



TO: The Professional Practice Committee

FROM: Douglas E. Lentivech

SUBJECT: Proposed Amendment of the Regulations of the Commissioner of Education Relating Interpretation and Translation Services to Limited English Proficient (LEP) Individuals in Pharmacies and to the Establishment of Standardized Patient-Centered Data Elements for Prescription Drug Labels

DATE: June 10, 2013

AUTHORIZATION(S):

SUMMARY

Issue for Decision

Should the Board of Regents approve the addition of new sections 63.11 and 63.12 of the Regulations of the Commissioner of Education relating to the interpretation and translation services for Limited English Proficient (LEP) individuals in pharmacies, and to the establishment of standardized patient-centered data elements for prescription drug labels?

Reason(s) for Consideration

Required by State statute.

Proposed Handling

This proposed amendment is presented to the Professional Practice Committee for recommendation and the Full Board for emergency action and adoption as a permanent rule at the June 2013 meeting of the Board of Regents. A Statement of Facts and Circumstances justifying the emergency action is attached.

Procedural History

A Notice of Proposed Rule Making was published in the State Register on March 20, 2013. Four parties provided comments. An Assessment of Public Comment is attached. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

The 2012 New York State budget legislation included amendments to the Education Law, which amendments are commonly referred to as the SafeRx Law (L. 2012, c. 57, Part V). This new law, which became effective March 30 2013, includes provisions to assist Limited English Proficient (LEP) individuals who need interpretation and translation services when filling prescriptions at pharmacies. The law also requires the Commissioner of Education to develop rules and regulations to provide more patient-friendly prescription labels for all patients.

Over the course of the months following passage of this legislation the Office of the Professions sought input from interested stakeholders. In addition to receiving written comments, there were three opportunities for oral presentations, one each in Buffalo, Albany and New York City. This input, and advice from the State Board of Pharmacy, assisted in the development of the proposed regulations.

Section 6829 of the Education Law, as added by section 3 of Part V of Chapter 57 of the Laws of 2012, includes the following provisions:

- The legislation applies to covered pharmacies, which the legislation defines as a pharmacy that is part of a group of eight or eight or more pharmacies, located within New York State and owned by the same corporate entity.
- Covered pharmacies are required to provide interpretation and translation services to LEP individuals in their preferred pharmacy primary language, free of charge.
- The legislation defines the preferred pharmacy primary languages as those that are spoken by 1% or more of the population, as determined by the U.S. Census, for each region, as established by the Department, provided that no pharmacy need provide services in more than seven languages.
- Interpretation and translation services may be provided by pharmacy staff or third-party contractors.
- Pharmacies will not be liable for injuries resulting from the actions of a third party as long as the pharmacy entered into the contract reasonably and in good faith.
- Every covered pharmacy must conspicuously display a notice, in the pharmacy primary languages, notifying patients of the available interpretation and translation services.
- The legislation requires the Department to develop a process whereby a covered pharmacy may seek a waiver from these requirements if it can

demonstrate that implementation is unnecessarily burdensome when compared to the need for services.

- The legislation also requires the Commissioner, in consultation with the Department of Health, to establish translation and interpretation requirements for mail-order pharmacies; such requirements will be effective March 30, 2014. The Department anticipates that it will come before the Regents with these regulations sometime early next year.

As noted above, the law delegated to the Department the responsibility of establishing the regions to be used in determining the languages in which translation and interpretation services must be provided. The Board of Pharmacy and Department staff considered a number of options, such as dividing the State into 6-8 regions, dividing the State into an upstate and a downstate region only, dividing the State on a county-by-county basis, and considering the State in its entirety as one region. After discussions with stakeholders representing both covered pharmacies and LEP individuals, it was determined that the last option was preferred because it provided services to a large portion of the LEP population in an efficient and cost-effective manner. Establishing the State as a single region will result in four pharmacy primary languages statewide – Chinese, Italian, Russian and Spanish. This approach will expedite the adoption of standardized interpretation and translation services by covered pharmacies and will provide for more languages to be covered in nearly all upstate communities than other options.

It should be noted that New York City has a local law regarding the provision of language assistance, interpretation, and translation services to LEP individuals. Both the enacting statute and the proposed regulations contain provisions that make it clear that neither the new law nor the regulations promulgated to implement it will diminish requirements existing pursuant to this New York City law.

Additionally, in the course of the development of the proposed regulations, the Civil Rights Bureau of the State Attorney General's Office provided information concerning settlement agreements it has with seven large retail pharmacy chains pursuant to which those chains have been providing language assistance, interpretation, and translation services in approximately 10 different languages to LEP individuals throughout the state. While all but one of those agreements will be expiring in 2013, there is nothing in the law or the proposed regulation that would prohibit any pharmacy from providing language assistance, interpretation, and translation services in additional languages.

Education Law §6830, as added by section 4 of Part V of Chapter 57 of the Laws of 2012, requires the Commissioner to develop regulations requiring the use of standardized patient-centered data elements on all prescription medication labels. It also requires the Commissioner to obtain input from its Boards of Pharmacy and Medicine, consumer groups, advocates for special populations, pharmacists, physicians, other health care professionals authorized to prescribe, and other interested parties, in the development of patient-centered prescription labels. Such labeling is intended to increase patient understanding and compliance with medication regimens.

Regarding patient-centered labeling, the Boards of Pharmacy and Medicine relied, in part, on previous studies conducted by the United States Pharmacopeia and by the National Association of Boards of Pharmacy. Based on these studies, the proposed amendment requires that prescription labels must have certain, critical elements, including patient name, the drug name and directions, that must be bolded and/or highlighted and be in at least 12-point font. The proposed regulation also requires that directions for patient use be written in full sentences. Other important information must also be included on the label, including among other things, the patient's address, the pharmacy address and the name of the prescriber, but the manner in which such information is included on the label must not detract from the critical elements.

Recommendation

It is recommended that the Board of Regents take the following action:

VOTED: That sections 63.11 and 63.12 of the Regulations of the Commissioner of Education be added, as submitted, effective July 3, 2013.

VOTED: That sections 63.11 and 63.12 of the Regulations of the Commissioner of Education be added, as submitted, effective June 27 2013, as an emergency action upon a finding by the Board of Regents that such action is necessary for the preservation of the public health and general welfare to ensure that the proposed amendment remains continuously in effect until it can be adopted as a permanent rule on July 3, 2013.

Timetable for Implementation

If the proposed regulations are adopted at the June Regents meeting, the emergency adoption will become effective on June 27, 2013 and the permanent rule will become effective on July 3, 2013.

STATEMENT OF FACTS AND CIRCUMSTANCES WHICH NECESSITATE
EMERGENCY ACTION

The proposed amendment to the Regulations of the Commissioner of Education is necessary to implement Section V of Chapter 57 of the Laws of 2012, which amended Education Law §§6829 and 6830 to require pharmacies to provide certain interpretation and translation services, free of charge, to patients with Limited English Proficiency and to require the Commissioner of Education to establish standardized patient-centered data elements for prescription drug labels.

The proposed amendments were adopted as an emergency measure at the March 2013 meeting of the Board of Regents. Because the Board of Regents meets at fixed intervals, the earliest the proposed amendment can be presented for adoption on a non-emergency basis, after expiration of the 45-day public comment period provided for in State Administrative Procedure Act (SAPA) section 202(1) and (5), is the June 2013 Regents meeting. Furthermore, pursuant to SAPA, the earliest effective date of the proposed amendment, if adopted at the June meeting, would be July 3, 2013.

Emergency action is necessary at the June 2013 Regents meeting for the preservation of the public health and general welfare in order to ensure that the rule that was adopted as an emergency action (in order to timely implement the provisions of the new law) remains continuously in effect until the proposed amendment can be adopted as a permanent rule.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6829 and 6830 of the Education Law

Sections 63.11 and 63.12 of the Regulations of the Commissioner of Education are added, effective June 27, 2013, to read as follows:

§63.11 Interpretation and translation requirements for prescription drugs.

(a) Definitions. As used in this section:

(1) Covered pharmacy shall mean any pharmacy that is part of a group of eight or more pharmacies, located within New York State and owned by the same corporate entity.

(2) Corporate entity shall include related subsidiaries, affiliates, successors, or assignees doing business as or operating under a common name or trading symbol of the covered pharmacy.

(3) Limited English proficient individual or LEP individual shall mean an individual who identifies as being, or is evidently, unable to speak, read or write English at a level that permits such individual to understand health-related and pharmaceutical information communicated in English.

(4) Translation shall mean the conversion of a written text from one language into an equivalent written text in another language by an individual competent to do so and utilizing all necessary pharmaceutical and health-related terminology. Such translation may occur, where appropriate, in a separate document provided to an LEP individual that accompanies his or her medication.

(5) Competent oral interpretation shall mean an oral communication in which a person acting as an interpreter comprehends a message and re-expresses that message accurately in another language, utilizing all necessary pharmaceutical and

health-related terminology, so as to enable an LEP individual to receive all necessary information in the LEP individual's preferred pharmacy primary language.

(6) Pharmacy primary languages shall mean those languages, up to a maximum of seven languages other than English, spoken by one percent or more of the population of the State, as determined by the U.S. Census. If more than seven languages other than English are spoken by one percent or more of the population, the pharmacy primary languages shall be limited to seven most spoken languages, as determined by the U.S. Census.

(b) Provision of competent oral interpretation services and translation services.
Except as otherwise provided in subdivision (e) of this section:

(1) For purposes of counseling an individual about his or her prescription medications or when soliciting information necessary to maintain a patient medication profile, each covered pharmacy shall provide free, competent oral interpretation services and translation services in such individual's preferred pharmacy primary language to each LEP individual requesting such services or when filling a prescription that indicates that the individual is limited English proficient at such covered pharmacy, unless the LEP individual is offered and refuses such services.

(2) With respect to prescription medication labels, warning labels and other written materials, each covered pharmacy shall provide free, competent oral interpretation services and translation services to each LEP individual filling a prescription at such covered pharmacy in such individual's preferred pharmacy language, unless the LEP individual is offered and refuses such services or the medication labels, warning labels and other written materials have already been translated into the language spoken by the LEP individual.

(3) Translation and competent oral interpretation shall be provided in the preferred pharmacy primary language of each LEP individual, provided that no covered pharmacy shall be required to provide translation or competent oral interpretation of more than seven languages.

(4) The services required by this subdivision may be provided by a staff member of the pharmacy or a third-party contractor. Such services shall be provided on an immediate basis but need not be provided in-person or face-to-face.

(c) Notification relating to language assistance services. Except as otherwise provided in subdivision (e) of this section:

(1) In accordance with Education Law section 6829(3), each covered pharmacy shall conspicuously post a notice to inform LEP individuals of their rights to free, competent oral interpretation services and translation services. Such notice shall include the following statement in English and in each of the pharmacy primary languages: "Point to your language. Language assistance will be provided at no cost to you."

(2) The statement in each of the pharmacy primary languages shall be in 20 point bold face, Arial type in a color that sharply contrasts with the background color of the sign. Each such statement shall be enclosed in a box, and there shall be at least a 1/4 inch clear space between adjacent boxes.

(3) The statements in each of the pharmacy primary languages shall be printed on one sign that shall be conspicuously displayed at or adjacent to each counter where prescription drug orders are dropped off and where prescriptions are picked up, and near every cash register at which payment is received for prescription drugs. Such signs

shall be positioned so that a consumer can easily point to the statement identifying the language in which such person is requesting assistance.

(d) Waivers. An application for a waiver of the provisions of subdivisions (b) and (c) of this section shall be made on a form prescribed by the department. The burden of substantiating the validity of a request for a waiver shall be on the applicant.

(1) Each application shall be specific to a registered covered pharmacy, regardless of common ownership.

(2) The applicant shall clearly document the financial or physical constraints, threat to other services provided, or other circumstances upon which the request is based.

(3) No waiver shall be granted in the absence of a showing that implementation of the provisions of subdivisions (b) and (c) of this section would be unnecessarily burdensome when compared to the need for the translation and competent oral interpretation services.

(4) The applicant shall identify alternative sources of competent oral interpretation services or translation services available for LEP individuals within a reasonable distance.

(5) In the event a request for waiver is approved, the pharmacy shall post a notice in the pharmacy primary languages informing LEP individuals of alternative sources.

(6) The duration of a waiver shall be one year and may be renewed upon approval of a new waiver application by the department.

(e) In accordance with Part V of Chapter 57 of the Laws of 2012, the provisions of this section shall preempt any contrary local law or ordinance; provided, however,

that cities with a population of 100,000 or more may retain or promulgate such local laws or ordinances imposing additional or stricter requirements relating to interpretation services or translation services in pharmacies. Nothing in this section shall diminish or impair any requirement that any pharmacy or pharmacist provide any language assistance, interpretation, or translation under any applicable federal or state law, local law or ordinance (unless preempted by this section), consent decree, or judicial settlement, judgment or order.

§63.12 Standardized patient-centered data elements to be used on all drug labels. In accordance with section 6830 of the Education Law, all prescription medicine dispensed to patients in this State must include standardized patient-centered data elements as prescribed by in this section

(a) Definitions. As used in this section:

(1) Critical elements shall consist of:

(i) patient name;

(ii) directions for use by the patient, which directions shall be structured in full sentences; and

(iii) drug name and strength.

(2) Important elements shall consist of:

(i) name, address and telephone number of the pharmacy;

(ii) patient's address;

(iii) name of prescriber;

(iv) the date of filling or refilling of the prescription; and

(v) the prescription number or other identifying number assigned to the prescription.

(b) All prescription drug labels shall contain all of the critical elements and all of the important elements.

(1) Critical elements of each prescription label shall be:

(i) emphasized by being highlighted in color, in bold type, or both: and

(ii) printed in a minimum of a 12-point font.

(2) Important elements of each prescription label and any other information contained on the label shall not be highlighted in color or in bold type, shall be legible and shall not be presented in a fashion that undermines the emphasis on the critical elements.

Assessment of Public Comment

A Notice of Proposed Rule Making was published in the State Register on March 20, 2013. Below is a list of the comments we received on the proposed amendment and the Department's responses.

Comment: One individual questioned if the requirement to provide patient information in another language obviates the need for an English-language label.

Response: The regulation requires written information in the limited English proficient patient's language in addition to an English Language label. Failure to provide an English language label would endanger the health of patients in that other providers, such as emergency medical personnel and emergency room staff, may be unable to determine the medications the patient is taking. Therefore, the Department will make this explicitly clear in a question and answer document under development that patient information must also be provided in English.

Comment: Several commenters indicated that they believe that oral and/or written translation and interpretation services should be provided in more than the four designated languages.

Response: Subdivisions (1)(c), (d) and (e) and (2) of section 6829 of the Education Law, as added by Part V of chapter 57 of the Laws of 2012 require covered pharmacies to provide translation services, both written and oral, in only those languages spoken by 1 percent or more of the population in a given region. Based on the Department's definition of New York State as one region, both written and oral services will be mandated in Chinese, Italian, Russian and Spanish only, though the Department's recommends that pharmacies provide additional transition services.

Comment: A coalition of organizations concurred with the definitions used in the regulation, except for section 63.11(a)(6) of the Regulations of the Commissioner of Education which defines pharmacy primary languages. The writers suggest the Department could use a different definition, based upon federal provisions, to require that translation services be provided in up to seven languages.

The coalition also suggests that the definition of oral translation services (8 NYCRR 63.11[b]) limits the number of the oral translation services required. It is suggested that this provision be eliminated, thereby requiring translation in a multitude of languages.

Response: The Department has reviewed and considered many suggested alternatives and determined that the regulation as drafted effectively implements the purpose and the provisions of the State statute. The suggestion that seven languages could be designated as pharmacy primary languages is inconsistent with the statutory definition of pharmacy primary language.

Comment: The coalition referenced above and another commenter sought the elimination of the waiver provision in the regulations and suggested that covered pharmacies be required to include notification of LEP services in advertisements and promotions.

Response: The Department notes that the statute explicitly requires a waiver process. The Department believes the provision is consistent with the law, and will result in limited, if any, waivers.

Comment: Two responders asked that covered pharmacies be required to establish training programs for staff, to incorporate internal tracking systems for compliance, and to report and monitor progress to the Department.

Response: The Department has reviewed and considered many of the suggested alternatives and determined that the regulation as drafted effectively implements the purpose and the provisions of the State statute, while leaving covered pharmacies sufficient flexibility to implement the new requirements in accordance with the circumstances presented. Covered pharmacies must comply with the provisions of the law and regulations, and the Department will investigate any complaint regarding non-compliance.

Comment: One commenter suggested that directions for use of medications on patient labels should incorporate full sentences and separate the dose itself from the timing of each dose; that numeric characters should be used instead of writing out numbers; and that Latin terms and medical jargon be specifically limited.

Response: Section 63.12 of the proposed amendment requires that directions be structured in full sentences. The Department considered requiring numeric characters but concluded that this should not be mandated in case a situation arose where it would be more appropriate to use numbers that are written out. The Department will, however, monitor this issue to determine whether a change should be made in the future.