

Rx for Safety

Establishing Standards for Clear and Accessible Prescription Medication

Detailing our findings on chain pharmacies' provision of language assistance services, and advocating for improved patient comprehension of prescription medication information through statewide legislation.



N Y L P I

A report by:
Make the Road New York
&
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Executive Summary

Every New Yorker should understand his or her prescription medication labels. The consequences of misunderstanding prescription labels can be dire and costly. Every year, unintended misuse of prescription medications causes over one million “adverse drug events,” resulting in expensive visits to the emergency room, hospitalization, and death. The solutions to this serious health problem are simple, inexpensive, and efficient for pharmacies to implement. Creating easy-to-understand, standardized prescription labels, and providing that information in a patient’s language, can significantly improve health outcomes.

Since 2007, Make the Road New York (MRNY) and New York Lawyers for the Public Interest (NYLPI) have been championing the issue of safe access to prescription medications in New York State, particularly with regard to language access. We worked with the New York State Office of the Attorney General (OAG) to enforce existing laws relating to language access in pharmacies, which resulted in settlement agreements with seven chain pharmacies operating across the state. We also worked with the New York City Council to pass the *Language Access in Pharmacies Act* (NYC-LAPA), which requires chain pharmacies in the city to provide translation and interpretation services for limited English proficient (LEP) consumers filling prescriptions.

For this report, we surveyed more than 200 chain pharmacies across the state to determine their capacity to provide language assistance services to LEP consumers.

Our results show that:

- **The settlement agreements and local law have led to significant improvements in the provision of language assistance services compared to when we began this work in 2007.**
- **However, nearly 50% of pharmacies surveyed statewide were still unable to report that they met prescription label translation requirements.**
- **Further, almost 30% of surveyed pharmacies statewide could not state that they provided mandated interpretation services for medication counseling.**
- **Pharmacies not subject to the settlement agreements or local law provide the poorest access to limited English proficient consumers.**

These results suggest that the oversight and additional regulation by state and local authorities in this area during the past few years has made a positive impact on patient access to pharmacies, but more work needs to be done. In addition to the ongoing language barriers, the fact remains that many consumers, regardless of the language that they speak, continue to have a difficult time understanding the instructions and labels that accompany their medication, and there is little in existing law to help them.

We therefore advocate for state legislation that would build on the current law and agreements by creating a framework for standardized and simplified prescription labels and expand New York City's pharmacy language access mandates statewide.

Overview of the Problem: Patient Misunderstanding of Prescription Labels

Prescription drug labels are only effective if patients are able to understand them. The feeling of confusion upon returning home from the pharmacy and not understanding how to take the medication is universal. With dozens of ways for a pharmacist to write “take once a day,”¹ it is often challenging for individual patients to understand and act correctly on just one prescription instruction. For those who take multiple medications, such as the elderly, this challenge is even greater. Age-related declines in vision, memory and cognitive skills means that small print and cluttered labeling are particularly problematic for the elderly. Similarly, for the over 2.4 million people in the New York who speak English less than “very well” and are therefore considered limited English proficient (LEP), the lack of translation makes labels literally incomprehensible.²

One primary reason for patients misunderstanding medication information is due to low levels of health literacy, which is defined as the ability to “obtain, process, and understand basic health information and services needed to make appropriate health decisions.”³ Research has shown that over one-third of the total adult population of the United States is considered to have only basic or below basic health literacy. The Center for Medicare Education estimates that as many as 80 percent of Medicare beneficiaries have low health literacy; as a consequence, Medicare patients take 40 percent of their medications incorrectly.⁴

The consequences of patient misunderstanding of prescription labels can be dire. Unintended misuse of prescription medications causes over one million yearly “adverse drug events,” resulting in visits to the emergency room, hospitalization and, in some cases, even death. Indeed, patient non-adherence with prescription instructions due to low levels of health literacy and other factors is responsible for 22% of all hospitalizations nation-wide. This problem places additional burdens on already under-resourced emergency rooms and hospitals and costs an extra \$300 billion per year in healthcare spending.⁵

It is no surprise, then, that providing easy-to-understand, standardized prescription label information, as well as providing that information in a patient's language, can improve health outcomes.⁶ For instance, a 2009 study of older patients demonstrated that adding clearer directions to prescription medication labels increased confidence that they were taking medications correctly for nearly 85% of patients.⁷ Without standardized prescription labels or consistent access to translation and interpretation services, though, millions of elderly and LEP individuals are rendered unable to fully understand medication information. As such, they are deprived of effective care, and their health and safety is seriously jeopardized. (For more information on the research related to patient comprehension of medication information, please see Appendix A of this report.)

Stories from the Community

The vignettes below provide a snapshot of how the data collected from our surveying actually play out on a regular basis for community members who require language assistance services to understand their prescription medication information.

RAMONA L.

Ramona L. has been a part of Make the Road for over a year now. She has had horrible experiences when it comes to pharmacies and translation services. On one occasion, she visited a chain pharmacy in Bushwick to pick up medicine and left with nothing. Ramona left empty handed because the employee there was not able to help her find the over the counter medication that she was shopping for nor did he attempt to find someone that could speak to her in Spanish. After that she decided that she would not return to that pharmacy again since she did not want to risk the change of choosing the wrong medicine, or not understanding the dosage.

Another time she decided to visit a different chain pharmacy, not too far from the previous one. This time she wanted to fill her prescription and again she left empty handed. There were no signs offering her translation services and the people there did not look welcoming at all. This time she did not even bother to ask for help.

Ultimately, Ramona decided that she would go fill her prescription elsewhere where a pharmacist could ensure that she understood information regarding her prescription. She wanted to be sure that the pharmacist would be able to speak to her in her language and explain the medication and the doses she needs to take. She went to a small, independent pharmacy and was completely satisfied with the service she was given and has continued to fill her prescriptions there ever since. She likes that the people are friendly but mostly that they can speak to her in Spanish and thoroughly explain any medication and answer her questions.

DORIS M.

Doris has always visited a chain pharmacy in Bushwick, mostly because it is convenient and near her home. Doris has asked to speak to a pharmacist in Spanish on several occasions but has been told that there is no one available. She has also noticed that there are no signs at this pharmacy offering interpretation services to the customers if they need it, and has seen other customers struggling in the pharmacy to find their prescriptions and understand the labels.

GLADYS S.

Gladys has been a member of Make the Road New York for almost 9 years now. She is an immigrant from Puerto Rico and has been in the U.S. for 30 years. In late December of 2009 she was in an accident where a car hit her and she ended up in the hospital. She went to get prescription medication at a chain pharmacy, but no one in the pharmacy was able to help her fill the prescription or find a similar over the counter drug that she could use instead. With her limited English, she searched on her own for a drug that “looked like” the medication (pain relief lotion) that she was prescribed (but could not afford to buy). No guidance or language assistance services were offered to her. She ended up choosing the pain relief lotion that she thought was the most similar to what she was prescribed, but she never knew if the lotion would be a good substitute. Gladys still does not have this medication that she was prescribed almost a year ago.

Please Note: Last names and full names have been withheld to protect privacy. Requests for interviews can be made to Make the Road New York (Theo Oshiro, Director of Health Advocacy).

Despite the above facts, there is no state law that requires pharmacies to print prescription drug labels in a standardized format to aid in consumer comprehension or to translate them so that all patients can understand them.

This report presents the case for enacting such a law. The next section provides an overview of the existing laws in this field and describes the efforts of Make the Road New York (MRNY) and New York Lawyers for the Public Interest (NYLPI) to enforce compliance with and promote changes to current laws, particularly those related to language access. The third section discusses the impact of these compliance and law reform efforts. It demonstrates how our advocacy on language rights in pharmacies has advanced the cause of ensuring that all patients can better understand prescription labels, but also highlights the fact that more needs to be done. The final section describes the proposed state law and how it will continue to improve patient understanding of prescription labels.

The Legal Landscape

This section provides an overview of local and federal laws pertaining to prescription label standardization and language access. It also details our recent campaigns to enforce compliance with and advocate for changes to current laws, particularly those related to language access.

Prescription Label Standardization

Federal law requires that certain information, such as the patient name and expiration date, be printed on the prescription container label.⁸ State law also regulates the content of labels so as to

Over 50 Ways to Write “Take 1 Tablet A Day”

Here are just a few examples of the variations:

- *Take one tablet orally every day.*
- *Take one tablet by mouth once daily.*
- *Take one pill by mouth at bedtime.*
- *Take one tablet one time each day.*
- *Take one pill by mouth once each day.*
- *Take 1 tablet 1 time daily.*

For individuals with low health literacy, including the elderly and consumers who are LEP, these variations make understanding prescription medication directions unnecessarily confusing.

prevent fraud, misbranding and the like, but no legislation or regulations are currently in place in New York that require medication instructions to be standardized. This allows for dozens of variations in the instructions provided on the labels for the same medication. This variability also extends to font size, color of the label, and whether or not icons appear as part of the instructions to aid in comprehension.⁹

Language Access

As far as language access is concerned, laws already exist that we have succeeded in both enforcing and building upon in order to ensure that all patients can understand prescription medication information. Title VI of the Civil Rights Act of 1964 is the oldest of these laws.¹⁰ This law prohibits any organization that receives federal money from discriminating against persons based on race, color, or national origin. Discrimination under Title VI includes preventing meaningful access to federally funded services for patients who are LEP. As such, people who are LEP are entitled to receive interpretation and translation services so that they may access programs that receive federal financial assistance on equal terms as everyone else.¹¹ Since most chain pharmacies receive federal money in some form or another, particularly through the Medicaid and Medicare programs, Title VI requires that these chain pharmacies provide LEP persons with interpretation and translation services so that they, like English-speakers, can access the pharmacy's services.

Did You Know? Interpretation & Translation Are Not the Same Thing!

Although the terms “interpretation” and “translation” are often used inter-changeably, they actually don't refer to the same thing!

Interpretation refers to the conversion of *oral* or *spoken* words from one language to another.

Translation refers to the conversation of *written* words from language to another.

In the pharmacy context, both interpretation and translation are important. Interpretation is needed when pharmacists are orally counseling patients, as required by law, about how to take their medications safely and effectively. Translation is required for all the written information—labels, pamphlets, etc.—that patients get when they take the medication home.

Unfortunately, federal language access requirements are quite broad and many pharmacies in New York did not know or simply were not complying with requirements. For example, a 2007 study by the New York Academy of Medicine found that New York City pharmacies overwhelmingly failed to provide their LEP customers with translated medication labels despite having the capacity to do so in at least some languages.¹²

In response, in July 2007, MRNY and NYLPI filed a civil rights complaint with the New York State Office of the Attorney General (OAG) after community members found themselves unable to understand prescription label instructions due to language barriers.¹³ As a result, the OAG investigated and entered into settlement agreements with several major chain pharmacies operating across New York in order to provide some specificity around broad federal mandates as well as relevant state laws.¹⁴ The chain pharmacies subject to the agreements are required to make translated prescription labels available in eleven languages and must provide in-person or telephonic interpretation services to patients who are LEP.

In 2008, MRNY and NYLPI teamed up once again to advocate for the New York City Language Access in Pharmacies Act (NYC-LAPA), which was signed by Mayor Bloomberg in September 2009. NYC-LAPA codifies and makes permanent many of the requirements in the OAG

settlement agreements, and requires all New York City chain pharmacies provide language assistance to patients who are LEP.¹⁵ Under the law, chain pharmacies in New York City must:

- post notifications informing patrons of their right to free language assistance services;
- provide oral interpretation services for medication counseling, prescription medication labels, warning labels and other written prescription material; and,
- provide written translation services for prescription drug labels, warning labels and other written prescription material.¹⁶

It is important to recognize that the NYC-LAPA was passed to give specificity to already-existing language access mandates that are very general in nature. This added specificity was necessary because pharmacies were not otherwise complying with their requirements under the law. However, the NYC-LAPA only covers New York City, and there are many pharmacies across New York State that are not required to provide translation and interpretation services to the level specified in the New York City law because they are not covered by it. Further, there is still no law on medication label standardization.

As our data in the subsequent section indicate, the enforcement of existing laws and the enactment of new laws at the local level have led to an improvement in pharmacies' accessibility to LEP consumers and in consumers' ability to understand the medications they receive. However, the data also suggest that pharmacies not subject to additional regulation, such as the NYC-LAPA, are still providing very poor access to patients who are LEP. Most significantly, the fact remains that many consumers—regardless of the language they speak—continue to have a difficult time understanding the instructions and labels that accompany their medication and that there is little in existing law to help them.

Data Analysis: A Survey of Pharmacy Compliance

NYC-LAPA and the OAG's settlement agreements were important first steps to ensuring that all New Yorkers understand prescription drug information and have significantly increased patient understanding of prescription drug information. That said, our monitoring efforts statewide clearly indicated that a more comprehensive state law is necessary to fully ensure the health and safety of all New Yorkers.¹⁷

From July through October, 2010, MRNY and NYLPI surveyed and monitored over 200 chain pharmacies across the state of New York to determine the extent to which pharmacies were meeting the language assistance needs of LEP consumers.¹⁸ Our data are decidedly mixed. Many pharmacies that we surveyed were largely in compliance with the law, which was an encouraging sign of the success of our efforts thus far, and an indication of substantial improvement over the results that the New York Academy of Medicine reported for New York City pharmacies in 2007.¹⁹ Particularly troubling, though, was the fact that surveyed chain pharmacies in upstate New York, which were not bound by NYC-LAPA and were not subject to the OAG's investigation, offer the lowest levels of translation and interpretation services for their patients.

Methodology

A standard survey instrument was used to survey each pharmacy (see Appendix B for the Survey Instrument), with the NYC-LAPA used as a guide to determine what specific elements must be in place to ensure adequate and equal access to pharmacies for LEP consumers. As part of our data collection, anonymous surveyors posed as the relatives of LEP family members and asked pharmacies about translation and interpretation services for both dominant languages in the neighborhoods where particular pharmacies were located, as well as languages that are not dominant. So, for example, surveyors asked about the availability of language services in Spanish in pharmacies in the Bronx, where Spanish is a dominant language, as well as for services in Arabic, which is not a dominant language in that borough. In addition, some surveyors actually conducted their tests of pharmacies in Spanish.

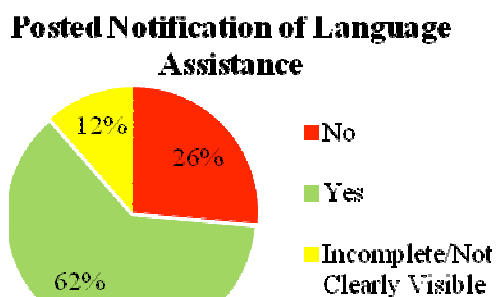
This study design has certain limitations, namely that: 1) our organizations did not have the capacity to survey every chain pharmacy location across New York or to always do so in person; and 2) our surveyors were not actual patients, and therefore could not confirm responses regarding the availability of label translation and interpretation services. That said, data from our considerable sample size demonstrate that there is still important work to do in order to ensure that all chain pharmacies consistently provide services to enhance patient understanding.

Language Assistance Signs²⁰

Under the NYC-LAPA, chain pharmacies in New York City must post a sign notifying patients about their right to free language assistance services at the pharmacy, and that the sign must be translated in the top seven languages spoken in the city.²¹ The sign must also be posted in a conspicuous location near the pharmacy counter itself to ensure it is visible to patients.

Our survey found that, of all pharmacies surveyed statewide:

- 62% had posted and fully visible notification signs
- 12% had signs posted, but they were either not clearly visible (e.g., hidden, obscured, ripped) or were incomplete
- 26% did not have signs posted, or had signs that were not visible



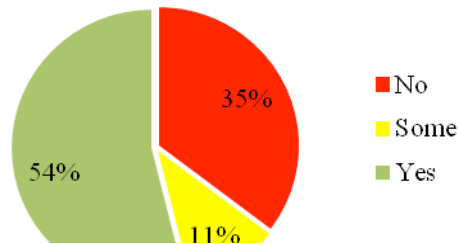
Most pharmacies have found a way to notify patients that they have a right to language assistance services. The fact that well over 1/3 of all surveyed pharmacies fail to do so entirely or to do so well, however, is problematic. Posting such a sign is a relatively easy step to take.

Translation Services

Under the NYC-LAPA, chain pharmacies must provide free, competent translation of prescription medication labels, warning labels and other written material to each LEP individual filling a prescription at such chain pharmacy. Pharmacies must translate labels into the top seven languages spoken in New York City.²²

Of the pharmacies surveyed statewide:

Translated Labels at Chain Pharmacies



- 54% claimed they provide translation in all languages requested
- 11% stated that they had some translation ability (e.g., English and Spanish only, simple instructions only, auxiliary information only)
- 35% responded that they printed labels and other auxiliary medication information only in

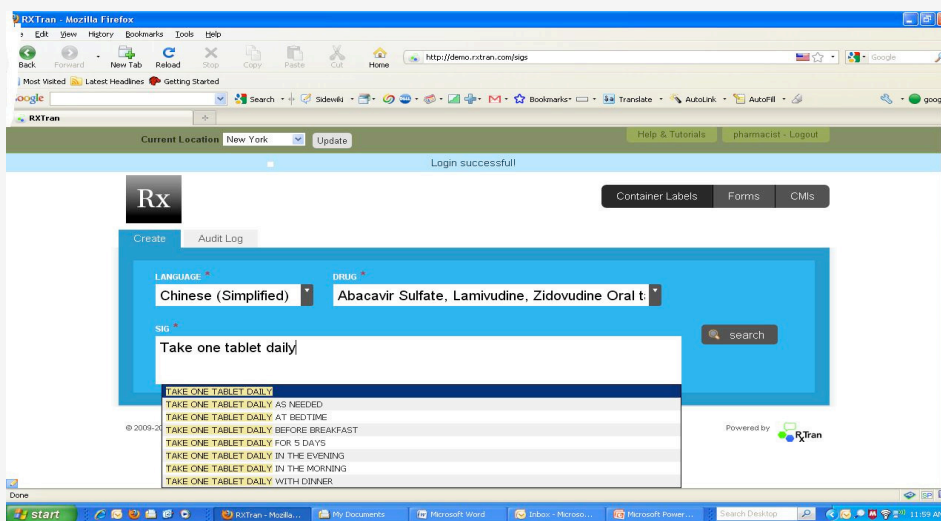
English

We were pleased to find that over half of surveyed pharmacies stated that they have the ability to provide a broad range of translation services for LEP patients. Unfortunately, nearly half of surveyed pharmacies were unable to state that they could provide the translation necessary to ensure adequate access for their LEP consumers. Indeed, our surveyors encountered at least twenty-five instances in which the pharmacist surveyed was confused about whether they could provide such services, or had no knowledge regarding whether their pharmacy could provide translation services.

How It Works: Label Translation

Translation service technology enables pharmacies to fill the language gap seamlessly and in a way that is consistent with a pharmacist's natural workflow, instead of expecting them to take additional or different steps to fill a prescription. For instance, a company called RxTran has developed a technology that allows pharmacies to print patient instructions, warning labels, and consumer medication information in about twenty languages on demand. Importantly, these services are very reasonably priced, and can be provided to pharmacies in most cases for less than \$2 a day. The technology works in a similar way to an internet search engine (e.g., Google or Yahoo). When assisting a patient who is LEP, the pharmacist:

1. Selects the correct prescription from the dropdown menu in the prescription field;
2. Selects the language from the dropdown menu that is the patient's preferred language; and
3. Types the directions to the patient for taking the medication.



The system then translates all pertinent prescription label and auxiliary drug information in the patient's preferred language. The pharmacist then can print the translated information for the patient. Moreover, RxTran is not the only company out there that has developed technology to translate labels and medication information. Pharmacies have a range of options to choose from for their translation needs.

Information and screenshot courtesy RxTran.

Interpretation Services

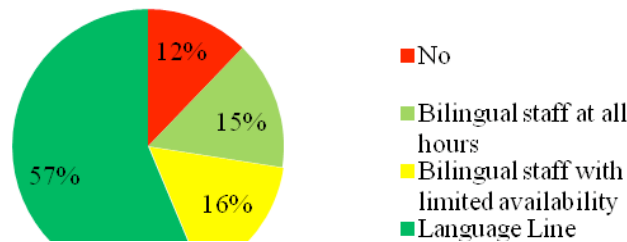
Under NYC-LAPA, chain pharmacies must provide free, competent oral interpretation services for medication counseling, as well as for interpretation of prescription medication labels, warning labels and other written material.²³ We found that:

- 57% claimed that they used a telephonic interpretation service (e.g., Language Line)
- 15% stated that they used bilingual staff members who were on hand at all times
- 16% said they used bilingual staff members, but were available only at limited times
- 12% stated that they did not provide any interpretation services

We were encouraged that 72% of surveyed pharmacies statewide claimed that they had the ability to provide interpretation services for all LEP patients. However, almost 1/3 of surveyed

pharmacies were unable to state that could do so. As with our survey findings around translation services, some pharmacists surveyed were confused as to whether their pharmacy even had the capacity to provide interpretation services. As one responded, “I’m sure there is a way but I don’t know how to use it.”

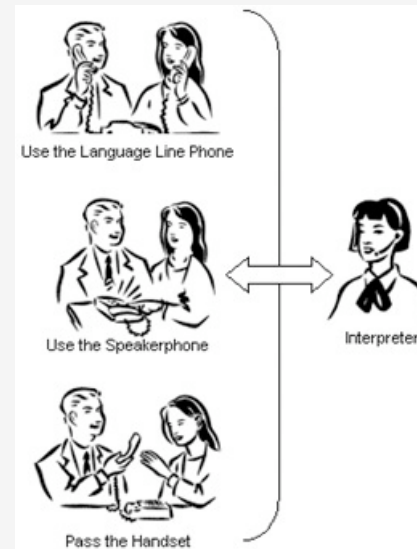
Interpretation Services at Chain Pharmacies



Chain pharmacies often raise concerns as to the practical and economic feasibility of providing translation and interpretation services. Current systems and technologies, however, demonstrate that these concerns are unfounded. Services such as Language Line, Meducation and RxTran,²⁴ to name a few, enable pharmacies to fill the language gap seamlessly and in a way that is consistent with a pharmacist’s natural workflow, instead of expecting them to take additional or different steps to fill a prescription. Indeed, existing systems provide pharmacies with the ability to print on demand patient instructions, warning labels, and consumer medication information in a variety of languages. Importantly, these services are very reasonably priced. For example, RxTran’s translation services can, in many cases, be provided to pharmacies in for less than \$2 a day. For further information on how translation services work, see the box on page 3; see the box on page 5 for information on how interpretation services work.

How It Works: Telephonic Interpretation

To provide quality interpretation, pharmacies do not have to have a team of interpreters for all languages on site. Telephonic interpretation services are available to allow pharmacies without in-person interpretation capability to effectively communicate with patients who are LEP. The process for using a telephonic language interpreter service, such as Language Line, is practical and straightforward. First, the pharmacist dials the language interpretation service phone number. Next, the pharmacist requests the language the patient speaks. From there, an interpreter is connected. When the interpreter is connected, the pharmacist can choose to use a speakerphone with the patient, pass the telephone handset back and forth, or use a special two-receiver telephone that some interpretation service companies, such as Language Line, provide their clients. As with translation services, there are a number of telephonic interpretation service providers. In addition, pharmacies can provide the best possible service through bilingual pharmacists and skilled, trained bilingual staff, as well as through contracts with in-person interpreters.

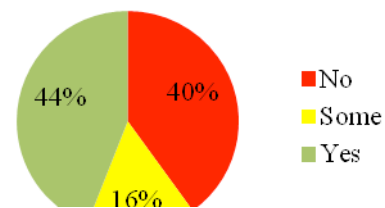


Information and visual from www.language.com.

Language Access Services at Chain Pharmacies Not Bound by NYC-LAPA or Settlements

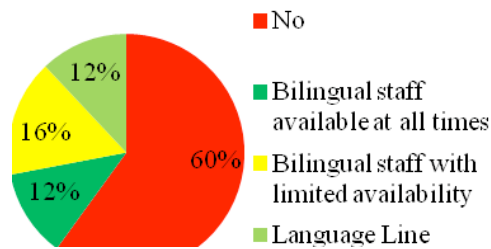
Not all pharmacies in New York State are covered by the OAG's settlement agreements or NYC-LAPA. In particular, upstate chain pharmacies like K-Mart or Wegmans are not subject to these existing requirements. To better understand our statewide results and get a clearer sense of where the gaps in language services provision were, we compared those pharmacies that are covered by existing laws and settlements to get a sense of whether additional statewide regulation actually improves access to services for patients. Our results show that while our efforts thus far have served to catalyze pharmacies' provision of such services, more still needs to be done to ensure the health and safety of all New Yorkers. In addition, our data demonstrate how our proposed state bill (see below) will help realize that goal.

Translated Labels at Chain Pharmacies Not Covered by LAPA or Settlement Agreements



For example, only 44% of surveyed pharmacies not covered by either NYC-LAPA or the settlement agreements stated that they provided the full range of written translations, as compared to 54% of those bound by the additional state and/or local regulation.

**Interpretation Services at
Chain Pharmacies Not Covered
by LAPA or Settlement
Agreements**



Additionally, only 24% of chain pharmacies not covered by NYC-LAPA or the settlement agreements stated that they provided oral interpretation services at all times, as compared to 57% of the covered pharmacies. Several of the pharmacies who did not provide these services referred our surveyors to another pharmacy several miles away. For an individual who is ill and needs prescription medication but cannot understand prescription instructions without language assistance services, this can mean significant additional time and energy involved

in locating and travelling to that other pharmacy.

Spotlight: Kraupner Pharmacy

Kraupner Pharmacy is an independent pharmacy located at 457 Knickerbocker Avenue in Bushwick, Brooklyn. Owned and operated by pharmacist Gary Goffner and family, Kraupner has served the Bushwick community for over 55 years. Goffner himself has worked as a pharmacist at Kraupner for more than twenty years, and now owns two other independent pharmacies in the New York City area.

Kraupner prides itself in serving the residents of Bushwick, and has always been particularly sensitive to their language and translation needs. Goffner estimates that nearly 80% of Kraupner’s customers speak Spanish as their primary language. Goffner himself speaks English and Spanish fluently, and has also made it a point to hire a diverse staff that can provide language assistance in Italian, Polish, French and Hebrew.

Also, at the behest of Make the Road New York, Goffner upgraded Kraupner’s computer system in 2007 so that his pharmacy can print labels, receipts, and other prescription information such as warnings and side effects in any language customers need. He has learned from talking to his customers that they are much more satisfied since he added this service: They have expressed the importance of being able to ensure that they are using medications in the most safe and effective manner, even after they have left the store. Goffner has also noticed a marked increase in business as a result of word-of-mouth referrals since he upgraded his computer system. He says that this additional business has more than covered the costs of upgrading his computer system.

Because Kraupner is an independent pharmacy and not a chain, it is not required to provide such assistance by the NYC-LAPA or settlement agreements. Also, as a small mom-and-pop pharmacy, Kraupner does not have the same resources as the major chain pharmacies. However, an appropriate concern with patient safety and satisfaction has led to positive improvements in language services at Kraupner and serve as a model for large and small pharmacies across New York State to follow.

Our data highlight how MRNY and NYLPI's efforts on increasing patient understanding of prescription medication information has been successful in getting chain pharmacies to ensure that all patients can understand prescription medication information. New York City's chain pharmacies and those bound by the settlement agreements should be commended for improving their language assistance services. That said, all chain pharmacies across New York can and must continue to improve their translation and interpretation services not only to simply comply with the law, but more importantly to ensure the health and safety of all New Yorkers.

A Prescription for Improved Safety and Understanding

In 2010, State Senator Tom Duane and Assembly Member Richard Gottfried introduced a state bill that attempts to address the issue of patient comprehension of medication information in a comprehensive, statewide way.²⁵ The bill would:

- ***Authorize the Creation of Standardized Prescription Drug Labels.*** The bill would give the State Board of Pharmacy the authority to develop clear, standardized prescription drug labels. This will improve comprehension of labels by all consumers and provide unambiguous and straightforward directions for prescription drug use.
- ***Ensure that Chain Pharmacies Translate Standardized Prescription Drug Labels.*** In addition, the bill would require pharmacies to provide written translations of the standardized prescription drug labels into the languages of patients who are LEP. As with interpretation services, pharmacies must also provide regular training to staff members on how to provide these services on behalf of patients. This provision will help patients who are LEP to understand how to take their prescriptions.
- ***Require Chain Pharmacies to Provide Oral Interpretation Services.*** Under the bill, pharmacies would be required to have interpreters available in person or by telephone for patients who are LEP. Pharmacies must also provide regular training to staff members on how to provide these services on behalf of patients. This will ensure that all patients receive prescription drug information and counseling in a language they understand.
- ***Enable Physicians to Facilitate Pharmacies in Providing Language Assistance Services.*** The bill would also modify prescription forms and electronic prescriptions to include a section for doctors to indicate whether their patients are LEP, and if so, what their preferred language is. This will assist pharmacists in serving patients who are LEP by allowing them to easily determine and accommodate customers' language preferences.

Conclusion

Everyone should be able to understand how to take their prescriptions. Research has shown that patient misunderstanding of prescription drug labels lies at the root of prescription misuse and that this misunderstanding costs us all in money, time, and health. The solutions to this problem are simple, easy and inexpensive for pharmacies to implement. Simply put, the proposed legislation gives New York, and New York's chain pharmacies, the opportunity to be industry leaders in ensuring that all patients, including the elderly and patients who are LEP, the ability to understand prescription drug labels.

Organization Information

Make the Road New York

Make the Road New York is a membership-led organization. MRNY builds the power of Latino and working class communities to achieve dignity and justice through organizing, policy innovation, transformative education, and survival services.

Our multi-faceted approach includes:

Organizing and Activism to build a stronger community, to make governing institutions subject to democratic community control, and to mobilize resistance to oppression based on race, class, gender, age, national origin, and sexual orientation.

Collaborative Learning to share ideas and experiences, to analyze the root causes of the problems we face, and to strategize about how we can take action together to resolve these problems in a way that values the voice, perspective and contribution of every person.

A Community of Support to provide badly needed services to members and leaders, to draw people into our educational and organizing activities, and to affirm an ethic of cooperation, mutual support, dignity and *animo*.

New York Lawyers for the Public Interest

New York Lawyers for the Public Interest (NYLPI) is a nonprofit, civil rights law firm that strives for social justice. The organizers and lawyers in the Health Justice Program partner with Make the Road New York and other community-based groups throughout New York to remedy systemic barriers to health care access through administrative enforcement of civil rights laws, litigation, legislation drafting, lobbying and other forms of advocacy.

Appendix A: Research on Patient Comprehension of Medication Information

This appendix provides a list of some pertinent research regarding patient comprehension of medication information. This list is divided by subject, and includes the article citation as well as the stated conclusions of the research.

Label Standardization Aids Patient Comprehension

Avron, Jerry, et al., (2006) Highlights and a Hidden Hazard — The FDA's New Labeling Regulations. *New England Journal of Medicine* 354;23.

This article indicates that system wide standardization of all patient information and labels is necessary to create better prescribing and usage practices.

Shrank, MD, William, et al. Educating Patients About Their Medications: The Potential And Limitations Of Written Drug Information. *Health Affairs*, 26 (3).

The conclusion of this study is that standardization of all written medication information is essential to providing patients with information that will educate them about their medication. If accurate and standard information is created, misuse of prescription medications may decrease.

Shrank, MD, William, et al. (2007) Effect of Content and Format of Prescription Drug Labels on Readability, Understanding, and Medication Use: A Systematic Review. *The Annals of Pharmacotherapy*, 41.

Evidence shows that specific format and content of prescriptions drug labels effects the efficacy of communication with and comprehension by patients.

Shrank, William H. MD; et al (2007). The Variability and Quality of Medication Container Labels. *ARCH. INTERN. MED*, 167 (16).

The formatting of most medication labels studied, emphasized characteristics of the pharmacy issuing the medicine rather than the medication itself. Patient-oriented labeling should be standardized to avoid labels that are focused on the pharmacy and not the medicine.

Language Barriers Impede Medication Comprehension

Bradshaw, Michael BS, et al., (2007) Language Barriers to Prescriptions for Patients With Limited English Proficiency: A Survey of Pharmacies *Pediatrics* 120(2) 225-235.

This study found that communication with limited English proficient individuals must be improved and can be through improved use of telephonic interpretation services and increasing usage of computerized translation systems for printed medication information.

Sharif, Iman, et al., (2006) Availability of Spanish Prescription Labels. *Journal of Health Care for the Poor and Underserved* 17(1) 65-69.

Spanish prescription labels were largely available in areas where almost half of the population was Spanish speaking. However, patients could only receive these labels if specifically requested. This study suggests that physicians should be able to indicate the need for translations when prescribing the medicine.

Weiss, Linda et al., (2007) Access to Multilingual Medication Instructions at New York City Pharmacies. *Journal of Urban Health* 84(6).

This study indicated the urgent need for a systemic approach to identify linguistic needs, training staff on the tools available for addressing those needs, and advertising the availability of linguistic services.

Effect of Low Literacy on Medication Use

Board on Neuroscience and Behavioral Health, Institute of Medicine (2004) *Health Literacy: A Prescription to End Confusion*. National Academies Press, Washington D.C.

A growing body of knowledge points to a causal relationship between low health literacy and poorer health outcomes. This study suggests that increasing responsiveness to health literacy among health services providers would, in part, lessen problems created by limited health literacy.

Davis TC, et. al. (2008) Improving patient understanding of prescription drug label instructions. *J Gen Intern Med.* 24(1) 57–62.

Four out of five patients (79%) in this study misinterpreted one or more of the ten common prescription label instructions they were given. Rates of patient understanding also varied widely across all literacy levels indicating the need for standard understandable labels.

Davis, Terry, et al. (2006) Low literacy impairs comprehension of prescription drug warning labels. *Journal of General Internal Medicine* 21(8).

Simple, patient centered, warning labels were more easily understood by all people in this study, regardless of literacy rate. Individuals with low-literacy had more difficulty understanding warning information indicating the need for concise medication information.

Dowse, Ros, et. al (2005) Medicine labels incorporating pictograms: do they influence understanding and adherence? *Patient Education and Counseling* 58(1) 63-70.

The presence of pictograms was found to contribute positively to both understanding of instructions and adherence. The majority of patients taking medicine with pictograms strictly adhered to their instructions while only 2% complied when they did not have pictograms illustrating how to use the medicine.

Georgetown University Center on an Aging Society, Fact Sheet: Low Health Literacy Skills Increase Annual Health Care Expenditures by \$73 Billion.

This study found profound economic effects from individuals being unable to read and understand the instructions contained on prescriptions or medicine bottles, appointment slips, informed consent documents, insurance forms, and health educational materials.

Keifer, Kristen (2001) Health Literacy: Responding to the Need for Help. Center on Medicare Education, Washington, D.C.

Over 80% of Medicare patients studied had low-health literacy. A systemic approach which makes medical information simpler and more readily understood by patients will be important in addressing this problem.

Wolf, Michael et. al. (2010) Improving Prescription Drug Warnings to Promote Patient Comprehension. Arch Intern Med. 170(1) 50-56.

This study found prescription drug warnings with simplified text, as well as with simplified text and icon labels were correlated with an increased rate of understanding among patients.

Wolf, Michael, et al., Misunderstanding of prescription drug warning labels among patients with low literacy. American Journal of Health-System Pharmacy, 63(11) 1048-1055

Less than half of all patients studied were able to correctly understand eight of the most commonly used warning labels, with the exception of one warning label.

Appendix B: Survey Instrument

Date and time of survey:

Name of surveyor:

Contact information for surveyor (phone and e-mail):

Pharmacy and address:

Be aware that pharmacists and employees have been instructed not to answer survey questions. Remember that you are an advocate for an individual and may ask how things work—whether there will be a phone for interpretation or a real person, how long patients generally wait there, and any other questions that seem relevant to you. Consider this a conversation you may have on behalf of a family member who needs you to find the best services in the neighborhood.

Please circle the target language about which you will be inquiring on this visit:

Spanish Russian Arabic Chinese Korean Haitian-Creole Other

Read these questions before your visit, fill in responses after your visit:

1. Were there signs posted notifying applicants to the right to an interpreter/translated documents?

Yes No Yes, but (explain below)

Comments (small, poorly location, ripped or otherwise in disrepair, etc.):

2. Was a Pharmacy Patient's Bill of Rights posted?

Yes No Yes, but (explain below)

Comments (small, poorly location, ripped or otherwise in disrepair, etc.):

3. Look for posted advertisements. Do the ads include notification of the right to an interpreter/translated documents?

Yes No Yes, but (explain below)

Comments:

Please circle the person with whom you spoke:

Cashier Pharmacist Store Manager/Technician Other/Unknown:

4. Please ask whether translated labels for your target language are available. Pretend that you are asking for a relative of yours who is limited English proficient. E.g. “I just helped move my grandmother into the neighborhood. She takes several medications and is trying to figure out which local pharmacy to use, but she speaks only _____.”

Check all responses that apply:

- Yes
- No: translation services were unavailable
- Other, please explain:

Comments (staff person was rude, confused, refused to answer, etc.):

5. Ask whether an interpreter for your target language is available. What was the pharmacy’s response? (Please check all that apply)

- told interpreter would be made available immediately
 - through use of Language Line (phone service)
 - through use of bilingual staff (available during all work hours). If staff, please indicate what kind of staff person. E.g. pharmacist, cashier etc.: _____
 - other (please explain):

- told interpreter would be available with a wait time of _____ (min, hours, days)
 - through use of Language Line (personnel)
 - through bilingual staff with limited availability
 - other (please explain):

told to bring someone who can interpret (e.g. “Why don’t you interpret for your Grandmother?”)

told someone from waiting area would be able to interpret

Comments (staff person was rude, confused, refused to answer, etc.):

Please write any additional notes/commentary about this pharmacy and your experience on this page. If you were impressed by the pharmacy’s language policy and technology, please make a note of that.

Endnotes

- ¹ Telephone interview with Brian Kratt, Chief Executive Officer, RIC International Company (Jul. 2, 2010).
- ² U.S. Bureau of the Census, American Community Survey, Table S1601, Language Spoken at Home, *available at* http://factfinder.census.gov/servlet/STTable?_bm=y&-context=st&-qr_name=ACS_2008_3YR_G00_S1601&-ds_name=ACS_2008_3YR_G00_-tree_id=3308&-redoLog=false&-_caller=geoselect&-geo_id=04000US36&-format=&-_lang=en.
- ³ See Kutner, M., et. al., *The Health Literacy of America's Adults: Results From the 2003 National Assessment of Adult Literacy* 2006. U.S. Department of Education, Washington, DC: National Center for Education Statistics, *available at* <http://nces.ed.gov/pubs2006/2006483.pdf>.
- ⁴ Kirsten M. Keifer. *Health Literacy: Responding to the Need for Help*, Center on Medicare Education, Washington, DC (2001).
- ⁵ Shrank WH, et.al., *Educating Patients About Their Medications: The Potential and Limitations of Written Drug Information*, HEALTH AFFAIRS, 2007 May-Jun;26(3):731—40.
- ⁶ *Id.*, citing Westberg SM., et. al., *Pharmacy-related health disparities experienced by non-English-speaking patients: impact of pharmaceutical care*, J AM PHARM ASSOC. 2005;45(1):48—54.
- ⁷ Davis TC, Federman AD, Bass PF, Jackson RH, Middlebrooks M, Parker RM, Wolf MS, *Improving Patient Understanding of Prescription Drug Label Instructions*, J GEN. INTERN. MED. (2008).
- ⁸ 21 C.F.R. §§ 1306.14(a), 1306.24; Food, Drug, and Cosmetic Act §503(b)(2), 21 U.S.C. § 353b2 (1951).
- ⁹ Shrank, WH, et. al., *Variability and Quality of Medication Container Labels*, 167 ARCH. INTERN. MED. 16 (2007).
- ¹⁰ 42 U.S.C. § 2000d.
- ¹¹ The United States Supreme Court has treated discrimination based on language as “national origin” discrimination. See *Lau v. Nichols*, 414 U.S. 563 (1974).
- ¹² Linda Weiss, et. al., *Access to Multilingual Medication Instructions at New York City Pharmacies*, JOURNAL OF URBAN HEALTH: BULLETIN OF THE NEW YORK ACADEMY OF MEDICINE, vol. 84, no. 6 (2007), pp. 742—54.
- ¹³ See Civil Rights Complaint Filed with New York State Office of the Attorney General, October 31, 2007, *available at* Health Justice NYC Blog, <http://healthjustice.wordpress.com/> (follow “Resources” hyperlink on homepage; then follow “Civil Rights Complaint” under Language Rights in Pharmacies section).
- ¹⁴ See New York State Office of Attorney General, “Cuomo Announces Agreements With Major Pharmacies To Provide Customers With Prescription Medication Instructions In Their Primary Language,” *available at* http://www.ag.ny.gov/media_center/2009/apr/apr21a_09.html.
- ¹⁵ Language assistance and translation is required for the top 7 languages spoken by LEP persons in New York City, determined biennially by the department of city planning based on data from the American Community Survey. Currently, this includes Spanish, Italian, Russian, Korean, Chinese, Haitian Creole, and Bengali.
- ¹⁶ See Linda Weiss, et. al., *Access to Multilingual Medication Instructions at New York City Pharmacies*, JOURNAL OF URBAN HEALTH: BULLETIN OF THE NEW YORK ACADEMY OF MEDICINE, vol. 84, no. 6 (2007).
- ¹⁷ All chain pharmacies in New York City were expected to be in compliance with NYC-LAPA by May 31, 2010.
- ¹⁸ N.Y.C. Administrative Code tit. 20, §§ 20-620 to -625 (2010). To view the settlement agreements, please visit http://www.ag.ny.gov/media_center/2009/apr/apr21a_09.html. The settlement agreements apply to the following pharmacies: Wal-Mart, Target, Costco, CVS, A&P, Rite Aid and Duane Reade. Under the settlement agreements, pharmacies across New York State were expected to be in full compliance with the settlements by May 15, 2010; all chain pharmacies in New York City were expected to be in compliance with NYC-LAPA by May 31, 2010.
- ¹⁹ *Supra* note 18.
- ²⁰ This element was not tested for upstate pharmacies.
- ²¹ N.Y.C. Administrative Code tit. 20, § 20-623 (2010).
- ²² *Id.* § 20-622 (2010).
- ²³ N.Y.C. Administrative Code tit. 20, § 20-621 (2010).
- ²⁴ See Language Line, www.language-line.com; Meducation, www.meducation.com; RxTran, www.rxtran.com.
- ²⁵ S.B. 8365/Assem. B. 11627, Relating to Accessible Prescription Medication Information. (N.Y. 2010).