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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

January 13, 2015

Members
Rosalyn Hackworth, Public Member, Chair
Albert Wong, PharmD, Professional Member
Ramon Castellblanch, PhD, Public Member
Allen Schaad, RPh, Professional Member

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1. FOR DISCUSSION AND POSSIBLE ACTION: Resumption of the Committee's Assessment of California's Patient-Centered Labeling Requirement

a. Translation of Labels and the Use of Translated Directions Available on the Board's Website

On December 10, 2014, the Communication and Public Education Committee met and discussed a draft proposal to require on a prescription label translated "directions for use" utilizing the vetted translations that are available in five non-English languages on the board's website, if a translation is requested by the patient. These directions for use are available in Chinese, Korean, Russian, Spanish, and Vietnamese.

At previous meetings, the committee and board members discussed the benefits of providing patients with medication instructions printed in the patient's native language, as well as the issue of a pharmacist's liability if there is an error on the label and the pharmacist cannot read or write the translated language on the label or in ancillary information. The committee discussed the mode of implementing such a proposal, be it via regulation or legislation. There was consensus that a starting point could be to require the use of the translated "directions for use" that are provided on the board's website.

At this meeting, the committee will continue its discussion of the draft language for the purpose of finalizing a recommendation and language to be considered at the January 2015 Board Meeting.

Attachment 1 contains draft language for the committee's continued discussion. This draft includes possible language to limit the liability of the dispenser should there be an error in the translated directions that are in a language the prescriber cannot read or understand. The board's counsel is attending the meeting to respond to the committee member's questions. Attachment 1 also contains a copy of New York's rule on interpretation and

translation requirements for prescription drugs, as well as an excerpt from the minutes of the committee's discussion in December 2014.

Also at the December meeting, Dr. Anandi Law, a professor and chair of the Department of Pharmacy Practice and Administration and director of ACCP-peer reviewed Fellowship in Health Outcomes at the College of Pharmacy, Western University of Health Sciences, participated by phone and presented "Updates on Why We Need Prescription Translations."

Dr. Law said Limited English Proficiency (LEP) is one of the barriers for patients to understand medical instructions and that 44% of California residents speak languages other than English at home. She reported that 43% of pharmacies report availability of translations in at least one language other than English; 21% report limited availability; and 35% report no availability of translations. She also said patient literacy can be an issue because some patients may not be able to read their native language. A copy of Dr. Law's PowerPoint presentation is provided in **Attachment 2**.

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings*

**(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))*

Attachment 1

4076.55 Standardized Directions for Use and Translations of Directions for Use on Labels

(a) For all dangerous drugs dispensed to patients in California, whenever possible, a dispenser shall use a standardized direction for use on the label of the prescription container from the list that appears in California Code of Regulations, Title 16, section 1707.5(a).

(b) The board shall make available translations of the standardized directions for use that are listed in California Code of Regulations, Title 16, section 1707.5(a) in at least the five most frequently spoken non-English languages in California. These translations shall be approved by state-certified translators. These translated standardized directions for use shall be posted on the board's website.

(c) Upon the request of a patient, a dispenser may select the appropriate translated standardized direction for use from those established in subdivision (b) and append it to the label on the patient's prescription container. Whenever a translated direction for use appears on a prescription container label, the English version of this direction must also appear on the label. The translated direction for use shall appear in the patient-centered area of the label pursuant to California Code of Regulations, Title 16, section 1707.5(a). The English version must appear in other areas of the label outside this patient-centered area.

(d) A dispenser shall not be liable for any error that results from a dispenser's inability to understand the non-English language translation made available under subdivision (b), unless gross negligence has been committed by the dispenser.

[Comment: If the board wants this type of "immunity from liability" language, it will have to be placed in the Civil Code and not in the B&P Code or in regulation.

[Suggested language: A dispenser shall not be held liable for any error associated with using an appropriate translated standardized direction for use from those established in subdivision (b), unless the dispenser commits gross negligence.

(e) A dispenser may provide his or her own translated directions as an alternative to the process identified in this section. The translated directions for use shall appear in the patient-centered area of the label pursuant to California Code of Regulations, Title 16, section 1707.5(a). The English version must appear in other areas of the label outside this patient-centered area.

New York State Pharmacy Law regarding language translations

http://www.op.nysed.gov/prof/pharm/part63.htm#interpret

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

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.

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." 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.
    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 covered pharmacy, or mail order 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 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 section 5 of Part V of Chapter 57 of the Laws of 2012, the provisions of subdivisions (a) through (d) 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.

Excerpt on Label Translations From Minutes of December 10 Communication and Public Education Committee Meeting

FOR DISCUSSION AND POSSIBLE ACTION: Translation of Labels and the Use of Translated Directions Available on the Board's Website

Anandi Law, B.Pharm., MS, PhD, FAACP, FAPhA, professor and chair of the Department of Pharmacy Practice and Administration and director of ACCP-peer reviewed Fellowship in Health Outcomes at the College of Pharmacy, Western University of Health Sciences, presented by phone "Updates on Why We Need Prescription Translations." Her presentation included the following information.

Why We Need It

Limited English proficiency (LEP): one of the barriers for patients to understand medical instructions

- 44% of California residents speak languages other than English at home
- Nearly half of Latino adults in the US report that they speak English "less than very well"[1]
- Latino patients found to be more likely to misunderstand directions on medication use

Where We Are Now

Methods of Translation

- Computer programs (86%): Google translates to programs
- Lay staff members (11%): someone in the pharmacy who speaks the language
- Professional interpreter (3%): more for counseling

Access

- 43% of pharmacies across the country report availability of translations; 21% report limited service; 35% report no service

Currently Available Languages

- California Board of Pharmacy website offers translations of common instructions in **Spanish, Chinese, Vietnamese, Korean, and Russian** (top 5 common non-English languages in California)

Challenges with Label Translation

Regulations and liability

- Concerns with pharmacists not being able to verify the label instruction for accuracy before dispensing

Accuracy

- Literature: overall error rate in Spanish-labels: 50% (Bronx, New York); there is access for Spanish labels, but it may not be correct. There are liability issues for pharmacists

Literacy of the patient

- Some patients may not be literate in reading their own language

For other healthcare providers

- Emergency situation requiring paramedics to understand patient's drug labels; needs to be in English, also

Standardization

- There are not completely understandable, patient-centered labels, even in English

Dr. Law also presented a revised sample label which included a timetable for when to take the medication.

During discussion, President Stan Weisser asked Dr. Law what errors were made in Spanish in the Bronx and New York study. Dr. Ramon Castellblanch asked about the citation for the study and noted that the information was from 2010, which was before the state law in New York was enacted that required larger pharmacies to provide written language translations. Dr. Law said the errors in Spanish were for incomplete instructions, English and Spanish languages mixed, and errors in spelling and grammar. Dr. Castellblanch emphasized that the study is dated. She suggested just translating the table in her presentation instead of the entire label.

Sarah de Guia, with California PanEthnic Health Network, asked if Dr. Law tested the label in other languages. Dr. Law said they are currently testing the label in Korean. Ms. de Guia asked if the testing was being done for multiple drugs or one specific drug. Dr. Law said they are testing a senior population on the five most commonly used drugs, including hydrocodone for pain. They found that giving the seniors a consultation on how to read labels improved comprehension. She said subjects who did not receive the consultation did not have any improvement. She said the study results are being published.

Steve Gray, with Kaiser, asked her how many languages were offered by the 43% of pharmacies that are offering translations and if only translating in one language qualified a pharmacist to be part of the 43%. Dr. Law said translating in at least one language qualified a pharmacy as providing translations. He said many pharmacies offer only Spanish translations. She agreed and said Spanish-only translations qualified a pharmacy to be included.

Chair Rosalyn Hackworth stated that at the last committee meeting, committee members agreed that patients benefit when translated instructions are provided in their native language; however, there are liability issues for pharmacists when they cannot read or write the language on the label or in ancillary information.

She said the committee discussed that requiring translations could first begin by requiring the use of the vetted instructions on the board's website, which appear in English and five different languages; and then addressing the issue of liability through legislation. She said there was also discussion about section 1716, which holds a pharmacist responsible for deviating from a prescriber's prescription order.

Chair Hackworth said that at the October Board Meeting, discussion included comments that requiring complete translations in all languages could be difficult for many pharmacies and could negatively affect the workflow. She said it was noted that a board survey showed that approximately 70% of the pharmacies indicated they already had a system in place to provide translations. Concerns were also raised about law enforcement or emergency medical workers needing to have the label printed in English, she said.

She said it was explained that the initial intent of the proposal is to have pharmacists use the standardized directions for use, which are on the board's website and are translated into five languages.

Chair Hackworth also said it was stated that the goal of the proposed language was not to provide translations for every language and for every possible type of prescription with complicated directions for use, i.e., Prednisone, but that the goal was to provide translations for the 90% of medications that are dispensed with standard directions for use in the top five non-English languages spoken by Californians.

She said during the full board meeting, board members were provided with draft language to consider, it was noted that the draft language specifically took the liability off pharmacists if they used the translations provided on the board's website. She stated the board asked that the item be brought back to the committee for further discussion and that the draft language be revised.

Chair Hackworth read the following revised draft language:

4076.55 Standardized Directions for Use and Translations of Directions for Use on Labels

(a) For all dangerous drugs dispensed to patients in California, whenever possible, a dispenser shall use a standardized direction for use on the label of the prescription container from the list that appears in California Code of Regulations, Title 16, section 1707.5(a).

(b) The board shall make available translations of the standardized directions for the use of dangerous drugs that are listed in California Code of Regulations, Title 16, section 1707.5(a) in at least the four most frequently spoken foreign languages in California. These translations shall be approved by state-certified translators. These translated directions for use shall be posted on the board's website.

(c) Upon the request of a patient, a dispenser may select the appropriate translated standardized direction of use from those established in subdivision (b) and append it to label on the patient's prescription container. Whenever a translated direction for use appears on a prescription container label, the English version of this direction must also appear on the label. The translated direction for use shall appear in the patient-centered area of the label established in California Code of Regulations,

Title 16, section 1707.5(a). The English version may appear in other areas of the label outside this patient-centered area.

(d) A dispenser shall not be liable for an error which results from a dispenser's inability to understand the foreign language translation made available under subdivision (b), unless gross negligence has been committed by the dispenser.

(e) Dispensers that wish to provide their own translated directions FOR use as an alternative to the process identified in this section may do so should they so choose.

Dr. Castellblanch said he felt the draft language answered the concerns that were raised at the last meetings and he asked for the definition of "dangerous drug." Chair Hackworth echoed his question. Ms. Herold said that "dangerous drugs" are defined in Section 4022 of the Business and Professions Code. She said that term is used because patients don't understand prescription drugs are dangerous drugs. She said dangerous drugs and prescription drugs are the same thing.

Dr. Castellblanch pointed out that there are five translations instead of the four stated in the draft language. Ms. Herold said some corrections needed to be made. She said in Section C, the sentence "The English version may appear in other areas of the label outside this patient-centered area," the word "may" should be changed to "must."

She said Section E would read better as "Dispensers who wish to provide their own translated directions FOR use MAY DO SO as an alternative to the process identified in this ~~section may do so should they so choose.~~

Dr. Castellblanch made a motion to approve the draft language with the changes.

Ms. Herold pointed out that this would be a legislative change. Dr. Castellblanch asked for clarification and Ms. Herold said this would not be a regulation, but would be a legislative solution. Ms. Herold said the board would sponsor the legislation and Dr. Castellblanch said the legislature already gave the board the authority to regulate the issue and Ms. Herold pointed out that the board cannot regulate civil liability issues, such as holding pharmacists harmless for translation errors. She said the language proposed as legislation would apply to all dispensers, not just pharmacists.

Dr. Castellblanch said that going through the legislative process could take years and asked if the board could use the New York solution. He said in New York, pharmacies use their own translation service, but in New York the third party translator would be liable. He said he didn't know if the New York language would remove the liability issue. He asked what board counsel said about the issue. Ms. Herold said that at the last board meeting, counsel said the board would have to use legislation to remove civil liability from a pharmacist because the board can't remove it with a regulation. She said counsel said the board needed to do a statute change and legal staff was involved in drafting the language presented at this meeting. Ms. Herold pointed out that if the board did a regulation it would only apply to pharmacies and not all dispensers. Dr. Castellblanch asked what the difference is between a pharmacy and a dispenser.

President Weisser said physicians and clinics also dispense medications and that a regulation would not apply to them.

Dr. Castellblanch wanted to know whether New York did translations as a regulation or legislation. He wanted to check legal counsel's opinion that legislation would be required.

Victor Law said that 70% of the pharmacies are already providing translations. He said requiring language translations will cause delays at pharmacies. He said he supports translations, but said if a pharmacy needs to do translations, it will. He said the market should be able to sort it out for itself.

Chair Hackworth disagreed and said there are times when a patient, who may not speak or read English, would need a translation and the pharmacy needed to be able to provide it. Dr. Law asked if that was the case then why limit translations to five languages. Chair Hackworth said it is a place to start.

Ms. Herold clarified that the board asked the committee to develop language for a statutory modification that mandated the use of standardized directions for use and the translated directions for use. However, at the last board meeting, some board members were very clear that their pharmacies already provided translations and they didn't want to be bound to provide only the standardized directions for use. She said this is why item E was added at the end of the draft language. She said the goal was to provide a transition from not providing any translations at all to providing translations that have been fully vetted in the communities where the languages are spoken. She said no one is using those translations on the board website because there is no waiver from potential liability. She said the board wasn't looking at requiring full translations, but was looking at using what is already readily available as a first step.

Mr. Law said the board should encourage translations and work with computer software that translations could be made from, instead of mandating translations. Dr. Castellblanch said that 35% of pharmacies provide no translations at all and that he is sure those pharmacies serve patients who need translations. He said this is a serious health hazard. He said what the legislature told the board is that the board shall promulgate regulations that require that there are standardized patient-centered prescription drug labels on all prescription medicines distributed in California.

Dr. Castellblanch said he had looked up and found the study Dr. Law included in her presentation about the 50% of New York Spanish translations being wrong and he said the study was from 2007 and it was seven years old and done before New York required language translations for prescriptions. He said it is not an indicator of what is now going on with translation services in New York.

Dr. Castellblanch withdrew his motion.

President Weisser asked how the board should deal with the liability issue. Ms. Herold said patients sue under the civil code and the board has no jurisdiction over the civil code. Mr. Law asked about the New York translation law and he was told that in New York, the translation is not on the prescription container label, it is on an additional piece of paper that is given to the patient. Mr. Law asked if there is room on the label for translations. Dr. Castellblanch said he is sure there is room for both. He said to

hand patients who don't understand or read English a pill bottle in English is dangerous and irresponsible. Chair Hackworth agreed.

President Weisser said the board is trying to deal with this, but there are differences of opinion on how to do it. He said during the New York translation presentation that one of the big issues was liability. Dr. Castellblanch said he thought the board could deal with liability in a regulation. He asked that the committee direct staff to ask legal counsel if the board could do a regulation without legislation for the liability issue. Ms. Herold said that legal counsel was involved in drafting the proposed language and they drafted it for legislation, not regulation. She said staff would ask counsel if there iss another way to deal with liability.

She pointed out that language for legislation for 2015 is due at the end of January, which coincides with the next full board meeting. She said the board could possibly draft the language and possibly find an author for the bill. She said the options are to go ahead and draft legislation just in case, or take it back to the next committee or board meeting. Dr. Castellblanch suggested the committee have a Plan A and a Plan B to cover both legislative and regulatory solutions. Chair Hackworth said her concern is that if the board doesn't do something about translations then someone else will do it for the board and it may not look anything like what the board wants it to.

The committee discussed having another committee meeting to discuss translations with legal counsel present before the January Board Meeting. Ms. Herold said staff could check if there is an alternative process to provide pharmacists with liability immunity, and try and find an author for the legislation without having to commit to that option until after a board decision is made.

President Weisser said he wanted a recommendation from the committee to come to the board at their next meeting and it was clear that they needed legal counsel's presence and input.

Sarah de Guia, with Pan-Ethnic Health Network, thanked the committee for their work. She said there are a number of consumer groups that are willing to offer their support. She also said that the comments made about definition of the term "dangerous drugs" were important and suggested there may be a way to connect back to that definition so that consumers understand. She said her organization understands the concerns of pharmacists, who don't speak or write other languages, and she wants to be sure they are protected for doing the right thing. She said the biggest concern is Section E and said her organization supports translations, but questions the quality of them. She said the translations on the board website went through a very good review process. She said that there is uncertainty as to the translation source for the 70% of pharmacies that said they are providing translations. She wants to ensure that there is information collected on how pharmacies are providing those translations. She also said that patients shouldn't have to ask for the translations and it should be the pharmacy's responsibility because patients don't know they have those rights. She said that instead of using the term "foreign language" that "non-English languages" is the correct term that should be used.

Brian Warren, from the California Pharmacists Association, said the draft was excellent and it reflected committee and board discussions about using the board's standardized instructions that are available on

the board website. He suggested in Subsection A to replace “whenever possible” to “when deemed appropriate in the professional judgment of the dispenser.” He said there are instances when a pharmacist may need to use his professional judgment to determine if the standardized instructions are appropriate.

On Section D, Mr. Warren said he had just confirmed with his association’s legal counsel that the board has the authority to provide pharmacists with immunity from regulatory liability, but not immunity from civil or criminal liability. He suggested the wording from the Good Samaritan Law in regards to Naloxone be used because it is broader. He said it contains more explicit language that could be used to protect a pharmacist, who in good faith is trying to give patients instructions in their language.

Dr. Castellblanch asked Mr. Warren to provide that information to staff in writing and he said he would provide it to Ms. Herold. Mr. Warren said he thought the changes could be made more quickly with legislation instead of with regulation. Mr. Warren said his association would support the legislation because it gives a pharmacist liability protection.

President Weisser asked Mr. Warren what he thought the timeline for passage would be. Mr. Warren said it could be passed in one year because there isn’t going to be opposition from the pharmacy community that had been present for past legislation. Ms. Herold said the first question asked when seeking legislation is “Who is going to oppose this?” She said the fact that the pharmacy community would be solidly behind this would help.

President Weisser asked what kind of a degree of difficulty would be added if all dispensers are included. Mr. Warren said his group supports having it apply to all dispensers, not just pharmacies. He said it could draw opposition from the medical community.

Mr. Law asked for clarification on what would be required. Ms. Herold said it would be the standardized directions for use on the board’s website available in five translated languages. She said this is a start. Mr. Law again reiterated that he supported “encouraging” the use of those items, but not requiring it. He also said he supports only translating in the five languages.

Ms. Herold said staff would confer with legal counsel on what could be done to provide pharmacist immunity with regulations and statutes and another committee meeting would be scheduled in January prior to the board meeting.

Attachment 2

Updates on Translated Rx Labels

Why We Need It

- Limited English proficiency (LEP): one of the barriers for patients to understand medical instructions[1]
  - 44% of CA residents speak languages other than English at home
  - Nearly half of Latino adults in the US report that they speak English "less than very well"[1]
- Latino patients found to be more likely to misunderstand directions on medication use[2]

Where We Are Now

- Methods of Translation[3]
  - Computer programs (86%)
  - Lay staff members (11%)
  - Professional interpreter (3%)
- Access[1,4]
  - 43% of pharmacies report availability of translations, 21% report limited service, 35% report no service
- Currently Available Languages
  - CA BoP website offers translations of common instructions in **Spanish, Chinese, Vietnamese, Korean, and Russian** (top 5 common non-Eng languages in CA)

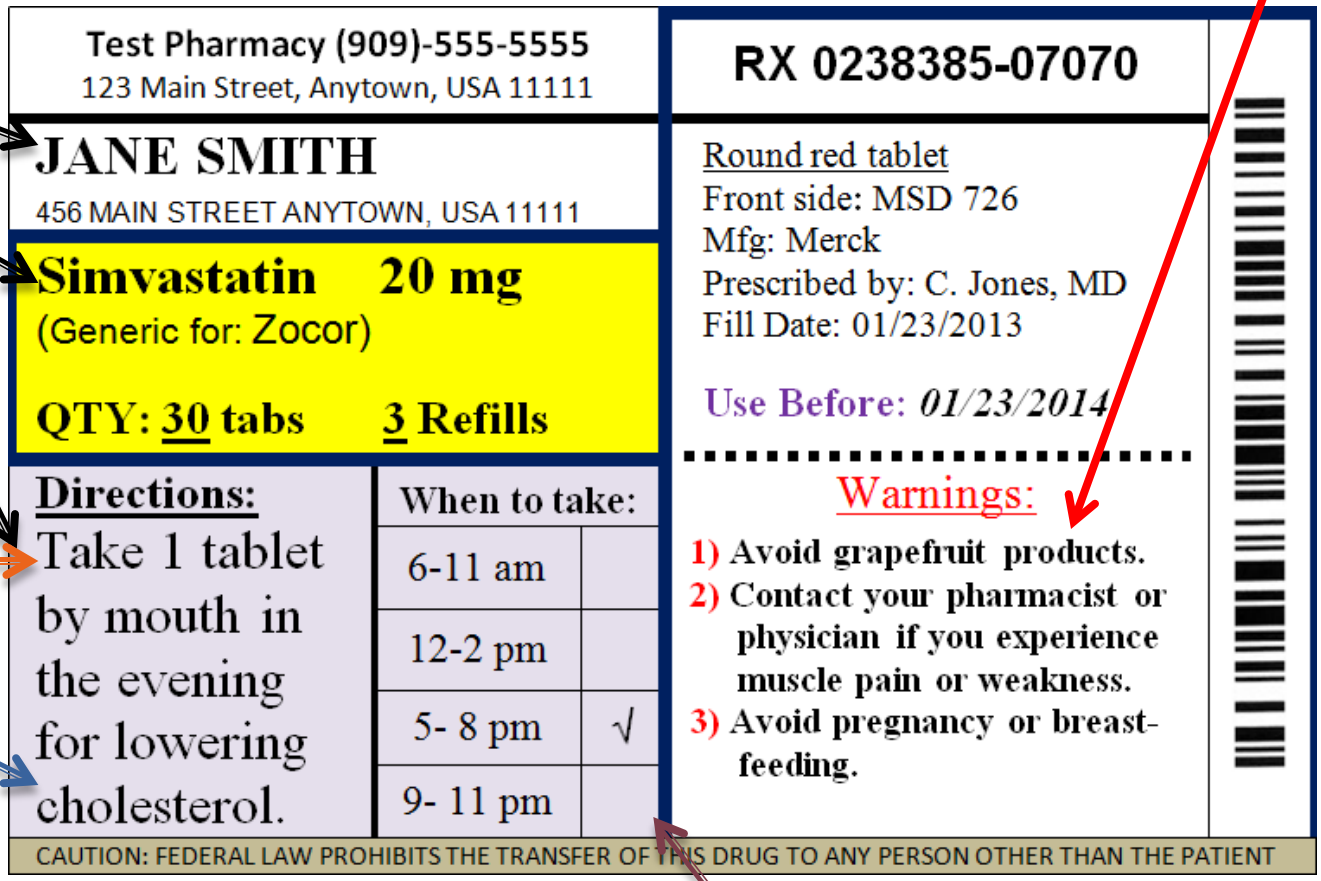
Challenges with Label Translation

- Regulations and liability
  - Concerns with pharmacists not being able to verify the label instruction for accuracy before dispensing
- Accuracy[3]
  - Overall error rate in Spanish-labels: 50% (Bronx, NY)
- Literacy of the patient
  - Even in their own language
- For other healthcare providers
  - Emergency situation requiring paramedics to understand patient's drug labels
- Standardization
  - Still an issue even in English

A Newly Designed Rx label

No separate auxiliary labels and abstract icons

- Familiar font and large font size (12-point Times Roman)
- Highlighting
- Bolding



Punctuated like a sentence

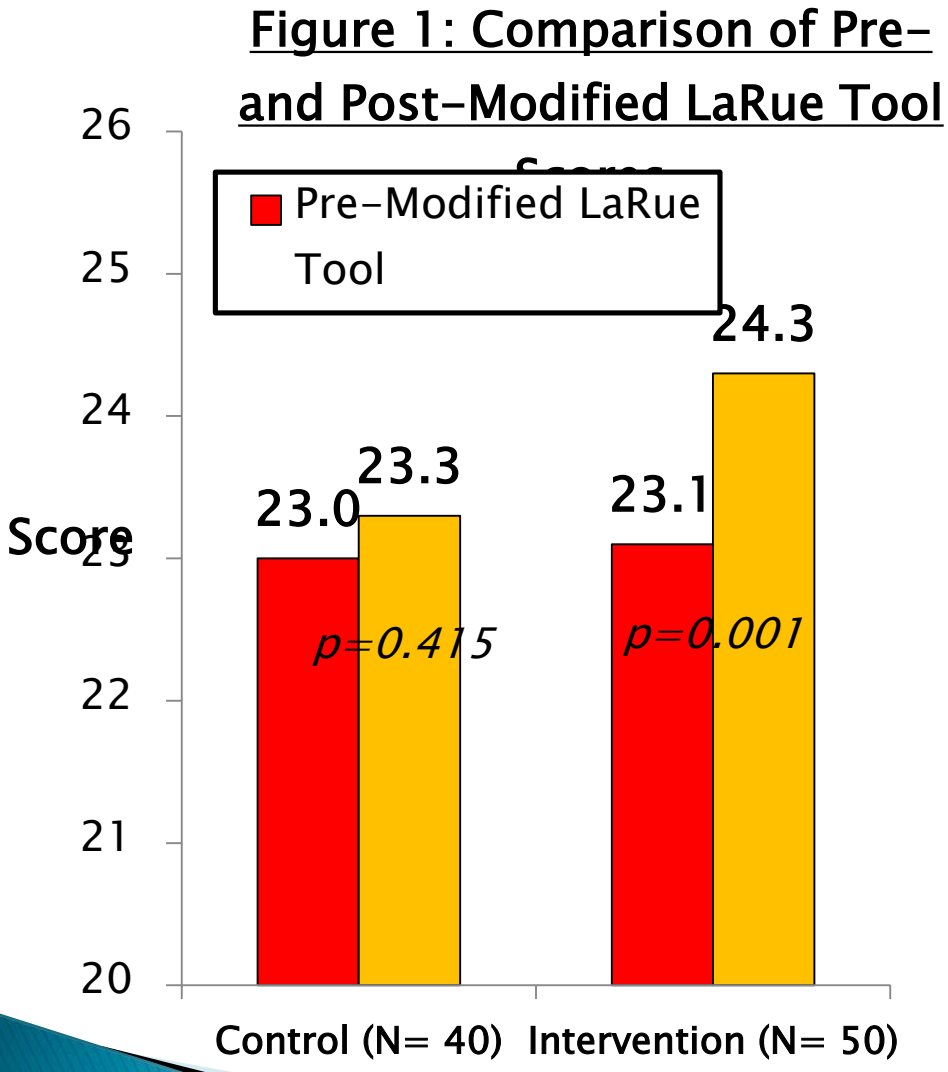
Indication included

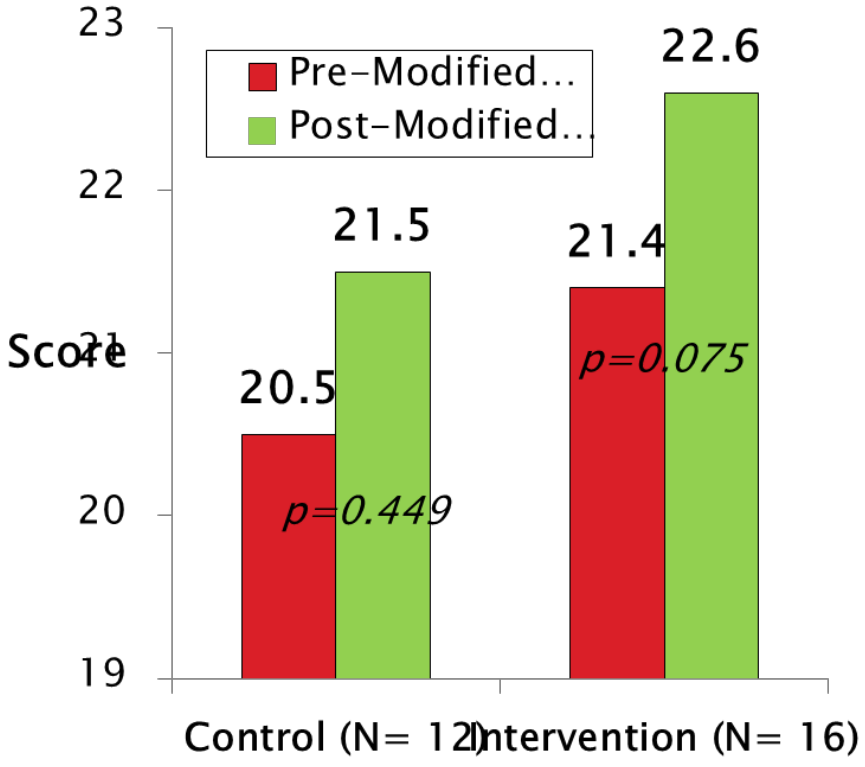
Horizontal text only for the whole Rx label

The need to turn the container is minimized

Table of administration times provides clear instructions for dosing intervals

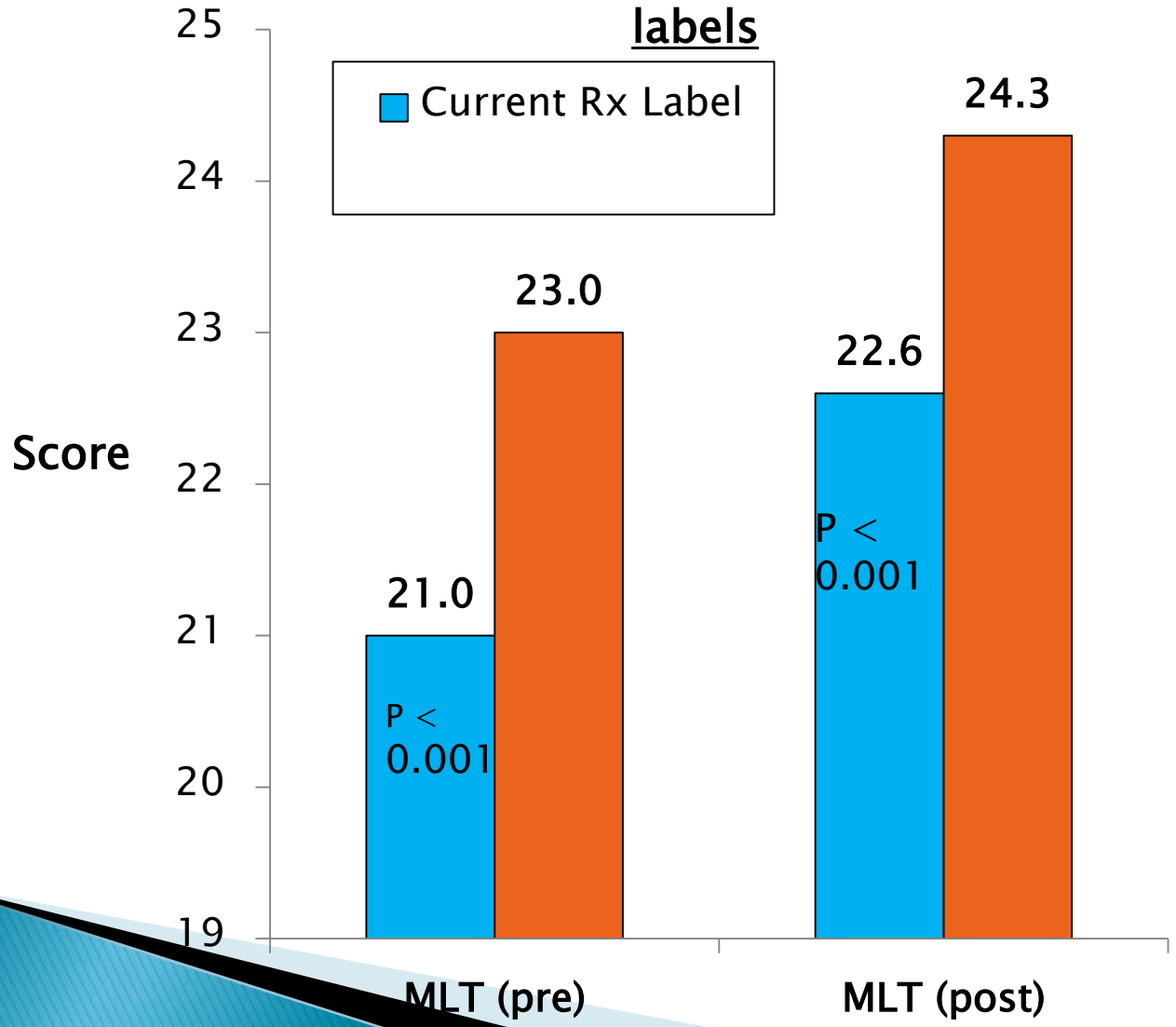
Redesigned Rx Label shows better FHL



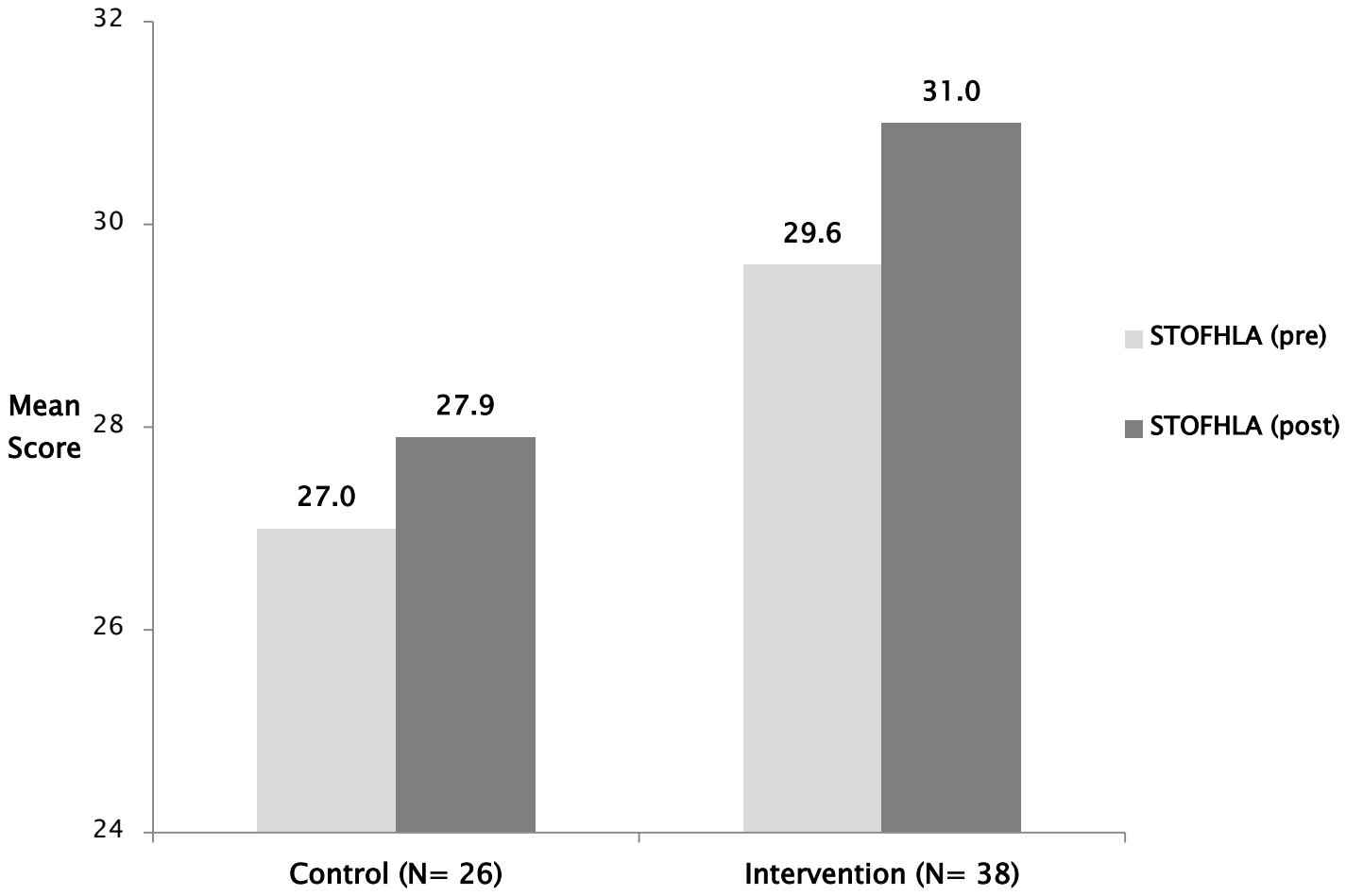


Control (N= 26) Intervention (N=38)

Figure 3: Comparison of Modified LaRue Tool (MLT) scores between current and redesigned Rx labels

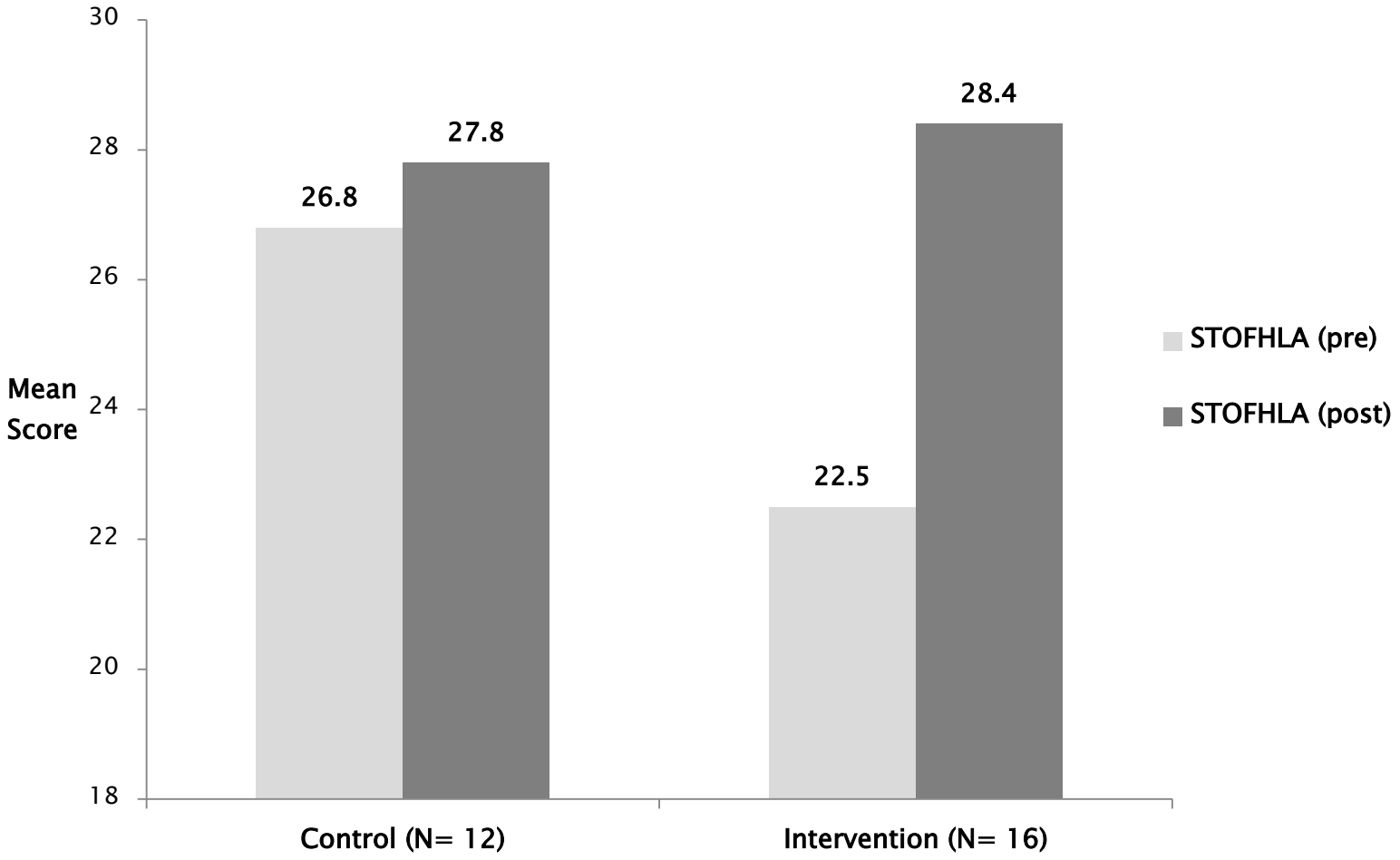


Pre-post change in STOFHLA mean-scores in redesigned label sample[a,b]



[a]No significant difference in the pre-scores between the study groups ($p > 0.05$)
[b]Significant effect of study group on post-score after adjusting for pre-score ($p = 0.044$)

Pre-post change in STOFHLA mean-scores in current label sample[a,b]



[a]No significant difference in the pre-scores between the study groups ($p > 0.05$)
[b]No significant effect of study group on post-score after adjusting for pre-score ($p = 0.215$)

References

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