



THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY12234

TO: The Professional Practice Committee

FROM: Douglas E. Lentivech

SUBJECT: Proposed Amendment to section 63.11 of the Regulations of the Commissioner of Education Relating to Interpretation and Translation Services for Limited English Proficient (LEP) Individuals by Mail Order Pharmacies

DATE: June 16, 2014

AUTHORIZATION(S):

SUMMARY

Issue for Decision

Should the Board of Regents amend section 63.11 of the Regulations of the Commissioner of Education relating to the provision of interpretation and translation services for Limited English Proficient (LEP) individuals by mail order pharmacies?

Reason(s) for Consideration

Required by State statute (Education Law section 6829[4], as added by Section 3 of Part V of Chapter 57 of the Laws of 2012).

Proposed Handling

The proposed amendment will be presented to the Professional Practice Committee for recommendation and to the full Board for adoption as permanent rule at the June 2014 meeting of the Board of Regents. In addition, a second emergency action is necessary to ensure that the emergency rule adopted at the March 2014 Regents meeting remains continuously in effect until July 9, 2014, which is the effective date of the adoption of the permanent rule. A copy of the permanent rule, the emergency rule, and a Statement of Facts and Circumstances Which Necessitate Emergency Action are attached.

Supporting materials are available upon request from the Secretary to the Board of Regents.

Procedural History

The proposed amendment was adopted as an emergency rule at the March Regents meeting, effective March 30, 2014. A Notice of Proposed Rule Making was published in the State Register on March 19, 2014 for a 45-day public comment period. A Notice of Emergency Adoption was published in the State Register on April 16, 2014. Because the emergency rule will expire on June 25, 2014, a second emergency action is necessary in order to ensure that the emergency rule remains continuously in effect until the permanent rule takes effect on July 9, 2014. Additionally, following the above-referenced publication of the Notice of Proposed Rule Making, the Department received one comment on the proposed amendment. An Assessment of Public Comment is attached, however, no change in the proposed amendment is recommended at this time.

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 law, which generally became effective March 30, 2013, includes provisions to assist LEP individuals who need interpretation and translation services when filling prescriptions at covered pharmacies.

Effective May 30, 2013, the Board of Regents approved regulations affecting those covered pharmacies located within New York State. Following a series of open forums and consultations with stakeholders, the Regents accepted the recommendation that the entire state be considered a single "region." In accordance with the statutory requirements and the analysis of census data, this determination resulted in a requirement that interpretation and translation services be provided in four languages, in addition to English. Other regional determinations were rejected since most led to fewer languages being covered in almost all upstate localities. Therefore, covered New York State pharmacies must now provide competent oral interpretation services and translation services in Chinese, Italian, Russian and Spanish.

The 2012 legislation also required the Commissioner of Education, in consultation with the Commissioner of Health (DOH), to promulgate regulations, effective March 30, 2014, to establish translation and interpretation requirements for mail-order pharmacies. Specifically, Education Law §6829(4) requires the regulations to address the concerns of affected stakeholders and reflect the findings of a thorough analysis of issues including: (a) how persons shall be identified as an LEP individual, in light of the manner by which prescriptions are currently received by mail order pharmacies; (b) which languages shall be considered; (c) the manner and circumstances in which competent oral interpretation services and translation services shall be provided; (d) the information for which competent oral interpretation services and translation services shall be provided; (e) anticipated utilization, available resources, and cost considerations; and (f) standards for monitoring compliance with

the regulations and ensuring the delivery of quality competent oral interpretation services and translation services.

Based upon consideration of the factors above, it is proposed that mail order pharmacies sending prescriptions to New York State residents be subject to the same requirements as are now required for covered pharmacies within the State. Specifically, with each initial transaction with patients seeking mail order pharmacy services, mail order pharmacies will provide printed materials, in at least the four above-referenced languages, explaining the availability of competent oral interpretation services and translation services. A client will be identified as an LEP individual when he or she requests such oral interpretation services and translation services or when such mail order pharmacy fills a prescription that indicates that the individual is limited English proficient. The manner and circumstances in which competent oral interpretation services and translation services will be provided is by a staff member of the mail order pharmacy or third-party contractor, and services will be provided on an immediate basis but need not be provided in-person or face-to-face. The information for which competent oral interpretation services and translation services shall be provided will be prescription medication labels, warning labels and other written materials. With respect to anticipated utilization, available resources, and cost considerations, based upon experience with the existing requirements for translation services in the New York City metropolitan area, the proposed requirements should prove to be neither costly nor logistically difficult for mail order pharmacies. Finally, regarding standards for monitoring compliance with the regulations and ensuring the delivery of quality competent oral interpretation services and translation services, as in all such matters, complaints of non-compliance will be investigated, and since out-of-state pharmacies require registration with the Department, they are also subject to the Department's professional discipline processes.

Recommendation

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

VOTED: That paragraph (7) of subdivision (a) of section 63.11 of the Regulations of the Commissioner of Education is added, and subdivision (b) and paragraph (1) of subdivision (c) of section 63.11 are amended, as submitted, effective July 9, 2014; and it is further

VOTED: That paragraph (7) of subdivision (a) of section 63.11 of the Regulations of the Commissioner of Education is added, and subdivision (b) and paragraph (1) of subdivision (c) of section 63.11 are amended, as submitted, effective June 26, 2014, 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 emergency rule adopted at the March 2014 Regents meeting to implement the requirements of Education Law section 6829(4) as added by Section 3 of Part V of Chapter 57 of the Laws of 2012 remains continuously in effect until the effective date of the amendment's permanent adoption, so that limited English proficient individuals can receive free, competent oral interpretation services and translation services from mail order pharmacies.

Timetable for Implementation

The proposed amendment was adopted as an emergency rule at the March 2014 Regents meeting, effective March 30, 2014 and will expire on June 25, 2014. If adopted at the June 2014 Regents meeting, the permanent rule will take effect on July 9, 2014 and the emergency rule will take effect on June 26, 2014.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6810 and 6829 of the Education Law

1. Paragraph (7) of subdivision (a) of section 63.11 of the Regulations of the Commissioner of Education is added, effective July 9, 2014, to read as follows:

(7) Mail order pharmacy shall mean a pharmacy that dispenses most of its prescriptions through the United States postal service or other delivery system.

2. Subdivision (b) of section 63.11 of the Regulations of the Commissioner of Education is amended, effective July 9, 2014, as follows:

(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 and mail order 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 or mail order 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 and mail order pharmacy shall provide free, competent oral interpretation services and translation services to each LEP individual filling a prescription at such covered pharmacy or mail order pharmacy in such individual's preferred pharmacy primary 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 or mail order 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 covered pharmacy or mail order 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.

3. Paragraph (1) of subdivision (c) of section 63.11 of the Regulations of the Commissioner of Education is amended, effective July 9, 2014, as follows:

(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." With each initial transaction with patients seeking mail order services, mail order pharmacies shall provide printed materials in English and in each of the pharmacy primary languages, explaining the availability of competent oral interpretation services and translation services. In addition, mail order pharmacies that are nonresident establishments shall provide any required information pursuant to section 63.8(b)(6) of this Part in English and in each of the pharmacy primary languages.

8 NYCRR §63.11

ASSESSMENT OF PUBLIC COMMENT

Since publication of a Notice of Proposed Rulemaking in the March 19, 2014 State Register, the State Education received the following comment:

COMMENT:

Certain Assembly members have requested that the number of languages in which mail order pharmacies are required to provide interpretation and translation services to Limited English Proficient (LEP) Individuals be increased Statewide to include the three additional languages required under New York City's local law for large retail chains (Korean, French Creole and Begali).

DEPARTMENT RESPONSE:

The Department discussed these requests with the Assembly members. The Department considered all of the factors required under Education Law §6829(4) when adopting the proposed amendment, including anticipated utilization, available resources and cost considerations. Based on data reviewed from the U.S. Census Bureau, it appears that there are many different primary languages throughout the State and that the four consistent primary languages are Chinese, Italian, Russian and Spanish. In an effort to be consistent with the languages required for translation services in large retail chains under Education Law §6829(2), the Department is proposing to require the same four languages for mail order pharmacies Statewide.

It is the Department's understanding that New York City has required three additional languages under local law for large retail chains (Korean, French Creole and Begali). New York City also has the authority to impose additional languages under its own local laws for mail order pharmacies. Therefore, the Department recommends that New York City adopt its own local law to add these three languages as opposed to a

Statewide requirement where services for these languages may not be utilized and it may impose additional costs on these mail order pharmacies, when such services may not be needed. After a discussion with the Assembly explaining the Department's rationale on the proposed amendment, it was determined by the Department that no change to the proposed amendment was needed at this time.

8 NYCRR §63.11

STATEMENT OF FACTS AND CIRCUMSTANCES WHICH NECESSITATE EMERGENCY ACTION

The purpose of the proposed amendment is to implement Education Law section 6829(4), as added by Section 3 of Part V of Chapter 57 of the Laws of 2012, which establishes interpretation and translation requirements for all mail order pharmacies conducting business in New York State. The proposed amendment implements the provisions of section 6829(4) of the Education Law that, effective March 30, 2014, requires all mail order pharmacies sending prescriptions to individuals in New York State to provide interpretation and translation services for Limited English Proficient (LEP) individuals. It also subjects mail order pharmacies to the same interpretation and translation services requirements as are now required for covered pharmacies within the state. The information for which competent oral interpretation and translation services shall be provided will be prescription medication labels, warning labels and other written materials.

The proposed amendment was adopted as an emergency action at the March 10-11, 2014 Regents meeting, effective March 30, 2014, and has now been adopted as a permanent rule at the June 23-24, 2014 Regents meeting. Pursuant to SAPA section 203(1), the earliest effective date of the proposed amendment is July 9, 2014, the date a Notice of Adoption will be published in the State Register. However, the emergency rule will expire on June 25, 2014. If the rule were to lapse, some limited English proficient individuals may be unable to obtain free, competent oral interpretation services and translation services from mail order pharmacies. To avoid the adverse effects of a lapse in the emergency rule, a second emergency action at the June 2014 Regents meeting is necessary for the preservation of the public health and general

welfare to ensure that the proposed rule adopted by emergency action at the March Regents meeting to implement the requirements of Education Law section 6829(4), as added by Section 3 of Part V of Chapter 57 of the Laws of 2012 remains continuously in effect until the effective date of its permanent adoption, so that limited English proficient individuals can receive free, competent oral interpretation services and translation services from mail order pharmacies.

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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.

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(4) The services required by this subdivision may be provided by a staff member of the covered pharmacy or mail order 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.

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(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." With each initial transaction with patients seeking mail order services, mail order pharmacies shall provide printed materials in English and in each of the pharmacy primary languages, explaining the availability of competent oral interpretation services and translation services. In addition, mail order pharmacies that are nonresident establishments shall provide any required information pursuant to section 63.8(b)(6) of this Part in English and in each of the pharmacy primary languages.