpretation services other than those provided by in person, face to face interpreters. Multiple modalities for providing language services and not just in person, face to face interpreters is needed.

Response:

The Department agrees that, based on current technology, there are many ways to successfully provide interpreter services beyond in person, face to face interpretation. As part of this regulation, we acknowledge that these other forms may be used by hospitals and we will clarify this in subsequent guidance to the hospitals.

Comment:

Concerns were raised about the annual needs assessment provisions. It was noted that no single source of demographic information is consistently reliable for projecting changes in language services needs across the geographic neighborhoods applicable to New York City hospitals. Flexibility is the key. No critical indicator accurately correlates the language spoken by persons within a given community with the critical issue of whether or not significant numbers of those persons are also limited in proficiency in speaking English. It was further noted that it is not clear what a total "hospital service area" includes. Is that the hospital's primary service area only (which could cause undercounting) or the hospital's secondary service area? Flexibility in any community language profile and needs assessment is essential. The best barometer of a new emergent language need for Limited English Proficient (LEP) purposes is the relevant hospital's administrative data in conjunction with other data such as census information.

Responses

In the regulation, the Department acknowledges that no single means of demographic information is always reliable. For this reason, the regulation allows hospitals to choose those information sources that work best for them. This approach will be covered in subsequent letters and training sessions for hospitals. No change to the regulation is needed.

Comment:

The proposal will require each hospital Language Assistance Program to include "signage, as designated by the Department of Health, regarding the availability of free language assistance services in public entry loca-

tions and other public locations." Substantial monies have already been expended to implement LEP signage programs. It would be an undue burden to have to replace such signage with new signs as designated by the Department of Health.

Response:

The Department, in carrying out its regulatory oversight, will allow hospitals to create and/or use their existing signage in lieu of a Department of Health sign so long as it includes relevant information about the availability of free interpreter services. No change to the regulation is needed.

Comment:

It was suggested that the phrase limited English proficiency interpreters be changed to language interpreter as a more accurate description of the interpreter.

Response:

The Department will remove references to limited English proficiency interpreters and will use the term interpreter as is in the original language of the regulation.

Comment:

One comment noted that the term reasonable accommodation is derived from Civil Rights Disability Law, most often being used with reference to employment issues under the federal Americans with Disabilities Act. Persons with limited English proficiency are not, for that reason, disabled and language assistance measures are not being provided to deal with an individual's disability. It was suggested that all references to reasonable accommodation be removed. The proposal could say the hospital shall develop a language assistance program to ensure meaningful access to the hospital's services for all patients who require language assistance.

Response:

The Department would view reasonable accommodation as a comparable standard to the term meaningful access. The regulation will not be changed.

Comment:

It would be useful to specify the scope of this regulation.

Response:

The Language Assistance provisions of this regulation amend Section 405.7 of Title 10 (Health) of the New York Codes Rules and Regulations (10 NYCRR). They are contained in Part 405 and pertain to general hospitals.

Comment:

It will be difficult for hospitals in rural locations or with limited access to interpreters skilled in communicating with hearing and vision impaired individuals to provide language assistance services within 20 minutes of a request for such services for inpatient and outpatient settings and 10 minutes of a request for such services for the Emergency Department setting. The time-limited alternatives to the provisions for rural hospitals language should be removed. This is to enable hospitals with significant challenges beyond to their immediate control to develop suitable alternative plans to meet the need.

Response:

Telephonic and/or video conferencing technology allows all hospitals to comply with time limitations. With this technology there should not be a need for time limited alternatives, but the Department would be willing to discuss other alternatives brought to our attention. No regulatory change is needed.

Comment:

What specific accommodations must be made for individuals who come from groups of less that 1% of our population?

Response

While the regulation specifies what additional requirements are imposed for populations greater than 1%, groups of less than 1% are covered by the general requirements.

Comment:

The cost of translation and reprinting of a significant number of forms will place a burden on all New York Hospitals. The standardization of materials and the ability to access the materials free of charge would greatly enhance compliance and most importantly meaningful access for individuals in need of language assistance. The State should assist hospitals in funding for any documented additional costs incurred in assuring compliance.

Response:

The Department agrees with the comment. It is our intent to work with hospital associations to secure translation of significant forms and make them available to hospitals. No regulatory change is made.