



## Pharmacy Language Solutions

### Pharmacies and Translation: The Regulatory Landscape in 2009

For the last decade, there has been a growing movement at federal and local levels to enact and enforce laws and regulations that mandate provision of translation and interpreting services to pharmacy customers who have limited English-speaking ability.

In this White Paper we summarize the Federal regulatory framework governing language services required of pharmacies. We then describe in some detail the recent regulations enacted in New York State - including New York City, and California which will affect pharmacies in 2010-2012.

## Summary of Regulations Governing the Provision of Translation and Interpreting Services by Pharmacies

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**About RxTran**

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RxTran helps pharmacies communicate effectively drug label safety information to their customers who may have limited command of the English language.

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We provide pharmacies with an on-line library of pre-translated prescription drug label information, such as Patient Instructions for Taking Medications (also known as SIG or Directions for Use of Prescription Medication) and Consumer Medication Information (CMI and Package Inserts). This information is translated into over a dozen foreign languages and is available to Pharmacies in real time to print out and distribute to patients with Limited English Proficiency (LEP).

**Pharmacy Language Solutions**

## Summary of Regulations Governing the Provision of Translation and Interpreting Services by Pharmacies

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A few states, as well as New York City, have passed comprehensive pharmacy language access laws to ensure that community pharmacies provide free translation and interpreting services to their customers with limited English proficiency (LEP).

Below we describe informally and briefly the gist of federal regulatory framework, as well as some specific requirements enacted in New York State – including New York City, and California. This is not intended to be an authoritative or legal interpretation of the requirements. The links to source documents are provided wherever possible. Please consult your attorney for any questions regarding interpretation of any laws and regulations mentioned below.

### **A. Federal Regulations Affecting Pharmacies Serving Customers with Limited English Proficiency.**

#### **A.1. The Legal Basis for Federal Language Services Regulations of Pharmacies**

##### ***Title VI of the Civil Rights Act***

On the federal level, the regulatory framework was set more than 45 years ago with the enactment of Title VI of The Civil Rights Act of 1964. Title VI prohibits discrimination on the basis of race, color, and national origin in programs and activities receiving federal financial assistance. Since most pharmacies in the US are recipients of federal funds, directly or indirectly, their activities fall under Title VI provisions. For example, a pharmacy that serves Medicare or Medicaid patients would be subject to Title VI.

In the last decade, the U.S. Department of Health and Human Services (HHS) and the Department of Justice (DOJ) started applying Title VI aggressively to protect national origin minorities with Limited English Proficiency (LEP) in the health care settings. The attitude of federal agencies was particularly affected by President Bill Clinton's executive order 13166, signed on August 2000. The order served to remind federal agencies to examine the services they provide, identify any need for services to those with limited English proficiency, and develop and implement a system to provide those services so LEP persons can have meaningful access to them. And by and large, the courts have agreed that language barriers are a form of discrimination.

##### ***The 4-factor Analysis of the HHS Guidelines of 2003***

The most specific regulatory guideline on the federal level was issued by the Department of Health and Human Services (HHS) in 2003. The Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons ([www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/policyguidancedocument.html](http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/policyguidancedocument.html)) specifies a number of criteria to use in determining what, when and how should translation and/or interpreting services be provided by health care providers, including pharmacies.

The pharmacies, in determining their level of services to LEP population are required to use the four-factor analysis:

- The number or proportion of LEP individuals served or encountered.
- The frequency of contact with the program.

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- The nature and importance of the program to beneficiaries.
- The resources available and cost considerations.

However, the HHS guidelines do not specifically state which parts of the drug label need to be translated, and under what circumstances and in which languages is patient counseling required to be provided.

One of the best sources of detailed analysis of the federal laws on language access as they relate to pharmacies is the The National Health Law Program ([www.healthlaw.org](http://www.healthlaw.org)).

## **B. New York State Pharmacy Translation Requirements**

### **B.1. Status of Regulations**

On April 21, 2009 New York State Attorney General signed agreements with seven major pharmacy chains. Under the terms of the agreement the pharmacies are required to provide limited English proficiency customers with interpreting and translation services in all of their New York stores.

#### ***Pharmacies Directly Affected:***

The agreements were signed with 7 of the largest pharmacy chains in New York State: A&P, Costco, CVS, Duane Reade, Rite-Aid, Target, and Walmart.

#### ***Which Individuals are Considered to be Limited English Proficiency (LEP):***

The threshold defined by the Attorney General for the purpose of this agreement is the standard one: An individual is considered to be LEP if his or her knowledge of English is not sufficient for communicating about the safe and effective administration of prescription medications.

### **B.2. The (Written) Translation Requirements for the Pharmacies**

#### ***Languages Requiring Translation:***

For written translation, the agreement covers 11 languages. Six languages are fixed at the start: Chinese, French, Italian, Polish, Russian, and Spanish. In addition, within 6 months after full implementation of their new pharmacy computer systems (scheduled to take place by March 31, 2010), each pharmacy chain is to add five additional languages based on their assessment of demographics and need in each chain's service area.

#### ***Information Required to be Translated:***

The pharmacies have to provide their LEP customers whose primary language is one of the 11 languages specified above the translated versions of all prescription drugs:

- Directions for Use of the Drug
- Warning Labels with information regarding the safe and effective use of the drug, including common side effects or adverse effects and contraindications
- Notices of Privacy Practices
- Written offers of counseling

If an LEP customer does not speak one of the 11 primary languages for the pharmacy, the above-specified information does not need to be provided to the person in written form in their language.

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However, that information has to be relayed to the person orally (e.g., via telephone interpreting) in their primary language.

### **B.3. The (Oral) Interpreting Requirements for the Pharmacies**

#### ***Languages Requiring Interpreting:***

Interpreting is to be available in **all languages** reasonably expected to be requested by each chain's customers.

#### ***Which (Oral) Interpreting Services are Required for LEP Individuals***

Pharmacy staff members who are not able to communicate adequately with an LEP individual in their primary language have to utilize, free of charge to the customer, an interpreter, either in-store or over the phone, when:

- Soliciting information to maintain a patient medication profile;
- Offering prescription drug counseling;
- Providing prescription drug counseling where such "**counseling is not refused by the Customer.**"
- Accepting prescription refill requests, either in-person or over the telephone.

#### ***Who Qualifies as a Competent Interpreter Under the Law:***

If communication with an LEP individual is done directly by a pharmacist or using another pharmacy staff person as an interpreter, the pharmacy person has to be certified as competent to communicate prescription drug information effectively in the specific language before that person can be relied upon for communication with the LEP customers. The testing and certification has to be performed by an outside vendor on behalf of the pharmacy.

### **B.4. Implementation**

#### ***Implementation Schedule:***

The agreements with the individual chains went into effect between November 12, 2008 and April 21, 2009. Each separate agreement has a phased implementation schedule, but in all cases the complete implementation of all the agreement provisions has to take place no later than May 15, 2010.

#### ***Notification Requirement***

Each affected pharmacy has to inform customers of their right to free language services. Multilingual posters announcing this requirement have to be conspicuously present in each pharmacy location and on the chains' websites.

#### ***Text of the Agreement***

The full text of a sample agreement signed by the Attorney General with the pharmacy chains is available at <http://www.rxtran.com/Pharmacy-Translation-New-York-State.pdf>.

## C. New York City Laws Governing Translation Service Requirements for Pharmacies

### C.1. Status of the Law

On 8/20/2009 the New York City Council passed Bill 859-A ([www.nyc.gov/html/om/html/2009b/pr395-09.html](http://www.nyc.gov/html/om/html/2009b/pr395-09.html)) "Provision of language assistance services in pharmacies." The bill was signed by the NYC Mayor Michael Bloomberg on September 3, 2009 and became Law No. 2009/055.

#### *Pharmacies Directly Affected by the Law:*

The pharmacy law affects all pharmacy chains with 4 or more stores anywhere in the US, not just in New York City.

#### *To Which Individuals Are Pharmacies Required to Provide Translation and Interpreting Services:*

The law counts as a Limited English Proficiency (LEP) customer any individual who self-identifies as being "unable to speak, read or write English at a level that permits such individual to **understand health-related and pharmaceutical information communicated in English**". Individuals who "evidently" don't have this level of English proficiency are also covered by the law, whether they are able to identify themselves as such or not.

### C.2. The (Written) Translation Requirements for the Pharmacies

#### *What Written Documents Have to be Translated:*

The Law mandates that every chain pharmacy in New York City has to provide free translation of prescription medication labels, warning labels, and other written material that the pharmacy considers vital to an LEP individual's safe and effective use of prescription medications.

#### *Languages Requiring (Written) Translation:*

The Law requires that all covered pharmacies provide written translation of certain materials in the seven languages that are the "primary languages" in New York City. The list of the 7 primary languages is to be determined annually by the City, but currently consists of Spanish, Chinese, Russian, Korean, Italian, Haitian Creole, and Bengali.

### C.3. The (Oral) Interpreting Requirements for the Pharmacies

#### *Which (Oral) Interpreting Services are Required for LEP individuals:*

Every chain pharmacy is required to provide "free, competent oral interpretation of prescription medication labels, warning labels and other written material to each LEP individual filling a prescription at such chain pharmacy, **unless the LEP individual is offered and refuses such services.**"

The law does not seem to circumscribe the list of languages requiring interpreting to the list of 7 "primary" languages that require written translation of drug labels. Potentially, all 150 or so languages spoken in the New York City fall under the scope of the interpreting requirement.

The pharmacies are required to provide interpreting services for all LEP individuals filling a prescription for the purposes of counseling such individual about his or her prescription medications or when

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soliciting information necessary to maintain a patient medication profile, **unless the LEP individual is offered and refuses such services.**

### ***Who Qualifies as a Competent Interpreter Under the Law:***

An essential requirement for interpreters is that, in addition to having adequate knowledge of English and the patient's primary language, the interpreter has to know the necessary pharmaceutical- and health-related terminology in both languages.

## **C.4. Implementation**

### ***Implementation Schedule:***

The law is to take effect on June 1, 2010, 270 days after its enactment.

### ***Notification Requirement***

Pharmacies affected by the New York City Law have to post conspicuous notices, in all seven primary languages, announcing that the patients have the right to free translation and interpreting services. These notices have to be posted at or adjacent to each counter where prescription medications are sold.

### ***Text of the New York City Language Assistance in Pharmacies Law***

The full text of the New York City Language Assistance in Pharmacies Law can be downloaded from (<http://www.rxtran.com/Pharmacy-Translation-Law-New-York-City-2009.pdf>).

## **D. California**

### **D.1. California Law SB 472**

California Senate Bill [SB 472](#) was signed by Governor October 11, 2007. The Bill requires that by January 1, 2011, California adopt a standardized prescription drug label. Specifically, the Bill tasks the California State Board of Pharmacy to design such a standardized, patient-centered, prescription drug label and mandate it's use by state pharmacies on all prescription medication dispensed in California.

The Bill requires the Board of Pharmacy to specifically consider the needs of patients with limited English proficiency in designing the new standardized drug label.

### ***Implementation of the Law***

The California Board of Pharmacy ([http://pharmacy.ca.gov/laws\\_regs/laws\\_and\\_regulations.shtml](http://pharmacy.ca.gov/laws_regs/laws_and_regulations.shtml)) is currently in the process of implementing SB 472. During 2008, the board held a series of public meeting throughout California, to gather information and input from consumers and the health professions. In 2009, the board is working on adopting regulations to standardize prescription labels. In 2010, all pharmacies dispensing drugs to California patients must convert their labels to this new format by the 2011 deadline.

The Board is still grappling with questions such as:

- Should the board develop translations of standardized SIGs in the top five languages for directions for use? Should the pharmacies themselves be required to translate the custom SIGs?

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- How should the board address the requirement to include the physical description of the contents of a medication on the label? Should the board require these be translated into diverse languages, or should a picture of the pill be considered as complying with the directions?
- If the board translates the directions for use, how should the board deal with translating other patient-centered items on the label, such as the auxiliary warning labels?

Currently, California Endowment (see <http://www.calendow.org/article.aspx?id=1380&ItemID=1380>) is sponsoring a project for evaluating and translating the standardized directions for use in the top 5 languages in California.

### ***Implementation Schedule:***

The new standardized labels are to be implemented by January 1, 2011. However, whether and how the labels are to be translated, and into how many languages, has not yet been decided by the California Board of Pharmacy.

### ***Text of the California Law SB 472***

The full text of the California SB 472 can be downloaded at <http://www.rxtran.com/Pharmacy-Translation-Law-California.pdf>.

## **E. RxTran Services for Pharmacies and Pharmacy System Providers**

RxTran has developed a unique suite of translation, interpreting, and certification services for the pharmacies to help them communicate with non-English speaking customers. These services satisfy all the current and anticipated future requirements for pharmacies across the United States.

### ***Multilingual Patient Instructions (SIGs) and Auxiliary Warning Labels***

Our software enables you to give your customers Patient Instructions (SIGs) and auxiliary warning labels in the language your customers are best able to understand them. Our software works with both standard and custom SIGs.

### ***Consumer Medication Information (CMI) Leaflets***

Use our on-demand on-line library of Consumer Medication Information, MedGuides, and Package Inserts. Print labels for your customers in over a dozen languages, including Spanish, French, Vietnamese, Italian, Polish, Korean, Russian, etc.

### ***FAQs, Educational Monographs, and Patient Instructions in Many Languages***

We provide pharmacies with the on-line on-demand library of multilingual Frequently Asked Questions (FAQs) and drug information, including descriptions on the proper use of medical devices dispensed by your pharmacy – all delivered right to your printer to give to your customers.

Better real-time printed information in the patient's language helps minimize the need for the more expensive over-the-phone interpreting services.

### ***Phone Interpreting***

RxTran provides over-the-phone interpreting services for patients who have specific questions to the pharmacists.

## **Pharmacy Language Solutions**

***Certification of Competency in Foreign Language***

RxTran has developed the only Pharmacy-specific *Certification of Competency in Pharmacy Patient Communication in Foreign Language* for those pharmacy employees who can directly and safely serve the limited English Proficiency (LEP) customers.

***How to Learn More about RxTran Pharmacy Language Services***

All of these services can be delivered to your stores in over a dozen languages on a low-cost pay-for-what-you-need efficient subscription basis.

To get more information about our pharmacy language services, call Evan (617-621-0940 x. 141 or 800-240-0246) or email at [info@RxTran.com](mailto:info@RxTran.com) to find out how RxTran can help you provide a more comprehensive set of services to your pharmacy clients.