

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 March 30, 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.