



**California State Board of Pharmacy**  
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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

## Regulation Hearing

### **Proposal to Adopt or Modify Proposed Section 1707.5 Relating to Patient-Centered Prescription Container Labels**

**ACTION: Adopt / Modify Proposed Section 1707.5 Relating to Patient-Centered Prescription Container Labels**

#### **Background:**

Senate Bill 472 (Chapter 470, Statutes of 2007) added Section 4076.5 to the Business and Professions Code, relating to development of patient-centered prescription drug labels. This statute requires the board to promulgate regulations for standardized, patient-centered, prescription drug labels on all prescription medication dispensed to patients in California by January 1, 2011. The board was also directed to hold special public forums statewide in order to seek input from the public on the issue of prescription labels. These forums and one-on-one surveys of consumers were conducted over a period of 17 months.

The timeline envisioned for this process was:

- 2008: conduct public hearings statewide
- 2009: develop regulations and adopt the requirements by the end of the year
- 2010: pharmacies implement requirements to be ready for 1/1/11 implementation
- 2011: requirements become effective and labels on prescription medicine are compliant

At the July, August and October 2009 Board Meetings, the board devoted time to development of the regulation requirements. In fact, the sole purpose of the August Board Meeting was to refine the regulation requirements.

At this January 2010 meeting, the board will hold a regulation hearing to adopt 1707.5. Written comments were submitted and due January 4. The original comments attached for your review.

During the hearing the board will accept additional comments on the regulation. At the end of the hearing, the board will discuss and deliberate on the comments and testimony received.

The board has various options including to:

1. Adopt the regulation as initially noticed
2. Modify the regulation to accommodate those comments desired by the board, and release for a 15-day comment period
3. Modify the regulation and renote it for 45 days.

Here is an overview of a timeline for adoption of the regulation:

October 22, 2009: Board initiates rulemaking and directs staff to release the language for 45 days

January 20 or 21, 2010: Board holds regulation hearing and either adopts or modifies language. If the board modifies language, the regulation will be re-noticed for 15 days of additional public comment. If the board adopts the language as initially noticed, staff will compile rulemaking file and submit to the Office of Administrative Law

February 17, 2010: Board adopts final language of the regulation at a Board Meeting (if needed) specifically scheduled for this purpose

April 2010: Rulemaking file reviewed and approved by the Department of Consumer Affairs and submitted to the Office of Administrative Law

Mid-May 2010: Rulemaking approved; board releases requirements to all pharmacies

#### Background (repeated from prior meetings)

#### Focus of SB 472's Requirements

Senate Bill 472 directed the board to focus on five items in developing its patient-centered label regulation (4076.5(c)):

1. Medical literacy research that points to increased understandability of labels.
2. Improved directions for use
3. Improved font types and sizes
4. Placement of information that is patient-centered
5. The needs of patients with limited English proficiency
6. The needs of senior citizens
7. Technology requirements necessary to implement the standards

Here is how the proposed regulation addresses these components:

**1. Medical literacy research that points to increased understandability of labels.**

*Since 2008,*

- *The board has reviewed numerous articles providing the state-of-the-art research in this area. This material was used to develop the regulation's requirements.*
- *Speakers at the November 2008 PACT Summit dealing with patient-centered labels addressed the basic elements to emphasize improved comprehension of label information and the issues of patient literacy and why prescription container labels are important to patients.*
- *Executive Officer Herold participated as a member of the National Association of Boards of Pharmacy (NABP) Task Force on Uniform Prescription Labeling Requirements. The guidelines developed by this task force are subsumed into the board's proposed regulation with only minor differences*
- *The US Pharmacopeia is developing its own set of prescription labeling requirements for patient-centeredness. Although the project is still under development, USP staff believe their requirements will be similar to those of NABP.*

**2. Improved directions for use.**

- *The board has used the directions for use developed by Michael Wolf, PhD, of the Medical School at Northwestern University. These requirements aim to be simple and prevent misunderstanding by patients, including those with low literacy. They have been vetted in consumer surveys.*

**3. Improved font types and sizes**

- *A sans serif font and 12 point type are documented throughout the literature as the best combination to make labels easy to read.*
- *However, to ensure the containers are not excessively large, and to permit a diversity of packages and containers to be used, only the most important patient information components (patient name, drug name, strength, directions and, if specified, purpose) are identified as needing to be in a 12 point, sans serif font.*

**4. Placement of information that is patient-centered**

- *The regulations specifies the order for the patient-centered elements – creating a template and standardization for all labels. The board further specifies that 50 percent of the label shall be dedicated to the five most important patient-centered elements (patient name, drug name &, strength, directions and, if specified, purpose), again ensuring these elements are among the largest elements on the label*
- *The regulation also encourages the use of color, bold typeface and use of white space to emphasize the patient-centered elements on the label.*

## **5. The needs of patients with limited English proficiency**

- *The regulation calls for interpretation of information at the pharmacy when dispensing medication to non-English speaking patients. This provision was submitted by the profession.*
- *The standardized directions for use currently listed in the proposed regulation, according to Dr. Wolf, will address about 90 percent of all directions in use. The California Endowment, in support of the board's regulation, is funding a project with Dr. Wolf to translate and field-test the directions for use into the five predominant non-English languages in California. Once finalized, the translations will be made available for use via the board's Web site. However, it will be an estimated year before these translations are available.*
- *SB 853 (Escutia, Chapter 713, Statutes of 2003) requires insurers and HMOs to provide enrollees with limited English skills access to translated written material and oral interpreters. Oral interpreters must be available at no cost to the pharmacy or enrollee.*
- *Individual pharmacies may have additional solutions to ensure patients with limited English proficiency are provided with information; for example Kaiser Permanente recently advised its enrollees about the existence of "talking" pill bottles.*
- *There is non-English material provided to patients by pharmacies. Since 2006, materials currently distributed to patients with medicine dispensed by three large pharmacy chains operating in California are available in 11 non-English languages.*

## **6. The needs of senior citizens**

- *The current versions of the regulation emphasize specific patient-centered components on a label be placed in a specific font size, with a standardized placement of this information on the label and with additional emphasis encouraged by way of bold or highlighted text or use of "white space."*
- *Additionally, the requirement that 50 percent of the label be used for the five elements will aid in readability.*
- *Inclusion of purpose for the medicine on the label will aid seniors and their caregivers in ensuring the proper drug is selected when the patient takes the medicine.*

## **7. Technology requirements necessary to implement the standards**

- *By specifying requirements only for the most patient-centered elements, pharmacies will be able to use existing technology and standard containers already in use when developing their labels to conform to the regulation's requirements.*

Attachments: •Initial Notice

•Initial Statement of Reasons

•Proposed Regulatory Text

•Comments Received

## TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on January 4, 2010.

Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held 1625 N. Market Blvd., Hearing Room, Sacramento, California, at 9:30 a.m. on January 20, 2010.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference. Pursuant to the authority vested by Section 4005 of the Business and Professions Code, and to implement, interpret or make specific Sections 4076 and 4076.5, of said Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

### INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Existing law sets forth the requirements for a prescription drug container label for any drug dispensed to a patient in California (Business and Professions Code section 4076). However, existing law does not describe with specificity what elements are necessary to make the label "patient-centered," as required by Business and Professions Code section 4076.5. Proposed regulation at Section 1707.5 specifies *how* prescription drug information is to be placed on the prescription drug container label, and clarifies what interpretive services are required to be provided by pharmacies in compliance with Section 4076.5 of the Business and Professions Code.

As mandated by Business and Professions Code section 4076.5 (The California Patient Medication Safety Act enacted by SB 472, Stats. 2007, ch. 470) and to make specific the prescription drug container label requirements found in Business and Professions Code section 4076, the Board of Pharmacy has proposed to add Section 1707.5 to Title 16 of the California Code of Regulations. This proposal would establish the requirements for a standardized, patient-centered prescription drug container label. This regulation would, among other things, mandate the format of all prescription drug container labels for prescription drugs dispensed in California, including: font type, font size, placement, wording, and grouping of information. It would require pharmacists, when applicable, to use standardized words and phrases, as specified, to describe directions for use of the drug on the drug container label.

This regulation would also require the California State Board of Pharmacy (Board) to publish on its Web site by October 2011 translations of certain directions for use, as specified, into at least five (5) languages other than English to facilitate the use of these translations by pharmacies. The Board would also be required, beginning in October 2010, to collect and publish on its Web site examples of labels conforming to the requirements of this proposed regulation.

In addition, this regulation would require a pharmacy, upon request by a patient with limited English proficiency, to provide oral translation of the prescription drug container label's information.

Under this proposal, the Board would be required to re-evaluate the requirements of this regulation by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5

#### FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

Business Impact: The board has made an initial determination that the proposed regulatory action would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This regulatory proposal applies to pharmacies that dispense prescription drug medications to patients in California – licensed pharmacy sites within California, as well as those nonresident sites outside of California.

Additionally, the proposed regulation requires that a pharmacy that dispenses prescription drug medication to patients in California, and upon request by the patient, to provide an oral language translation of specified information on the label. To address the needs of patients with limited English proficiency and who require oral language interpretation of prescription drug label information, subdivision (d) of the proposed regulation contains language requiring a pharmacy, upon request of the patient, to provide an oral language interpretation of the prescription drug label information specified in subdivision (a)(1). The board received testimony from chain and retail pharmacy industry representatives that this service is already provided to patients with limited English proficiency and that a regulation requiring a pharmacy to provide this service would not impose any further economic impact. Additionally, and as required in subdivision (b) of the proposed regulation, the board will post on its Web site the translation of the standard

directions for use phrases (subdivision (a)(4)) in five non-English languages. The board will work with health care advocates to develop these translations.

For more than two years prior to this notice, the Board has publicly engaged in discussions at hearings and at public meetings to seek input and determine how the board can best implement its mandate to promulgate regulations by January 1, 2011, to develop a patient-centered prescription drug label. The board has received input and information from industry representatives, affected businesses, and others and has determined that the proposed regulation will provide patients with a prescription drug container label that they can better understand, as well as one that will aid the patient to take their prescription drug medications as instructed by their physician. Ultimately, this will improve patient adherence to a prescription drug therapy and aid in better health by reducing medication errors.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that the proposed regulatory action would have no significant statewide adverse economic impact affecting business, including the ability of California businesses to compete with businesses in other states.

The following studies/relevant data were relied upon in making the above determination:

Senate Concurrent Resolution No. 49—Relative to Medication Errors. Resolution Chapter 123, Filed with Secretary of State September 2005.

SCR 49 Final Report on Medication Errors

SCR 49, Senate Health Committee Analysis (for bill version 6/15/05, hearing date 6/22/05)

Senate Bill 470 (Corbett)—Chapter 472, Statutes of 2007

Meeting Materials and Minutes from the following:

Information, comments and/or testimony received at Senate Bill 472 Medication Label Subcommittee Public Forums held on the following dates: April 12, 2008, November 20, 2008, January 27, 2009 and March 12, 2009

Information, comments and/or testimony received at Communication and Public Education Committee meetings held on the following dates: June 27, 2007, January 8, 2008, April 12, 2008, July 23, 2008, and October 2, 2008.

Information, comments and/or testimony received at Legislation and Regulations Committee meetings held on the following dates: April 3, 2007, July 5, 2007, July 10, 2008, and October 29, 2008.

Information, comments and/or testimony received at Board of Pharmacy Board Meetings held on the following dates: August 19, 2009, and October 21-22, 2009.

Hernandez, Lyla M., Rapporteur. Roundtable on Health Literacy. "Standardizing Medication Labels: Confusing Patients Less, Workshop Summary." ISBN: 0-309-11530-2

Testimony from Doreena Wong, National Health Law Program, November 20, 2008; and Issue Brief: Language Services in Pharmacies: What is Required?

Board of Pharmacy Prescription Container Label Survey; survey responses; and Fact sheet: Do you understand the directions on your Rx medicine label?

Improving Prescription Drug Container Labeling the United States, A Health Literacy and Medication Safety Initiative. A White Paper commissioned by the American College of Physicians Foundation, October 12, 2007.

Effect of Content and Format of Prescription Drug Labels on Readability, Understanding, and Medication Use: A Systematic Review, *The Annals of Pharmacotherapy*, 2007 May, Volume 41

Shrank, William H., MSHS, MD; Agnew-Blais, Jessica, BA; Choudhry, Niteesh K., MD PhD; Wolf, Michael S., PhD, MPH; Kesselheim, Aaron S., MD, JD; Avorn, Jerry, MD; Shekelle, Paul, MD PhD. *The Variability and Quality of Medication Container Labels*. ARCH INTERN MED/VOL 167 (No. 16), September 10, 2007.

2009-2010 Chain Industry Pharmacy Profile, National Association of Chain Drug Stores

Cost Impact on Representative Private Person or Business: The Board of Pharmacy is not aware of any cost impacts that a representative private person would incur in reasonable compliance with the proposed action. This regulation proposal applies to pharmacy sites licensed by the board, not individual licensees.

For a pharmacy licensed by the board that distributes prescription drug medications to patients in California, that business may incur one-time costs associated with the configuration or re-configuration of how their prescription drug labels are printed. The board received testimony in October 2009 from one industry member who indicated that his pharmacy may incur a \$1,000 one-time cost to re-configure the printing of that pharmacy's prescription labels to ensure compliance with the proposed regulation.

The board heard testimony in October 2009 from the California Retailers Association and pharmacy chain representatives who indicated that the interpretive language services they currently provide to patients with limited English proficiency as a result of their compliance with regulations established by the Department of Managed Health Care and the Department of Insurance (SB 853, Chapter 713 Statutes of 2003) will be extended to all pharmacy patients. Thus, the board is not aware of a significant cost impact to industry for providing oral language interpretive services of specified prescription label content.

Effect on Housing Costs: None

### EFFECT ON SMALL BUSINESS

To determine the number of small businesses that may be affected by this proposed regulation, the board utilized data from the National Association of Chain Drug Stores (NACDS) 2009-2010 Chain Pharmacy Industry Profile (2008 data), which reports that in 2008 California had 4,828 chain drug, supermarket, mass merchant and independent drug store locations. Of that number, NACDS considers 1,670 (or approximately 35%) to be independent pharmacies. The board also utilized its own licensee data that shows that as of December 2008 the board issued licenses to 6,149 pharmacies. (This number does not include those licenses issued to correctional facilities, hospitals or licensed clinics – these are pharmacies that rarely dispense prescription drug medications to outpatients.) Utilizing the NACDS profile data, if 35% of California’s pharmacies are considered independent pharmacies, this would represent that – using actual licensee data – California would have approximately 2,150 independent pharmacies.

### CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments in writing relevant to the above determinations by e-mailing, mailing, or transmitting by facsimile to the Contact Person on or before January 4, 2010. Interested persons may also present to the board statements or arguments orally or in writing relevant to the above determinations at the regulation hearing scheduled for January 20, 2010.

### INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

### TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy’s Web site ([www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)).

### AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the Board of Pharmacy's Web site ([www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)).

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Carolyn Klein
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
Fax No.:	(916) 574-8618
E-Mail Address:	Carolyn_Klein@dca.ca.gov

The backup contact person is:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7910
Fax No.:	(916) 574-8618
E-Mail Address:	Anne_Sodergren@dca.ca.gov

Website Access. Materials regarding this proposal can be found at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

## Title 16. Board of Pharmacy Proposed Language

**To Add Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

### **1707.5 Patient Centered-Labels on Medication Containers**

- (a) Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.
- (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point, sans serif typeface, and listed in the following order:
- (A) Name of the patient
  - (B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.
  - (C) Directions for use
  - (D) Purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy and its inclusion on the label is desired by the patient.
- (2) For added emphasis, the label may also highlight in bold typeface or color, or use "white space" to set off the items listed in subdivision (a)(1).
- (3) The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a)(1), and may appear in any style and size typeface.
- (4) When applicable, directions for use shall use one of the following phrases:
- (A) Take 1 tablet at bedtime
  - (B) Take 2 tablets at bedtime
  - (C) Take 3 tablets at bedtime
  - (D) Take 1 tablet in the morning
  - (E) Take 2 tablets in the morning
  - (F) Take 3 tablets in the morning

- (G) Take 1 tablet in the morning, and Take 1 tablet at bedtime
  - (H) Take 2 tablets in the morning, and Take 2 tablets at bedtime
  - (I) Take 3 tablets in the morning, and Take 3 tablets at bedtime
  - (J) Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening
  - (K) Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening
  - (L) Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening
  - (M) Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime
  - (N) Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime
  - (O) Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime
  - (P) Take 1 tablet as needed for pain. You should not take more than \_\_\_ tablets in one day
  - (Q) Take 2 tablets as needed for pain. You should not take more than \_\_\_ tablets in one day
- (b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.
- (c) Beginning in October 2010, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.
- (d) For patients who have limited English proficiency, upon request by the patient, the pharmacy shall provide an oral language translation of the prescription container label's information specified in subdivision (a)(1) in the language of the patient.
- (e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code.

Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

## Board of Pharmacy

### Initial Statement of Reasons

Hearing Date: January 20, 2010

Subject Matter of Proposed Regulation: Patient-Centered Prescription Labels

Sections Affected: Add 16 Cal.Code Reg. §1707.5

#### Specific Purpose of the Proposed Changes:

Existing law sets forth the requirements for a prescription drug container label for any drug dispensed to a patient in California (Business and Professions Code section 4076). However, existing law does not describe with specificity what elements are necessary to make the label "patient-centered," as required by Business and Professions Code section 4076.5. Proposed regulation at Section 1707.5 specifies *how* prescription drug information is to be placed on the prescription drug container label, and clarifies what interpretive services are required to be provided by pharmacies in compliance with Section 4076.5 of the Business and Professions Code.

As mandated by Business and Professions Code section 4076.5 (The California Patient Medication Safety Act enacted by SB 472, Stats. 2007, ch. 470) and to make specific the prescription drug container label requirements found in Business and Professions Code section 4076, the Board of Pharmacy has proposed to add Section 1707.5 to Title 16 of the California Code of Regulations. This proposal would establish the requirements for a standardized, patient-centered prescription drug container label. This regulation would, among other things, mandate the format of all prescription drug container labels for prescription drugs dispensed in California, including: font type, font size, placement, wording, and grouping of information. It would require pharmacists, when applicable, to use standardized words and phrases, as specified, to describe directions for use of the drug on the drug container label.

This regulation would also require the California State Board of Pharmacy (Board) to publish on its Web site by October 2011 translations of certain directions for use, as specified, into at least five (5) languages other than English to facilitate the use of these translations by pharmacies. The Board would also be required, beginning in October 2010, to collect and publish on its Web site examples of labels conforming to the requirements of this proposed regulation.

In addition, this regulation would require a pharmacy, upon request by a patient with limited English proficiency, to provide oral translation of the prescription drug container label's information.

Under this proposal, the Board would be required to re-evaluate the requirements of this regulation by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5

## Factual Basis/Rationale

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy and the administration of Chapter 9 of Division 2 of the Business and Professions Code.

Business and Professions Code section 4076 specifies information that is required to be placed on a prescription drug container label dispensed to a patient in California.

Business and Professions Code section 4076.5 requires the board to promulgate regulations on or before January 1, 2011, that require a standardized, patient-centered prescription drug container label for all prescription drugs dispensed to patients in California. It also specifies what factors the Board of Pharmacy must consider in establishing such a label. Those factors include:

- Medical literacy research
- Improved directions for use
- Improved font types and sizes
- Placement of information that is patient-centered
- Needs of patients with limited English proficiency
- Needs of seniors
- Technology requirements for implementation

## Background

In 2005, Senator Jackie Speier authored Senate Concurrent Resolution 49 (SCR 49), Chapter 123 Statutes of 2005, to create a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. As required, that panel prepared and submitted to specific legislative committees a final report (referenced as the SCR 49 Report) containing its conclusions and recommendations to recommend improvements, additions or changes which would result in errors associated with the delivery of prescription and over-the-counter medications to consumers.

Additionally, Senator Ellen Corbett authored SB 472, resulting in the enactment of the California Patient Medication Safety Act (Chapter 470, Statutes of 2007). Therein, the Legislature stated the importance of reducing medication-related errors and increasing health care literacy regarding prescription drugs and prescription container labeling—which can increase consumer protection and improve the health, safety and well-being of consumers. Additionally, the Legislature affirmed the importance of identifying deficiencies in, and opportunities for improving, patient medication safety systems in order to identify and encourage the adoption of structural safeguards related to prescription drug container labels. To further these objectives, the Legislature authorized the Board per SB 472 (now Business and Professions Code section 4076.5) to adopt regulations to implement standardized, “patient-centered” prescription drug container labels in California.

To facilitate development of this regulation proposal, the President of the Board appointed a SB 472 Label Subcommittee to conduct public forums and to develop recommendations to implement the provisions of SB 472 to establish a patient-centered prescription drug label. Public forums, separate from regularly-scheduled board meetings, were held throughout the state. At these public forums, at other outreach events, through its Web site, and at other board and committee meetings, the board sought public input and feedback on what elements of a prescription drug container label were important to them and how that label could be improved. The board developed and made available to the public a prescription label survey in May 2008. The questions were open-ended, allowing participants to provide as little or as much information as desired. Board staff used the survey to interview consumers at public outreach events including health/community fairs in Sacramento, Elk Grove, Los Angeles, Riverside, San Diego, Merced, and San Francisco. Printed surveys and self-addressed return envelopes were provided to attendees who chose to return responses by mail. The survey was provided in English and Spanish. The board also provided fact sheets entitled, "Do you understand the directions on your Rx medicine label?" and samples of faux prescription labels serving as visual aids. The survey was posted on the Board's public Web site and to interested parties and organizations including the Gray Panthers and the Latino Coalition for a Healthy California. Board members also interviewed consumers, and returned the responses by mail. Survey results were provided to the board at SB 472 Subcommittee public forums and at public board meetings.

At public forums and at board and committee meetings, the board considered testimony and information provided on medical literacy research, improved directions for use, improved font types and sizes, the placement of information that is patient-centered, the needs of patients with limited English proficiency, the needs of senior citizens, and technology requirements necessary to implement the standards developed. The minutes of these meetings, as well as the documents listed in the "Underlying Data" section, reflect the information received and considered. Based upon the foregoing information received and considered by the Board, the Board developed this proposed language to implement the requirements of Business and Professions Code section 4076.5.

In exercising its authority over the practice of pharmacy in the state of California, the board believes that this proposed regulation is necessary to implement Section 4076.5. By providing a uniform, standardized format for prescription drug container labels and requiring pharmacies to provide oral language translations to patients with limited English proficiency, the Board believes that this proposed regulation will aid in the reduction of medication errors associated with the delivery of prescription drugs dispensed to patients in California. (Subsections (a), (d) of proposed Section 1707.5.)

This regulation is also necessary to assist pharmacies with implementation of the new patient-centered drug container label standards contained in the proposed regulations. Proposed subsections (b) and (c) would require the Board to publish on its Web site by October 2011 translations of certain directions for use, as specified, into at least five (5) languages other than English. The Board would also be required, beginning in October 2010, to collect and publish on its Web site examples of labels conforming to the requirements of this proposed regulation. The board intends to address this in two ways. First, the board is working with health care advocates to

translate the standard directions for use phrases identified in subparagraph (a)(4) and have those available on the board's Web site by October 2011. Second, subdivision (d) contains language requiring a pharmacy, upon request of the patient, to provide an oral language interpretation of the prescription drug label information specified in subdivision (a)(1) for non-English speaking patients. The board received testimony from chain and retail pharmacy industry representatives that this service is already provided to their non-English speaking patients and that providing this service would not impose any further economic impact.

To ensure continuing consideration and analysis of the effectiveness of this proposal in light of the factors contained in Section 4076.5 (e.g., new developments in technology), this regulation is necessary to mandate that the board will re-evaluate the requirements of the regulation by December 2013.

Underlying Data

1. Senate Concurrent Resolution No. 49—Relative to Medication Errors. Resolution Chapter 123, Filed with Secretary of State September 2005.
2. SCR 49 Final Report on Medication Errors
3. SCR 49, Senate Health Committee Analysis (for bill version 6/15/05, hearing date 6/22/05)
4. Senate Bill 470 (Corbett)—Chapter 472, Statutes of 2007
5. Meeting Materials and Minutes from
  - a. Senate Bill 472 Medication Label Subcommittee Public Forums
 

April 12, 2008	January 27, 2009	
November 20, 2008	March 12, 2009	
  - b. Communication and Public Education Committee Meetings
 

June 27, 2007	January 8, 2008	July 23, 2008
	April 12, 2008	October 2, 2008
  - c. Legislation and Regulations Committee Meetings
 

April 2007	July 10, 2008
July 5, 2007	October 29, 2008
  - d. Board of Pharmacy Meetings
 

August 19, 2009
October 21-22, 2009
6. Hernandez, Lyla M., Rapporteur. Roundtable on Health Literacy. "Standardizing Medication Labels: Confusing Patients Less, Workshop Summary." ISBN: 0-309-11530-2

7. Testimony from Doreena Wong, National Health Law Program, November 20, 2008; and Issue Brief: Language Services in Pharmacies: What is Required?
8. Board of Pharmacy Prescription Container Label Survey; survey responses; and Fact sheet: Do you understand the directions on your Rx medicine label?
9. Improving Prescription Drug Container Labeling the United States, A Health Literacy and Medication Safety Initiative. A White Paper commissioned by the American College of Physicians Foundation, October 12, 2007.
10. *Effect of Content and Format of Prescription Drug Labels on Readability, Understanding, and Medication Use: A Systematic Review*, The Annals of Pharmacotherapy, 2007 May, Volume 41
11. Shrank, William H., MSHS, MD; Agnew-Blais, Jessica, BA; Choudhry, Niteesh K., MD PhD; Wolf, Michael S., PhD, MPH; Kesselheim, Aaron S., MD, JD; Avorn, Jerry, MD; Shekelle, Paul, MD PhD. *The Variability and Quality of Medication Container Labels*. ARCH INTERN MED/VOL 167 (No. 16), September 10, 2007.
12. 2009-2010 Chain Industry Pharmacy Profile, National Association of Chain Drug Stores

#### Business Impact

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the following facts or evidence/documents/testimony and also applies to pharmacies outside of California that provide prescription drug products to California patients.

Consistent with the requirements of Senate Bill 853 (Escutia, Chapter 713 Statutes of 2003), the Department of Managed Health Care and the Department of Insurance have established regulations that require oral language interpretation services for their patients with limited English proficiency at all points of care. To facilitate clients with these requirements, many pharmacies already provide such interpretive services to California patients. The board heard testimony in October 2009 from the California Retailers Association as well as pharmacy chain representatives who indicated that the interpretive language services provided to patients with limited English proficiency are already provided to their pharmacy patients.

One industry member testified at the October 2009 board meeting that they may incur one-time costs to configure the labeling of that pharmacy's prescription drug label – resulting in a one-time approximate cost of \$1,000.

To determine the number of small businesses that may be affected by this proposed regulation, the board utilized data from the National Association of Chain Drug Stores (NACDS) 2009-2010 Chain Pharmacy Industry Profile (2008 data), which reports that in 2008 California had 4,828 chain drug, supermarket, mass merchant and independent drug store locations. Of that number, NACDS

considers 1,670 (or approximately 35%) to be independent pharmacies. The board also utilized its own licensee data that shows that as of December 2008 the board issued licenses to 6,149 pharmacies. (This number does not include those licenses issued to correctional facilities, hospitals or licensed clinics – these are pharmacies that rarely dispense prescription drug medications to outpatients.) Utilizing the NACDS profile data, if 35% of California’s pharmacies are considered independent pharmacies, this would represent that – using actual licensee data – California would have approximately 2,150 independent pharmacies.

Additionally, as of December 2008, California issued licenses to 359 non-resident pharmacies – those located outside the state that ship, mail, or deliver, in any manner, controlled substances, dangerous drugs, or dangerous devices into California. The board does not maintain separate statistics to show if these licensees are independent, community, or chain drug stores; however, the board does not believe these licensees are small businesses.

Likewise, the board included in the proposed regulation, the board’s requirement to re-evaluate the requirements of the regulation by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

To address the needs of patients with limited English proficiency and who require oral language interpretation of prescription drug label information, subdivision (d) of the proposed regulation contains language requiring a pharmacy, upon request of the patient, to provide an oral language interpretation of the prescription drug label information specified in subdivision (a)(1). The board received testimony from chain and retail pharmacy industry representatives that this service is already provided to patients with limited English proficiency and that a regulation requiring a pharmacy to provide this service would not impose any further economic impact. Additionally, and as required in subdivision (b) of the proposed regulation, the board will post on its Web site the translation of the standard directions for use phrases (subdivision (a)(4)) in five non-English languages. The board will work with health care advocates to develop these translations at no cost to the agency.

#### Specific Technologies or Equipment

While this regulation does not mandate the use of specific technologies or equipment, pharmacies may need to modify how their prescription container labels are printed so as to be in compliance with the font type, font size and placement of information on a prescription drug container label for prescription drugs dispensed to a patient in California.

#### Consideration of Alternatives

The Board of Pharmacy is mandated to promulgate regulations to specify a standardized, patient-centered prescription drug container label by January 1, 2011. Therefore, failing to adopt regulations is not a legally viable alternative.

The board considered information and testimony received over a period of approximately 18 months and believes that no alternative it considered would be either more effective than or as effective as and less burdensome on affected private persons than this proposed regulation.

No reasonable alternative to amending the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons than the proposed regulation.

December 30, 2009

Carolyn Klein  
Manager, Legislation and Regulations  
California State Board of Pharmacy  
1625 N. Market Blvd., N219  
Sacramento, CA 95834  
Fax: (916) 574-8618  
Email: Carolyn\_Klein@dca.ca.gov

**Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels**

Dear Ms. Klein:

New York Lawyers for the Public Interest ("NYLPI") is a nonprofit civil rights law firm in New York City that has been a national leader in the effort to promote language access in pharmacies for people with limited English proficiency ("LEP").<sup>1</sup> We have been closely watching California's own efforts to ensure that LEP individuals receive accessible health care and prescription medications. In particular, the passage of Senate Bill No. 472 in 2007, which requires the California State Board of Pharmacy to develop standardized medication labels that, among other things, take into account the needs of LEP consumers, is an important step toward the goal of ensuring safe and equitable access to prescription medication for all. We applaud your state's achievements thus far and write now to offer comments to strengthen the regulations that have been proposed based on our experience in New York.

In particular, we were pleased that the proposed regulations require the State Board of Pharmacy to publish on its website translations of all of the standardized directions for medication use into at least five languages by October 2011. However, we are concerned that there is no requirement in the regulations for pharmacies to make these translated labels available to their customers. In New York, a study by the New York Academy of Medicine found that New York City pharmacies overwhelmingly failed to provide their LEP customers with translated medication

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<sup>1</sup> For more information related to NYLPI's efforts with regard to language access in pharmacies, please visit: <http://healthjustice.wordpress.com/resources/#Rx>.

labels *despite having the capacity to do so in at least some languages.*<sup>2</sup> Pharmacies were not voluntarily offering the language assistance services necessary to ensure their patients' health and safety. This has now begun to change in response to a civil rights complaint our office filed on behalf of our community partners, which resulted in settlement agreements with all of the major chain pharmacies operating in New York. Under the settlements, CVS, Rite Aid, Costco, Target, Wal-Mart, A&P and Duane Reade pharmacies are required to make translated labels available in six languages and must add five more languages within six months of updating their computer systems to track language preference. In other words, chain pharmacies in New York will have the capacity to translate medication labels into at least 11 languages within the next year. We do not think this would have happened without a requirement for pharmacies to do so, and we therefore encourage the California State Board of Pharmacy to incorporate stronger, mandatory language into its proposed regulations regarding label translation. Many of the pharmacies that are subject to the settlement agreements in New York also operate in California and therefore have the capacity to provide the translations.

Implementing SB 472 with strong regulations that require patient-centered, translated, and standardized labels on all prescription medications will send a forceful message to consumers and providers across the country that the civil rights of LEP individuals are to be protected and honored. California is viewed as a leader in advancing the rights of LEP consumers to prescription medications. Advocates in other states are looking to California to learn from your efforts to standardize and translate prescription drug labels, making it all the more important for the Board to maintain and exemplify this commitment by immediately adopting these regulations.

Without translated medication labels, millions of individuals are denied meaningful care which jeopardizes their health and denies them their civil rights. We urge you to continue California's excellent work and adopt regulations that include a requirement for pharmacies to translate medication labels. If you have any questions or would like to contact us please do not hesitate to email me at [nagarwal@nylpi.org](mailto:nagarwal@nylpi.org) or to call me at 212-453-5861. We will continue to follow California's efforts and your Board's progress on this matter.

Many thanks for your consideration.

With best wishes,



Nisha Agarwal  
Director, Health Justice Program

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<sup>2</sup> 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), pp. 742-754.

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## August Colenbrander, MD

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December 19, 2009

Ramón Castellblanch  
Associate Professor, Health Education  
Member, California State Board of Pharmacy

Dear Ramon,

You asked my comments on the proposed rule that all pharmacy labels in California should be printed in 12 point sans-serif font.

I would like to offer the following comments.

### How large is 12 pt?

Many people assume that the point size notation indicates the size of the print. This is not so. Printer's points refer to the size of the slug on which letters were mounted when type was still hand-set from individual letters. Since the ratio of the letter to the slug varies, so does the actual print size for different fonts. Here are some examples for the Arial font:

ABCDEFGHIJKLMN OP abcdefghijklmnop	Arial Narrow 12 pt
ABCDEFGHIJKLMN OP abcdefghijklmnop	Arial 12 pt
<b>ABCDEFGHIJKLMN OP abcdefghijklmnop</b>	<b>Arial 12 pt (bold)</b>
ABCDEFGHIJKLMN OP abcdefghijklmnop	Verdana 12 pt
<b>ABCDEFGHIJKLMN OP abcdefghijklmnop</b>	<b>Arial Black 12 pt</b>

This shows that even for the variants of this common font actual print sizes vary.  
Note: this letter is printed in Arial 11 pt.

### Is 12 pt large enough?

Adequate legibility of pharmacy labels is important to avoid medication errors. This is an important issue, since the population is getting older, and since old age is often accompanied by poorer eye sight as well as by more medication use.

Obviously, the larger the print, the more people will be able to read it. However, no matter which print size is used, there will be some people for which it is not large enough. There also is a practical limit on how large the print can be on a given label. So any decision will be a compromise.

To calculate which percentage of patients will still have difficulty with 12 pt print one would need to know the incidence of reduced reading ability, which will be different for different age groups. Unfortunately, I do not know of any reliable quantitative data about this.

Even for users whose vision is too poor to read a standard label. With an appropriate magnifier reading pharmacy labels is still possible for 98% of them. Attached is a poster about a study the occupational therapist in our low vision rehabilitation service did some years ago. Obviously, the type and power of the magnifier and the reading training must be individualized, depending on the degree of vision loss.

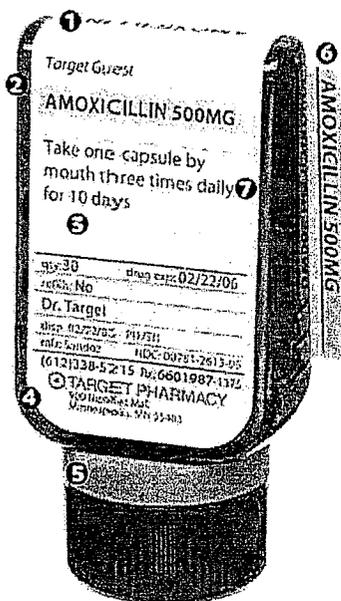
This finding, however, does not negate the fact that it is desirable to have labels that are readable without a magnifier for the majority of those with mild or moderate vision loss.

### Is sans-serif a good choice?

The readability of various fonts depends on more than just the letter size. Line spacing and letter spacing also play an important role. Many people like fonts with serifs (such as Times Roman). It is thought that the serifs make it easier to follow along the line for continuous reading. This may be the reason why Times Roman is still used in most newspapers and magazines.

However, label reading is different from continuous text reading. For labels I support the sans-serif choice, if only because it avoids the much greater variability among fonts with serifs.

### What is the best layout?



You may be familiar with the pill bottles used by the Target pharmacy. I have attached a description of how they were developed. A significant feature is that the bottle is not round, but has two flat surfaces, which makes reading easier. The flat surface also facilitates the use of magnifiers when needed.

I measured the font size on a Target bottle. The name of the medication is printed in **14 pt**. The instructions are in 12 pt (non bold). Less important details (date, refills, physician name, etc.) are printed in 10 pt (some are bold).

The use of smaller print for some items frees up space for larger print for more important items. This arrangement also attracts most attention to the most important information.

For instance: it is desirable that the number of pills to take stands out from other numeric information on the label. For instance: one might consider bold facing the words "one capsule" on the bottle shown; alternatively, bold face the number of capsules if it is not one.

### My recommendation

I am a strong proponent of readability standards for pharmacy labels. I support the choice of a sans-serif font.

Rather than requiring a 12 pt font for all information, I would recommend a standard that allows some variation, depending on the importance of the information. I would offer the Target labels as an example.

Your board may want to define what is most important (such as the name of the medication), what is important (such as the instructions) and what is less important (such as order number, refills, etc.). This determination should be based on a study of medication errors where misreading played a role. Such studies are probably available from the literature.

I hope that this information is helpful.

Sincerely,

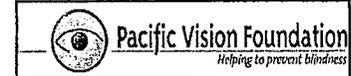
August Colenbrander, MD

Attachments:

- Curriculum Vitae
- Print size samples
- Pharmacy labels – Target
- ARVO poster 2007



## Ability to Read Medication Labels Improved by Participation in Low Vision Rehabilitation Program



C.K. Kent<sup>1</sup>, S.N. Markowitz<sup>2</sup>, R.A. Schuchard<sup>3</sup>, D.C. Fletcher<sup>1</sup>

California Pacific Medical Center Dept of Ophthalmology and Smith-Kettlewell Eye Research Institute<sup>1</sup>; Univ. of Toronto<sup>2</sup>; Atlanta VA Rehab R&D Center<sup>3</sup>

### Purpose:

- To compare medication label reading performance pre- and post- low vision rehabilitation.

### Methods:

- 57 low vision patients referred for rehabilitation and currently taking medications were enrolled in a study to evaluate their ability to read medication bottle labels pre and post low vision rehabilitation.
- Medication bottles with standard labeling not being used by the patients were used for the evaluation.
- An occupational therapist evaluated the patients medicine bottle reading ability at initial evaluation and at the time of discharge from the program. Patients were allowed to use their own magnifiers for this evaluation. Thus, if a device was prescribed in their rehab program it was used at the time of discharge evaluation.
- Patients were rated as either
  - 0 = unable to access
  - 1 = able to access partially but not with confidence
  - 2 = able to accurately and reliably read the printed directions
- Low vision rehabilitation included visual function assessment, trial of vision enhancement equipment and adaptive training provided by and experienced OT.
- Non visual techniques for medication identification were not included in this study.

### Population:

N = 57  
 Age: 44 - 95 years Median: 80  
 Gender: 39% male, 61% female  
 Visual Acuity 20/40 - 20/635 Median: 20/105  
 Diagnoses AMD..... 78%  
 Glaucoma.... 9%  
 Other.....13%

### Medications per patient

Range: 1 - 14 Average: 4  
 96% were on more than one medication

### Results:

Medication Access	Pre Rehab	Post Rehab
•Unable:	0 = 33	0 = 1
•Partial:	1 = 23	1 = 2
•Accurate:	2 = 1	2 = 54

### Cost

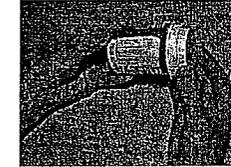
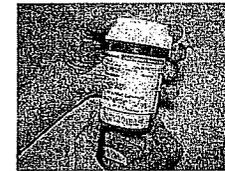
- To accomplish medicine bottle reading, 52/56 patients required optical devices for vision enhancement at an average cost to the patient of \$76.
- 4/56 patients required video magnifiers at an average cost of \$1075
- Patients received an average of 2 OT training sessions - Medicare covered expense of about \$250.

### Associations

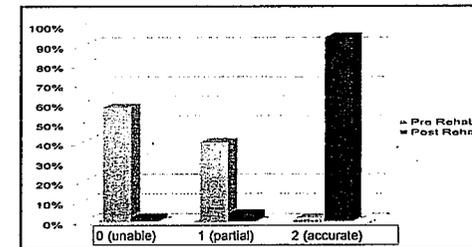
- The change in ratings is highly significant.
- The change in rating is not significantly related to age or visual acuity.

### References:

- Kravitz R.L. & Melnikow J. (2004). Medical adherence research: Time for a change in direction? *Med Care*, 42: 197-199
- MacLaughlin E., Raehl C., Treadway A., Sterling, T., Zoller, D., & Bond, C. (2005). Assessing medication adherence in the elderly. *Drugs & Aging*, 22(3):231-55
- Haynes, R.B. (2001). Determinants of compliance: the disease and the mechanisms of treatment. Haynes, R.B., Taylor, D.W., Sackett, D.L., Eds. *Compliance in Health care*. Baltimore, MD: Johns Hopkins University Press; 1979; 49-62.
- World Health Organization (2003). *The magnitude of the problem of poor adherence*.



Medication Bottle Reading Performance



### Medication Bottle Reading Performance (n = 57)

	0 = Unable to Access	1 = Partial Ability	2 = Accurate Access
Pre-Rehabilitation	58%	40%	2%
Post-Rehabilitation	2%	4%	94%

### Conclusions:

- The primary source of information available to a patient at the time of medication consumption is the prescription product label. Poor medication adherence has been associated with worsening of disease, death and increased healthcare costs.
- In this group of low vision patients, a significant improvement in ability to read medication labeling was observed with modest time and resource investment.
- For patients unable to visually read their labels other non-visual techniques can be utilized. These were not evaluated in this study.
- This appears to demonstrate an important outcome benefit to low vision rehabilitation.

Support: Pacific Vision Foundation

# The Perfect Prescription

How the pill bottle was remade—sensibly and beautifully.

Published May 21, 2005

By the time an object, or an apartment, or a company hits the half-century mark, it's usually been through a redesign or two. Yet the standard-issue amber-cast pharmacy pill bottle has remained virtually unchanged since it was pressed into service after the second World War. (A child-safety cap was added in the seventies.) An overhaul is finally coming, courtesy of Deborah Adler, a 29-year-old graphic designer whose ClearRx prescription-packaging system debuts at Target pharmacies May 1.

Adler grew up in a family of doctors in Chappaqua, New York, but escaped medicine for an M.F.A. at the School of Visual Arts. She was inspired to return, at least tangentially, after her grandmother Helen accidentally swallowed pills meant for her husband, Herman. The drugstore prescription bottle, it occurred to Adler, is not just unattractive, it's actually dangerous. Statistics back her up: According to a recent poll conducted for Target, 60 percent of prescription-drug users have taken medication incorrectly.

For her SVA thesis project, called Safe Rx, Adler revamped the familiar canister, then approached the FDA—but one of Target's creative directors saw her work last summer, snapped up the patent, and rolled it out in record time. It's already approaching design-classic status: ClearRx will be included in a MoMA exhibit this October. Your medicine cabinet is next. Here's how Adler got from A to B.



(Photo credit: Davies + Starr)

Step 1

## The Industry Standard

### Inconsistent labeling.

Every pharmacy's bottle has a different style and placement of information. At Duane Reade, the drug name appears at the bottom of the label, with the quantity below; at Metro Drugs, the quantity appears before the name of the medication, on the same line.

### Branding trumps all.

The first and largest piece of type on a label is often the drugstore's logo and address—not the name of the drug and instructions on how to take it, which should be given priority.

### Confusing numbers.

Numerals are often printed without explanation. The number 10 floating in empty space, for example, could be read as ten pills or "take ten times a day."

### Poor color combinations.

Color-coded warning stickers—like those that say take with food, for example—don't contrast strongly enough with either bottles or text. Black type set against a navy background is hard to decipher. An orange sticker can hardly be read against an orange bottle.

### Curved shape is hard to read.

Existing pill bottles have no flat surfaces and are too narrow for an entire label to be visible at once. In order for all pertinent information to be observed, the bottle must be rotated.

### Tiny type.

The FDA requires a separate information sheet to be included with all medication. The long lines of tightly spaced type mean it's usually discarded unread.

#### Step 2

### The Prototype



#### Function over form.

Adler's initial sketches had an antique apothecary design. She eventually realized that this approach sacrificed clarity for aesthetics. "People want to know the name of the drug first," she says, "then how they should take it. But it's never presented that way."

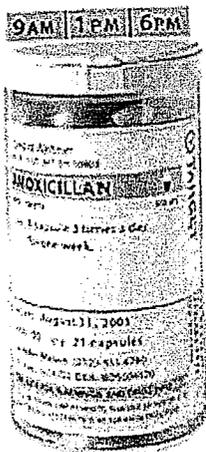
(Photo: Davies + Starr)

#### Color coding.

To avoid confusion, the label on each family member's medication was given a different color. This concept was later modified owing to the expense of supplying pharmacies with color printers.

#### Intelligent expiration.

A Condé Nast security badge that develops a large red X after 24 hours gave Adler the idea to add a similar marker to the label. A version that works over months, not hours, will be ready in 2006.



(Photo: Davies + Starr)

#### Shaping the bottle.

After rejecting triangles and squares as too extreme, Adler decided on a D-shape—a wider front and a flat back would be easier to read. It was abandoned owing to the time required to certify the unusual semi-circle cap for child safety.

#### Info attached.

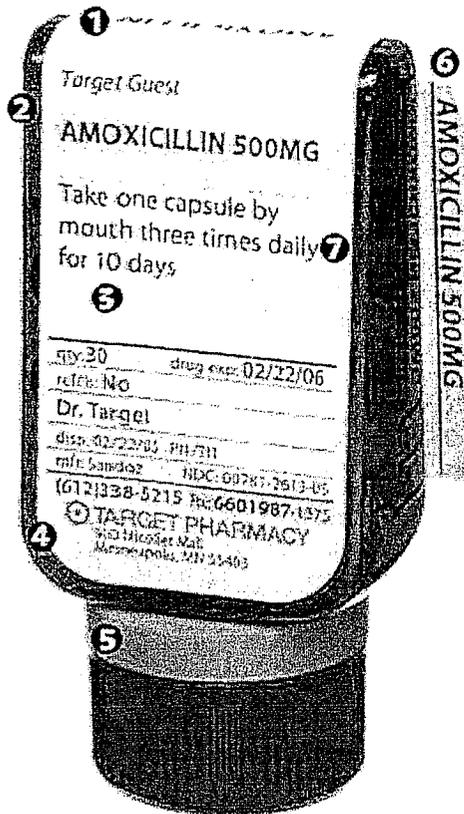
Full medication details are normally stapled to a paper bag—and thrown away. Adler created grooves on the bottle that would hold a paper card with text set in columns. This plan was altered when the shape changed.

#### Close reading.

In case the type was too small to read, Adler included a thin magnifying lens. It's still under consideration.

#### Intake schedule.

Instructions on when to take medication originally peeked over the top of the bottle. But doctors don't pinpoint time so precisely, and pharmacists don't want to be held responsible for such specific directions.



(Photo: Davies + Starr)

### Step 3

### The Solution

The ClearRx system Adler designed for Target includes bottles for pills and liquids and a measuring syringe. Here's the pill bottle that hits shelves in May.

#### (1) Easy I.D.

The name of the drug is printed on the top of the bottle, so it's visible if kept in a drawer.

#### (2) Code red.

The red color of the bottle is Target's signature— and a universal symbol for caution.

#### (3) Information hierarchy.

Adler divided the label into primary and secondary positions, separated by a horizontal line. The most important information (drug name, dosage, intake instructions) is placed above the line, and less important data (quantity, expiration date, doctor's name) is positioned below.

#### (4) Upside down to save paper.

Klaus Rosburg, a Brooklyn-based industrial designer hired by Target, came up with an upside-down version that stands on its cap, so that the label can be wrapped around the top. Every piece of paper in the package adds up to one eight-and-a-half-by-fourteen-inch perforated sheet, which eliminates waste and makes life easier for pharmacists.

#### (5) Green is for Grandma.

Adler and Rosburg developed a system of six colored rubber rings that attach to the neck of the bottle. Family members choose their own identifying shade, so medications in a shared bathroom will never get mixed up.

#### (6) An info card that's hard to lose.

A card with more detailed information on a drug (common uses, side effects) is now tucked behind the label. A separate, expanded patient-education sheet, designed by Adler, comes with three holes so it can be saved in a binder for reference.

#### (7) Take "daily."

Adler avoided using the word once on the label, since it means eleven in Spanish.

#### (8) Clear warnings.

Adler decided that many of the existing warning symbols stuck on pill bottles don't make much sense—the sign for "take on an empty stomach," for instance, looked like a gas tank to her—so together with graphic designer Milton Glaser, for whom she now works, she revamped the 25 most important.

ARIAL FONT at various font sizes

ABCDEFGFG Arial 15 pt

abcdefg Arial 15 pt

ABCDEFGFG Arial 14 pt

abcdefg Arial 14 pt

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ABCDEFGFG Arial 7 pt

abcdefg Arial 7 pt

VARIOUS 12 pt SANS SERIF FONTS

ABCDEFGHJKLMNOP abcdefghijklmnop Cordia new 12 pt

ABCDEFGHJKLMNOP abcdefghijklmnop Tunga 12 pt

ABCDEFGHJKLMNOP abcdefghijklmnop Arial Narrow 12 pt ←

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ABCDEFGHJKLMNOP abcdefghijklmnop Arial 12 pt ←

ABCDEFGHJKLMNOP abcdefghijklmnop Lucida Sans 12 pt

ABCDEFGHJKLMNOP abcdefghijklmnop Century Gothic 12 pt

**ABCDEFGHJKLMNOP abcdefghijklmnop Arial 12 pt (bold) ←**

ABCDEFGHJKLMNOP abcdefghijklmnop Verdana 12 pt ←

ABCDEFGHJKLMNOP abcdefghijklmnop Lucida Console 12 pt

**ABCDEFGHJKLMNOP abcdefghijklmnop Arial Black 12 pt ←**

# CURRICULUM VITAE

August Colenbrander, M.D.

## SUMMARY SHEET

Dr. Colenbrander was born in Holland where he received his medical and ophthalmological training and served on the faculty of Leiden University Medical School until 1969.

In 1969 he was invited to the Department of Ophthalmology at the University of Iowa as a visiting professor. In 1971 he moved to San Francisco to become a member of the faculty of the Department of Ophthalmology at California Pacific Medical Center and an affiliate Scientist at the Smith-Kettlewell Eye Research Institute.

His principal clinical interest is in **Low Vision Rehabilitation**. Since 1974 to his clinical retirement in 1998, he was Director of the California Pacific Low Vision Services. His activities in the Low Vision field continue. He has promoted a multidisciplinary team approach for service delivery for the visually handicapped, conducted several studies of vision requirements in the work environment and served on national and international committees, including the Committee on Low Vision Rehabilitation of the American Academy of Ophthalmology. He was a founding Board member of the International Society for Low Vision Research and Rehabilitation (ISLRR) and represents the sub-specialty of Vision Rehabilitation on the Advisory Committee of the International Council of Ophthalmology (ICO).

Other professional interests include **Medical Information Systems, Classification and Coding**. His involvement started as a resident at the Royal Dutch Eye Infirmary in Utrecht, Netherlands (1960) and resulted in the worldwide implementation (1978) of a new Eye section in the 9<sup>th</sup> Revision of the International Classification of Diseases (ICD-9). For the ICO, he was involved with the development and promotion of an international Visual Acuity Measurement Standard (1984) and authored the 2002 Visual Standards report on Aspects and Ranges of Vision Loss, the 2006 report on Vision Requirements for Driving Safety and the 2008 report on Assessment of Functional Vision. He is co-chair of the Topic Advisory Group (TAG) for Ophthalmology to assist the WHO in the development of ICD-11.

Dr. Colenbrander has worked on the development of various **Instructional Materials** including a national curriculum in ophthalmology for medical students and a mannequin for direct ophthalmoscopy. He has been involved in WHO workshops on the prevention of blindness and has served as a WHO consultant to the South East Asia region.

Since 1977, until his clinical retirement in 1998, he established and maintained several successful **Matching Programs** for residency applicants for Ophthalmology, Ophthalmology Fellowships, Neurological Surgery, Otolaryngology, Neurology, and Plastic Surgery and for related Fellowships.

Dr. Colenbrander can be reached at: [gus@ski.org](mailto:gus@ski.org)

Selected publications are available at: [www.ski.org/Colenbrander](http://www.ski.org/Colenbrander)

## CURRICULUM VITAE

**August Colenbrander, M.D.****EDUCATION:**

1943-1949                   Gymnasium B, Delft, Netherlands  
 1949-1959                   Leiden University: Medical School, Internships and licensure (1959)  
 1960-1964                   Utrecht University: Residency in Ophthalmology  
 1964                         Qualified as Ophthalmologist, Netherlands Specialty Board  
 1964                         'Doctor's' degree (Ph.D.) at Utrecht University

**APPOINTMENTS AND PROFESSIONAL EXPERIENCE:**

1989-1991                   Program Coordinator, Radiation Oncology Matching Program  
 1986-1998                   Program Coordinator, Plastic Surgery Matching Program  
 1982-1998                   Program Coordinator, Neurological Surgery Matching Program  
                                   including Fellowships since 1993  
 1982-1998                   Program Coordinator, Otolaryngology Matching Program  
                                   including Fellowships since 1993  
 1980-1983                   Program Coordinator, Dermatology Matching Program  
 1980-1998                   Program Coordinator, Neurology Matching Program  
 1977-1998                   Program Coordinator, Ophthalmology Matching Program  
                                   including Fellowships since 1985  
 1974-1998                   Director, Low Vision Services,  
                                   California Pacific Medical Center, San Francisco  
 1971-present               Full-time faculty, Dept. of Ophthalmology,  
                                   California Pacific Medical Center, San Francisco  
 1991-present               Affiliate Senior Scientist, Smith-Kettlewell Eye Research Institute, San Francisco  
 1982-1991                   Affiliate Scientist, Smith-Kettlewell Eye Research Institute, San Francisco  
 1979                         World Health Organization, South East Asia Region,  
                                   Consultant for Prevention of Blindness, Thailand  
 1972-1973                   Member planning team for 'A School of Health Professions',  
                                   School of Medical Sciences, University of the Pacific,  
                                   Pacific Presbyterian Medical Center  
 1969-1971                   Consultant on Strabismus Research Study, University of Iowa  
 1969-1971                   Consultant on Hospital Information System, University of Iowa  
 1964-1969                   Ophthalmological Consultant, Leiden University Hospital  
 1969                         Acting Head, Medical Records, Leiden University Hospital  
 1966-1969                   Designed, promoted and implemented a computerized central patient  
                                   information system at Leiden University Hospital  
 1960-1964                   Royal Dutch Eye Infirmary, Utrecht University  
                                   Chief Resident (1963-64), Resident (1960-63),  
 1961-1963                   Basic research on the response of the visual system to gravity forces

**HONORS:**

- 2000 "Outstanding Lifelong Contributions in Low Vision", Association for Education and Rehabilitation of the Blind and Visually Impaired (AER), Division 7.
- 1996 Honored Guest, Association of University Professors of Ophthalmology.
- 1985 Distinguished Service Award, American Academy of Ophthalmology.
- 1982 Honor Award, American Academy of Ophthalmology.

**COMMITTEES:****International:**

- World Health Organization / International Council of Ophthalmology – Co-chair  
Topic Advisory Group for Ophthalmology for ICD-11 (2008- present)
- Vision-2020 – Member of the Low Vision Working Group (2003- present)
- World Health Organization – Member, Expert Consultation Group on  
Characterization of Vision Loss (Geneva, September, 2003)
- International Council of Ophthalmology – Advisory Committee, Consultant  
(2000-2002), Representative for Vision Rehabilitation (2002- present)
- International Society for Low Vision Research and Rehabilitation, Founding  
Board Member (1993-2002)
- International Council of Ophthalmology, Visual Functions Committee,  
General Secretary (1982-1986)
- International Council of Ophthalmology, Committee on Information,  
Secretary (1970-74), Chairman (1974-82)
- World Health Organization, Participant, WHO workshop to draft Guidelines for  
Blindness Surveys (San Francisco, 1979)
- World Health Organization, Participant, WHO workshop to draft Guidelines for  
Prevention of Blindness Programs (Asilomar, 1978)

**National:**

- American Medical Association, *Guides* Advisory Committee (2007- present)
- Revision Committee, AMA *Guides for Evaluation of Permanent Impairment*  
, 5<sup>th</sup> edition (1998-2000), 6<sup>th</sup> edition (2006, 2007).
- Expert Panel on Disability Determination for Special Senses, Social Security  
Administration (1992)
- Low Vision Rehabilitation Committee, American Academy of Ophthalmology  
Member (1978-1993), Chairman (1986-1989)
- Low Vision Advisory Committee, American Foundation for the Blind  
(1976-1979)
- Ophthalmology Advisory Committee, National Association for Visually  
Handicapped (1975-present)
- Advisory Board, Council of Citizens with Low Vision (1983-1995)
- Working Group #39 (Standards for Visual Acuity), Committee on Vision,  
National Research Council (1976)
- Committee on Terminology, American Academy of Ophthalmology  
(1971-1986)
- Commission on Clinical Nomenclatures Coding and Classifications, American  
College of Surgeons, Director for American Academy of  
Ophthalmology, member Steering Committee (1983-1985)
- Committee on Medical Informatics (E31-12), American Society for  
Testing of Materials, Co-chairman (1985-1987)
- American National Metric Council, Biomedical Sector Committee, (1979)
- Committee on Medical Student Education, American Academy of  
Ophthalmology and Association of University Professors of  
Ophthalmology (1974-1985)
- American Medical Association, consultant for 'Current Procedural  
Terminology,' 3rd edition (1972-73), 4th edition (1976-1986)

American Medical Association, Coordinating Committee on PSRO  
Criteria Project (1979)  
College of American Pathologists, member board of editors for  
SNOMed (1973-1980)

**State, Local:**

Blind and Visually Impaired of Marin, Board member (2005 – present)  
California Pacific Medical Center, Institutional Review Board, Alternate member  
(1994 – 2005), Full member (2008 – present)  
Advisory Committee, San Francisco VDT Ordinance (1991-1998)  
Advisory Committee, Vision Requirements for California Driver's Licenses,  
California DMV (1992-1993)  
Advisory Committee on VDT terminals, California-OSHA (1987-1989)  
California Medical Association, consultant for California  
Relative Value Studies (1972-75)  
Medical Records Committee, Presbyterian Hospital (1971-1982)  
Library Committee, Pacific Presbyterian Medical Center (1975-1991)

#### MONOGRAPHS, INSTRUCTIONAL MATERIALS, TEXT BOOK CHAPTERS:

1. Eye and Otoliths. A study on the human centrifuge of the ocular response to otolith stimulation. Thesis for 'Doctor's' (Ph.D.) degree, Utrecht University, Utrecht, the Netherlands, 1965.
2. Coding System for Disorders of the Eye. J. Schappert-Kimmijser, A. Colenbrander, S. Franken. S. Karger, Basel (Switzerland) and New York, 1968.
3. Ophthalmoscopy: Basic Self-instruction for Medical Students. Gary M. Arsham, August Colenbrander, Bruce E. Spivey. Washington: National Audiovisual Center, 1973.
4. Glaucoma Screening - Tonometry: A Self-instructional Unit. Gary M. Arsham, August Colenbrander, Bruce E. Spivey. Washington: National Audiovisual Center, 1973.
5. General Ocular Examination: A Self-instructional Unit. August Colenbrander, Jane Creech, Gary M. Arsham. Washington: National Audiovisual Center, SIMO Project, 1976.
6. Basic Diagnostic and Treatment Procedures in Ophthalmology: A video-tape. Gary M. Arsham, Jane Creech, Robert L. Stamper, August Colenbrander. Washington: National Audiovisual Center, SIMO project, 1976.
7. Ophthalmologic Services, Procedural Terminology for Ophthalmology. American Academy of Ophthalmology and Otolaryngology, 1975 (principal coordinator).
8. Otolaryngologic Services, Procedural Terminology for Otolaryngology. American Academy of Ophthalmology and Otolaryngology, 1975 (principal coordinator).
9. Ophthalmology Study Guide for Students and Practitioners of Medicine. American Academy of Ophthalmology (and Otolaryngology), (special consultant),  
1<sup>st</sup> edition 1975, 2<sup>nd</sup> edition 1976, 3<sup>rd</sup> edition 1978, 4<sup>th</sup> edition 1982.
10. Principles of Ophthalmoscopy, Vol. 1, chapter 63, in Clinical Ophthalmology, (T. Duane, ed.), Harper and Row, publishers, 1979, updated in 2003 edition.
11. Coding Manual for Medical Eye Services. California Association of Ophthalmology, 1980.
12. Low Vision Rehabilitation, Special issue of: Ophthalmology Clinics of North America, Colenbrander, Fletcher eds., 7, 2, 1994.
13. The Visual System. Chapter 12 in Guides to the Evaluation of Permanent Impairment, 5<sup>th</sup> edition (L. Cocchiarella, G.B.J. Anderson, eds.), AMA Press, Chicago, 2001.

14. The Visual System. Chapter 12 in Master the AMA Guides (L. Cocchiarella, S.J. Lord, eds.), AMA Press, Chicago, 2001.
15. Measuring Vision and Vision Loss, Vol. 5, chapter 51, in Duane's Clinical Ophthalmology, 2001 edition.
16. The Visual System. Chapter 36 in Disability Evaluation, 2<sup>nd</sup> edition (S.L. Demeter, G.B.J. Anderson, eds.), Mosby (Elsevier Science), St. Louis MO 63146, 2003.
17. The Visual System. Chapter 12 in Guides to the Evaluation of Permanent Impairment, 6<sup>th</sup> edition (Rondinelli RD, Genovese E et al. eds.), AMA Press, Chicago, 2007.
18. Measuring Vision and Vision Loss – chapter for *Duanes Ophthalmology* (expected April 2010).
19. Classification of Vision-related Functioning – A Framework – Chapter for book on *Visual Impairment in Children Due to Damage to the Brain* (in process).
20. Vision Rehabilitation – Chapter for Lange, *Clinical Ophthalmology* (in process).

#### REPORTS, SPECIAL STUDIES:

1. Classification of Disorders of the Eye - redesign of the Eye section of ICD-9, with national and international input. Field trial, 1975. Incorporated in:  
International Classification of Diseases and 9th revision (ICD-9), WHO, Geneva, 1977.  
ICD-9-CM (Clinical Modification for the U.S.), Committee on Professional and Hospital Activities, Ann Arbor, 1978.
2. Classification of Visual Performance, Field trial, 1976. Incorporated in:  
International Classification of Impairments, Disabilities, and Handicaps, WHO, Geneva, 1980.
3. International Visual Acuity Standard - with input from Visual Functions Committee,  
Approved by the International Council of Ophthalmology, 1984.
4. Vision Requirements Survey for Highway Maintenance Personnel, A study for the California State Personnel Board, with Brian Brown, OD, PhD, 1982.
5. Color Vision Requirements for 51 State Job Classes, A study for the California State Personnel Board, with Anthony J. Adams, OD, PhD, 1982.
6. Vision Requirements Survey for Correctional Officers, A study for the California Department of Corrections, with Leslie V. Woods, OD, 1985.
7. Guide for the Evaluation of Visual Impairment, prepared for the International Society for Low Vision Research and Rehabilitation (ISLRR), for the VISION-99 International Conference on Vision Rehabilitation (coordinator, with international advisory group). Pacific Vision Foundation, San Francisco, 1999.
8. Visual Standards, Aspects and Ranges of Vision Loss with Emphasis on Population Surveys. International Council of Ophthalmology, 2002. Available at: [www.icoph/standards](http://www.icoph/standards).
9. Visual Standards, Vision Requirements for Driving Safety, with Emphasis on Individual Assessment. International Council of Ophthalmology, 2006. Available at: [www.icoph/standards](http://www.icoph/standards).
10. (Visual Standards) Assessment of Functional Vision and its Rehabilitation. International Council of Ophthalmology and International Society for Low Vision Research and Rehabilitation, 2008. Available in: *Acta Ophthalmologica* (March 2010)

#### PAPERS, etc.:

1. The Influence of G Forces on the Counter-rolling of the Eye. A. Colenbrander, *Ophthalmologica* 146:309-313, 1963.

2. Quantitative Analysis of the Relations between Gravity, Head Position and the Subjective Plumb-Line. A. Colenbrander, Ophthalmologica 151:646-651, 1966.
3. Eye and Otoliths. A. Colenbrander, Aeromedica Acta 45-91, 1965.
4. Pediatric Ophthalmology. Bruce E. Spivey, August Colenbrander and R. R. Flickinger, Jr., Hospital Medicine 7:37-53, 1971.
5. University of Iowa Hospitals and Clinics Convert to the Metric System. A. Colenbrander, Journal of Iowa Medical Society 61:219-224, 1971.
6. Basic Instruction in Ophthalmology for Medical Students: A Systems Approach. G. M. Arsham, A. Colenbrander, B. E. Spivey, Proceedings of the 5th Rochester Conference on Self-Instruction in Medical Education, Rochester Clearinghouse, University of Rochester, Rochester, New York, 1972.
7. Comparison of Selected Ophthalmologic and Orthoptic Measurements in Families. David Smith, Peter Grutzner, August Colenbrander, J. P. Hegmann, Bruce E. Spivey, Arch. Ophth. 87:278-282, 1972.
8. Uniform Terminology. B. E. Spivey, A. Colenbrander, Editorial, Trans. AAOO 76:14-16, 1972.
9. A Simulation Device for Ophthalmoscopy. A. Colenbrander, Am. J. Ophth. 74:738-740, 1972.
10. International Expectation for Medical Student Performance in Ophthalmology. A. Colenbrander, Proc. 10<sup>th</sup> Annual Conf. on Research in Med. Ed., AAMC, 1971.
11. Instruction for Mastery in Medical Education. G. Arsham, A. Colenbrander, B. E. Spivey, Proc. 10<sup>th</sup> Annual Conf. on Research in Med. Ed. (abstract), AAMC, 1971.
12. A Prototype for Curriculum Development in Medical Education. Gary M. Arsham, August Colenbrander, Bruce E. Spivey, Journal of Medical Education 48:78-84, 1973.
13. Information Systems in Ophthalmology. A. Colenbrander, Current Concepts in Ophthalmology, Frederick Blodi, ed. C.V. Mosby Company, St. Louis, 1972.
14. Classification of Visual Performance. B. E. Spivey, A. Colenbrander, Arch. Ophth., 94:1227, 1976.
15. Classification and Coding in Ophthalmology and Otolaryngology. A. Colenbrander, Journal of Clinical Computing V, 2:83, 1976.
16. Low Vision, Definition and Classification. A. Colenbrander, in Clinical Low Vision, Eleanor Faye, ed. Little, Brown and Company, Boston, 1976.
17. A Clear Perspective on Low Vision, A. Colenbrander, Blindness, AAWB Annual, 1977-78, pp. 94-106.
18. How blind is blind? A. Colenbrander, Proceedings 2nd National Conference on Aging and Blindness, American Foundation for the Blind, 1978, pp. 15-24.
19. Aging and Visual Loss, invited testimony, A. Colenbrander, Record of the Senate Committee on Aging, August, 1978.
20. Low Vision Care, Epitome of Progress, Western Journal of Medicine (1979).
21. Dimensions of Visual Performance, A. Colenbrander, Low Vision Symposium, American Academy of Ophthalmology, Transactions AAOO, 83:332-337, 1977.
22. Classification and Coding in Ophthalmology, August Colenbrander, Computers in Ophthalmology, pp. 79-85, IEEE Computer Society, 1979.
23. Clinicians and Coding Systems. Can They Mix? August Colenbrander, Computers in Medicine, pp. 390-396, IEEE Computer Society, 1979.
24. Intraocular Lens Data. Robert L. Stamper, August Colenbrander. Ophthalmology, Instrument and Book Supplement, 1982:125-179.
25. Intraocular Lens Data. August Colenbrander, Leslie V. Woods, Robert L. Stamper. Ophthalmology, Instrument and Book Supplement, 1983:120-135.

26. Intraocular Lens Data. Robert L. Stamper, August Colenbrander, Jan-Petter Haugen. Ophthalmology, Instrument and Book Supplement 1984:164-180.
27. Effect of luminance, contrast, and eccentricity on visual acuity in senile macular degeneration. Brown B, Zadnik K, Bailey IL, Colenbrander A. Am J Optom & Phys Optics. 61(4):265-70, 1984.
28. Intraocular Lens Data. August Colenbrander, Leslie V. Woods, Robert L. Stamper. Ophthalmology, Instrument and Book Supplement, 1985:1-19.
29. International Visual Acuity Standard, Poster Exhibit, American Academy of Ophthalmology, 1985.
30. Lenses Mightier than Lasers, Invited speaker, Symposium on Aging, American Academy of Ophthalmology, 1986.
31. Intraocular Lens Data. August Colenbrander, Leslie V. Woods, Robert L. Stamper. Ophthalmology, Instrument and Book Supplement, 1986:37-46.
32. Intraocular Lens Data. August Colenbrander, Leslie V. Woods, Robert L. Stamper. Ophthalmology, Instrument and Book Supplement, 1987:1-13.
33. Intraocular Lens Data. August Colenbrander, Leslie V. Woods, Robert L. Stamper. Ophthalmology, Instrument and Book Supplement, 1988:38-46
34. Visual Acuity Measurement Standard. August Colenbrander, MD, Visual Functions Committee, Consilium Ophthalmologicum Universale. Italian J. Ophth. II/I 1988:1-15.
35. Intraocular Lens Data. August Colenbrander, Leslie V. Woods, Robert L. Stamper. Ophthalmology, Instrument and Book Supplement, 1989:20-27.
36. Visual Acuity Measurements in Low Vision Patients. August Colenbrander, MD, Donald C. Fletcher, MD. Journal of Vision Rehabilitation, 4(1):1-9 (1990).
37. Low Vision Rehabilitation: Basic Concept and Terms. August Colenbrander, MD, Donald C. Fletcher, MD. Journal of Ophthalmic Nursing and Technology, 11(1):5-9 (1992)
38. Low Vision Rehabilitation: Visual Acuity Measurement in the Low Vision Range. August Colenbrander, MD, Donald C. Fletcher, MD. Journal of Ophthalmic Nursing and Technology, 11(2):62-69 (1992)
39. Low Vision Rehabilitation: Vision Requirements for Driving. August Colenbrander, MD, Donald C. Fletcher, MD. Journal of Ophthalmic Nursing and Technology, 11(3), 111-115 (1992)
40. How to Stabilize Gaze during Vision Tests in patients with Maculopathies. Manfred Mackeben, PHD, August Colenbrander, MD. Invest. Ophthal. Vis. Sc. 34/4 (Suppl.), # 3615, March 1992.
41. Mapping the Topography of Residual Vision in Patients with Maculopathies. August Colenbrander, MD, Manfred Mackeben, PHD. Invest. Ophthal. Vis. Sc. 34/4 (Suppl.), # 3622, March 1992.
42. Preliminary implementation of the Functional Vision Score system on the Humphrey Field Analyzer. August Colenbrander, MD, Marc F. Lieberman, MD, Daniel C. Schainholz, MD. Perimetry Update 1992/93, (Proceedings of the International Perimetric Society, Kyoto, October 1992), Kugler publications, 1993, pp 487-496.
43. The Operation was Successful, but the Patient Cannot See any Better - Where Do We Go from Here? Donald C. Fletcher, MD, August Colenbrander, MD. In: Management and Care of the Cataract Patient, editor: Frank J. Weinstock, MD, Blackwell Scientific Publications, Boston, 1992.
44. The Assesment of Residual Vision in Patients with Maculopathies. Mackeben M, Colenbrander A. Non-invasive Assessment of the Visual System, Technical Digest, Vol. 3 NMB3, 1993

45. The Functional Vision Score. A Coordinated Scoring System for Visual Impairments, Disabilities and Handicaps. August Colenbrander, MD. In: Low Vision - Research and New Developments in Rehabilitation, Kooiman et al. eds., Studies in Health Technology and Informatics, IOS Press, Amsterdam, 1994, pp. 552-561.
46. Visual Acuity Measurement for Low Vision. August Colenbrander, MD. In: Low Vision - Research and New Developments in Rehabilitation, Kooiman et al. eds., Studies in Health Technology and Informatics, IOS Press, Amsterdam, 1994, pp. 542-551.
47. Comparison of Three Ways to Assess Residual Vision in Patients with Macular Vision Loss. M. Mackeben, PhD, A. Colenbrander, MD, D. Schainholz, MD. In: Low Vision - Research and New Developments in Rehabilitation, Kooiman et al. eds., Studies in Health Technology and Informatics, IOS Press, Amsterdam, 1994, pp. 51-58.
48. Mapping the Topography of Residual Vision after Macular Vision Loss. M. Mackeben, PhD, A. Colenbrander, MD. In: Low Vision - Research and New Developments in Rehabilitation, Kooiman et al. eds., Studies in Health Technology and Informatics, IOS Press, Amsterdam, 1994, pp. 59-67.
49. Low Vision Rehabilitation. August Colenbrander, MD. In: Office Management of Refractive Error, Ophthalmology Clinics of North America, 1993, 6,4:591-597.
50. Low Vision and Vision Rehabilitation. August Colenbrander, MD, Donald C. Fletcher, editors. June 1994 Issue of: Ophthalmology Clinics of North America, June 1994, 7, 2.
51. Low Vision and Quality of Life - Aspects of Vision Loss. August Colenbrander, MD. In: Low Vision and Vision Rehabilitation; Colenbrander, Fletcher eds., Ophthalmology Clinics of North America, 1994, 7,2:127-130.
52. Quantifying Low Vision - Ranges of Vision Loss. August Colenbrander, MD. In: Low Vision and Vision Rehabilitation, Colenbrander, Fletcher eds., Ophthalmology Clinics of North America, 1994, 7,2:131-136.
53. The Basic Low Vision Examination. August Colenbrander, MD. In: Low Vision and Vision Rehabilitation, Colenbrander, Fletcher eds., Ophth. Clinics of North America (1994), 7-2: 151-162.
54. Basic Concepts and Terms for Low Vision Rehabilitation, August Colenbrander, MD, Donald C. Fletcher, MD. Am. J. Occupational Therapy, 49-9: 865-869 (Oct. 1995)
55. What's in a Name: More People are Blinded by Definition than by any other Cause, August Colenbrander, MD, J. of Videology, 1:1: 13-20.
56. Visual Acuity Measurement in the Low Vision Range. August Colenbrander, MD. Invest. Ophthal. Vis. Sc. 37/3, # 3306, Feb. 1996.
57. Visual Acuity Measurement in the Low Vision Range. August Colenbrander, MD. Proceedings, VISION-96, International Low Vision Conference, Madrid, 1996.
58. Quick assessment of the topography of macular vision loss using a new PC-based field analyzer. Mackeben, M. and Colenbrander, A. Proc. of the Int'l Low Vision Conference, O.N.C.E., Madrid, 1996
59. Preface in 'Foundations of Low Vision', Clinical and Functional Perspectives (AL Corn, AJ Koenig Eds.), AFB Press, New York, 1996.
60. Analysis of Match Algorithms. August Colenbrander, MD. Academic Medicine - 71:10 (10/96 Suppl.) S94-96
61. PC-based mapping of remaining letter recognition after foveal vision loss. Mackeben, M., Colenbrander, A. and Gofen, A. Invest. Ophthal. & Vis. Sci. 39, No.4 (Suppl.), 1998
62. Use your PC to quickly map remaining vision after foveal vision loss. Mackeben, M., Colenbrander, A. and Gofen, A. Perimetry Update (M. Wall & J.M. Wild, eds.), pp 307-316, Kugler Publications. (Proceedings of the XIIIth International Perimetric Society Meeting, Gardone Riviera, Italy, 1998)

63. Introducing Rehabilitation. Donald C. Fletcher, August Colenbrander, in Low Vision Rehabilitation, Caring for the Whole Person, Monograph #12, American Academy of Ophthalmology, San Francisco, 1999.
64. Evaluating Visual Function. August Colenbrander, Ronald A. Schuchard, Donald C. Fletcher, in Low Vision Rehabilitation, Caring for the Whole Person, Monograph #12, American Academy of Ophthalmology, San Francisco, 1999.
65. Enhancing Impaired Vision. August Colenbrander, Jeffrey T. Liegner, Donald C. Fletcher, in Low Vision Rehabilitation, Caring for the Whole Person, Monograph #12, American Academy of Ophthalmology, San Francisco, 1999.
66. Topographic measurements of low contrast letter recognition for diagnosis and rehabilitation. Mackeben, M., Colenbrander, A. IOVS 40/4 (Suppl), # 2261, 1999
67. Topographic Measurements of Low Contrast Letter Recognition as a Tool for Diagnosis and Vision Rehabilitation. Manfred Mackeben, August Colenbrander, in Vision Rehabilitation (Papers from Vision-99, International Low Vision Conference, New York, 1999). Swets & Zeitlinger, Netherlands, 2000.
68. How Blind is "Blind"? – Survey of Definitions of Blindness – Poster presentation at the Third International Symposium on Ophthalmology in the Developing World. San Francisco, 2001.
69. Visual Acuity Measurement – A Historical Perspective. August Colenbrander. Proceedings, Cogan Ophthalmic History Society, March 2001, 177 – 185.
70. How Blind is Blind? Colenbrander A. Poster presentation for the Third International Symposium on Ophthalmology in the Developing World, American Academy of Ophthalmology, San Francisco, (March 2001).
71. Preservation of Vision or Prevention of Blindness? Colenbrander A. Editorial, Am. J Opth. 133:263-265, (2002).
72. Aspects and Ranges of Vision Loss. Basic and Clinical Science Course, Section 13, Chapter III (pp 37-53). American Academy of Ophthalmology, San Francisco, 2002.
73. Aspects of Vision Loss – Visual Functions and Functional Vision. Colenbrander A. Visual Impairment Research, 5(3): 115-136 (Dec., 2003).
74. Evaluation of a New Mixed Contrast Reading Card. ARVO-2004, poster # 4352.
75. The Mixed Contrast Reading Card Shows Aspect of Contrast Processing that Is Independent of Detail Processing, August Colenbrander, Donald C. Fletcher ARVO 2005, poster # 4587.
76. A Simple Screening Test for Contrast Sensitivity – The Colenbrander Mixed Contrast Reading Card. AAO 2005, poster # 387
77. Contrast Sensitivity and ADL Performance. A Colenbrander, DC Fletcher. ARVO 2006, poster # 5834.
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80. Visual Functions and Functional Vision. Colenbrander A International Congress Series, 1282:482-486 (Proceedings of Vision-2005 conference, London, 2005).
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82. The Historical Evolution of Visual Acuity Measurement. August Colenbrander. Visual Impairment Research 10(2,3):57-66.

83. The Functional Classification of Brain damage-related Vision Loss. August Colenbrander. *Journal of Visual Impairment and Blindness* 103(2):118-123.
84. Assessment of Functional Vision and its Rehabilitation. August Colenbrander. 2008 report for ICO and ISLRR. *Acta Ophthalmologica* (expected April 2010).
85. Measuring Vision and Vision Loss – chapter for *Duanes Ophthalmology* (expected April 2010).
86. Classification of Vision-related Functioning – A Framework – Chapter for book on *Visual Impairment in Children Due to Damage to the Brain* (in process).
87. Vision Rehabilitation – Chapter for Lange, *Clinical Ophthalmology* (in process).

Some of the documents are available on the website: [www.ski.org/Colenbrander](http://www.ski.org/Colenbrander)



City College of San Francisco  
Health Care Interpreter Certificate Program

RECEIVED BY QUALITY  
BOARD OF PHARMACY  
2009 DEC 15 PM 2:04

Carolyn Klein  
Manager, Legislation and Regulations  
California State Board of Pharmacy  
1625 N. Market Blvd., N219  
Sacramento, CA 95834

RE: draft regulations for the standardization and translation of prescription drug labels, as required by SB 472

Dear Ms. Klein:

I am a CA certified Administrative Hearing Interpreter (which includes medical interpreting), and also an instructor of healthcare interpreting at City College of San Francisco. As such, I have been acutely aware of the difficulties that our many patients have in understanding their prescription drug instructions. Prescription drug labels translated into the patient's language are vital for quality care. Also, pharmaceutical counseling is vital – and either telephonic or face-to-face interpreting needs to be part of the services offered to patients who cannot yet speak English.

To facilitate the written information on prescription drug labels, the Board should provide pharmacies with standard labels translated into at least the 14 languages spoken by groups of 10,000 or more limited-English speakers in California. The cost for these translations is minimal with a large health payoff.

For non-standardized labels and other languages, individual pharmacies could be responsible for providing translated labels. However, I would like the Board to provide these pharmacies with a listing of certified translators (by the American Translator's Association) and qualified interpreters (such as graduates of programs at the community colleges), so that ~~they~~ who do not speak English well can have their prescription drug instructions orally interpreted. As you know, this is a Civil Right!

Additionally, I strongly support the provision that labels must be printed in 12-point font or larger

Sincerely,

Nora Goodfriend-Koven MPH

City College of San Francisco Health Education Dept.  
Health Care Interpreter Certificate Training Program  
50 Phelan Ave Box C363 ♦ San Francisco ♦ CA 94112  
Phone 415-452-5158 ♦ Fax 415-452-5162 ♦ Email [ngoodfri@ccsf.edu](mailto:ngoodfri@ccsf.edu)

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BOARD OF PHARMACY

2009 DEC 28 PM 4:48



**Omnicare**

Scott R. Huhn PharmD  
Omnicare  
879 Second Street  
Santa Rosa, CA 95404  
707-486-7801  
[scott.huhn@omnicare.com](mailto:scott.huhn@omnicare.com)

Virginia Herold, Executive Director  
California State Board of Pharmacy  
1625 North Market Blvd, Suite N219  
Sacramento, CA 95834

December 23, 2009

Dear Ms. Herold,

**Request to Amend for Exemption  
California Board of Pharmacy  
Proposed Language Section 1707.5 of Division 17 of Title 16 of the California Code of  
Regulations**

The various dispensing systems involved with our patients in long term care include punchcards, Automed strip packs, and Opus cassettes. The medications are administered by licensed nurses and caregivers at various health care facilities; skilled nursing, intermediate care, psychiatric, assisted living and board/care.

The systems our pharmacies provide for medication administration are time pass oriented, involving a method of documentation via medication administration records (MAR) and centrally stored medication records (CSMR). Patients do not typically administer their own medications, unless requested and their healthcare provider determines the patient's cognitive abilities to allow for self-administration.

Please consider an exemption to this regulation for pharmacies servicing the above mentioned health care facilities because it does not involve direct to consumer prescription dispensing.

For additional information, I may be reached at 707-486-7801 or via email at [scott.huhn@omnicare.com](mailto:scott.huhn@omnicare.com). Thank you in advance for your time and consideration.

Sincerely,

Scott R. Huhn PharmD

January 4, 2010

BOARD OF DIRECTORS

2009-10

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Debra Nakatomi

Victor Kaiwi Pang

Niyanta Spelman

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National Advocates for  
Asian American,  
Native Hawaiian &  
Pacific Islander Health

Carolyn Klein  
Manager, Legislation and Regulations  
California State Board of Pharmacy  
1625 N. Market Blvd., N219  
Sacramento, CA 95834

RE: Comments on Title 16, Board of Pharmacy Proposed Language

Dear Ms. Klein:

Thank you for the opportunity to provide comments on the proposed language to add section 1707.5 of Division 17 of Title 16 of the California Code of Regulation implementing Business and Professions Code section 4076.5 (The California Patient Medication Safety Act). Ensuring that effective communication takes place between patients and pharmacists is critical to patient adherence to medication instructions and prevention of adverse events as a result of failure to communicate: the dosage form, dosage, route of administration and use by the patient; special directions and precautions for preparation, administration and use by the patient; common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur; techniques for self-monitoring drug therapy; proper storage; prescription refill information; and action to be taken in the event of a missed dose.

We do not believe that the proposed regulations are sufficient to ensure that effective communication concerning the above critical elements takes place with respect to limited English proficient patients in California, nor do we believe that the regulations are sufficient to ensure compliance with Title VI of the Civil Rights Act of 1964 and its implementing regulations.

With respect to the translation of the standard directions for use, the California Board of Pharmacy can do better than translation of these directions in five languages by October 2011. The cost for translating these 17 simple directions listed in (a)(4) is minimal and is a one time cost. California is a leader in the nation, translating its Healthy Families application into 10 languages. The California Department of Social Services has a bilingual unit that translates social services notices into over 16 different languages.

<http://www.cdss.ca.gov/cdssweb/entres/pdf/DSSFormsList.pdf> While the language of the proposed regulations requires that the directions be translated into at least five languages, we urge you to raise the minimum number to at least 15 languages, and because the cost is one time, more languages should be added over time as well as more standardized directions for use. For example, the regulation could be changed to require the directions be translated into at least 15 languages by October 2011 and at least five additional languages in each of the following years. One way to save on translation costs is for the Board to provide a glossary of the terms already translated

to avoid retranslating. The State of Washington has glossaries for social services that are available in many languages. Washington also translates notice, forms and letters to recipients in about 90 different languages. In New York State, the Attorney General recently entered into agreements with seven major pharmacy chains to provide language assistance to limited English proficient patients. The agreements include providing translations of ALL directions for use on pharmacy labels for five languages and an additional five languages six months after the pharmacy's new computer system is in place. We urge you to add a provision in the regulation to require that pharmacies translate non-standardized labels in the most prevalent languages spoken in the service area.

Regarding section (d) and oral translation of the prescription container label's information, the pharmacies must be required to provide notice that interpreter services are available at no cost to persons with limited English proficiency. Most pharmacies are recipients of Federal financial assistance and are required to comply with Title VI of the Civil Rights Act of 1964. The Title VI implementing regulations require that recipients of Federal financial assistance must provide meaningful access to their programs, services and activities for LEP persons. See "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," U.S. Department of Health and Human Services, 68 Fed. Reg. 47311 (August 8, 2003). The proposed Board regulations only require an oral language translation of the prescription container *upon request of the patient*. Unless the patient is aware that this request can be made, the patient is unlikely to request it. Furthermore, pharmacies that are subject to Title VI should provide interpreter services to limited English proficient persons beyond just providing a sight translation of the prescription label. Interpreter services are needed to solicit information necessary to maintain a patient medication profile; to offer prescription drug counseling; to provide that counseling when requested; accepting in-person and telephonic prescription drug refill requests; and at other times to ensure the safe and effective use of prescription drugs. We urge you to require that pharmacies post notices informing limited English proficient persons of their rights under these regulations and under Title VI. The California Department of Health Care Services has translated a Language Services Notice in twelve languages. <http://www.dhcs.ca.gov/formsandpubs/forms/Forms/MC%204034.pdf> With translation costs ranging from .20 - .80 per word, translating such a notice into many more languages and posting it on the Board's webpage for pharmacies to reproduce and use would entail minimal costs.

Thank you again for the opportunity to provide comments to strengthen the Board's regulations to meet SB 472's goal of ensuring prescription labels are truly patient-centered. Please feel free to contact me at: 202-466-7772 or [djang@apiahf.org](mailto:djang@apiahf.org), if you have any questions.

Sincerely,



Deana L. Jang, JD  
Policy Director



"Laverone, Stephen"  
<Stephen.Laverone@cdcr.ca.gov>

11/23/2009 02:19 PM

To <Carolyn\_Klein@dca.ca.gov>

cc

bcc

Subject RE: Proposed Regulations: 1707.5 Patient-Centered Prescription Label

Thank you, I already looked at the web site. Mandating **where items appear** on the Rx label may cause pharmacies and software providers to expend large amounts of money which is not a welcome proposition in these recessionary times.

**Steve Laverone, RPh**  
**Pharmacist II**  
**Northern California Youth Correctional Center**  
**7650 S. Newcastle Road**  
**Stockton, CA 95215**  
**[Stephen.Laverone@cdcr.ca.gov](mailto:Stephen.Laverone@cdcr.ca.gov)**  
**Pharmacy (209) 463-9085**  
**Pharmacy Office (209) 944-6365 Ext. 6725**  
**Pharmacy FAX (209) 465-8627**

**From:** Carolyn\_Klein@dca.ca.gov [mailto:Carolyn\_Klein@dca.ca.gov]

**Sent:** Monday, November 23, 2009 2:14 PM

**To:** Laverone, Stephen

**Subject:** Fw: Proposed Regulations: 1707.5 Patient-Centered Prescription Label

Mr. Laverone,

I'm sorry the text of my email transmitted was small (my view appears at least 12 pt).

The email sent was to let you know that the proposed regulations can be found on the Board of Pharmacy's Web site:

**[http://www.pharmacy.ca.gov/laws\\_regs/regulations.shtml](http://www.pharmacy.ca.gov/laws_regs/regulations.shtml)**

If you have any difficulty pulling the documents off the board's Web site, please let me know.

Regards,  
Carolyn Klein  
California State Board of Pharmacy  
(916) 574-7913

----- Forwarded by Carolyn Klein/Pharmacy/DCANotes on 11/23/2009 02:10 PM -----

"Laverone, Stephen" <Stephen.Laverone@cdcr.ca.gov>



California Pan-Ethnic Health Network

January 4, 2010

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Director of the Having Our Say Coalition  
and Senior Policy Analyst

**Kenneth H. Schell, PharmD**  
President  
California Board of Pharmacy  
1625 N Market Blvd, N219  
Sacramento, CA 95834  
Via Fax (916) 574-8618

**Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels**

Dear Dr. Schell and Members of the California Board of Pharmacy:

On behalf of the California Pan-Ethnic Health Network (CPEHN) we submit the following comments to proposed regulations related to patient-centered prescription drug labeling. In particular we are concerned with ensuring the Board's regulations are sufficient to improve the care and safety of the 40% of Californians who speak a language other than English at home.

CPEHN's mission is to improve access to health care and eliminate health disparities by advocating for public policies and sufficient resources to address the health needs of communities of color. CPEHN works to ensure that all Californians have access to health care and can live healthy lives.

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California.

While we are pleased the Board advanced the process at its October 2009 meeting, there is still work to be done to create stronger regulations for language access. In particular, the Board backed away from requiring labels to be translated into every patient's primary language. This provision was in the recommendations submitted by staff to the Board. We believe this provision should be brought back.

Prescription drug labels translated into the patient's language are vital for quality care. At the public hearing in October, you and the Board heard dramatic testimony from members of our communities on their desperate need for labels translated into their

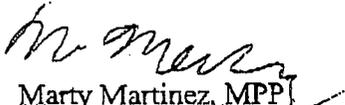
languages. You also heard from pharmacies who currently do translation of labels. You heard from them that it is doable and in some cases already required under public programs.

The final regulations approved by the Board must include the following provisions:

- We strongly support the provision that labels must be printed in 12-point font or larger. This is essential for seniors and those with limited vision.
- The Board should help pharmacies comply with providing translated labels to their patients. The Board should place on its website standard labels translated into at least the 14 languages spoken by groups of 10,000 or more limited-English speakers in California. The cost for these translations is minimal with a large health payoff. Attached to this letter is the census data indicating which languages are the top limited English languages.
- For non-standardized labels and other languages, individual pharmacies must be responsible for providing translated labels.
- All patients who do not speak English well must have the right to have their prescription drug instructions orally interpreted. This provision is in the current draft of the regulations. It is a necessary component of quality care but is not a substitute for a translated label. The final regulations must have provisions for both a written translated label and an oral interpretation of instructions for each patient who needs it.

Thank you for receiving these comments. We look forward to working with you on the continued effort to revise these regulations and improve care for our communities.

Sincerely,

  
Marty Martinez, MPP  
Policy Director

**COMBINED Don't speak English well & Don't speak English in CA**

1. SPANISH 2,841,237

2. CHINESE 265,269

3. VIETNAMESE 150,330

4. KOREAN 114,097

5. TAGALOG 55,894

6. ARMENIAN 44,245

7. RUSSIAN 37,798

8. JAPANESE 33,319

9. PERSIAN 24,807

10. PANJABI 24,431

11. MON-KHMER CAMBODIAN 22,472

12. ARABIC 17,037

13. HMONG 16,132

14. LAOTIAN 13,547

15. PORTUGUESE 9,493

16. FORMOSAN 9,113

17. THAI 8,539

18. HINDI 5,436

19. URDU 5,020

20. GUGARATHI 4,108

Source: 2005 American Community Survey

Link to source document:

[http://www.mfa.org/map\\_data\\_results&SRVY\\_YEAR=2005&geo=state&state\\_id=6&county\\_id=&mode=geographic&lang\\_id=&zip=&place\\_id=&city\\_id=&region\\_id=&division\\_id=&ll=&ca=&order=&ca-y&pc=1](http://www.mfa.org/map_data_results&SRVY_YEAR=2005&geo=state&state_id=6&county_id=&mode=geographic&lang_id=&zip=&place_id=&city_id=&region_id=&division_id=&ll=&ca=&order=&ca-y&pc=1)



**California Medical Association**  
*Physicians dedicated to the health of Californians*

---

January 4, 2010

Carolyn Klein  
Department of Consumer Affairs  
California State Board of Pharmacy  
1625 N. Market Blvd., N219  
Sacramento, CA 95834

**RE: Patient-Centered Prescription Labels**

Dear Ms. Klein:

The California Medical Association (CMA) appreciates the opportunity to comment on the Board of Pharmacy's (Board) proposed regulations regarding patient-centered prescription labels. CMA is a professional organization that represents more than 35,000 California physicians. Dedicated to the health of Californians, CMA is active in the legal, legislative, reimbursement and regulatory areas on behalf of California physicians and their patients.

In 2007, CMA supported The California Patient Medication Safety Act enacted by SB 472 (Corbett) in order to reduce medication errors by increasing the effectiveness of communication through prescription labels. CMA continues to support the intent of these proposed regulations to improve health care literacy and to reduce errors associated with the delivery of prescription and over-the-counter medication to consumers.

More specifically, CMA supports including the generic name of the drug on prescription labels as identified in §1707.5(a)(1)(B) of the proposed text. CMA believes that this requirement will facilitate patients' understanding of their prescribed medication as well as increase compliance with the directions for use.

CMA also supports proposed §1707.5(b), which would require the Board to publish on its Web site a translation of the directions for use into at least five languages other than English. CMA is committed to linguistic sensitivity in the provision of medical care, and we believe that effective communication with patients is essential to maintaining quality care and assuring a patient's compliance with treatment plans. We would, however, suggest that this provision be expanded to require the Board to publish translations of these directions on its Web site into at least the 14 languages spoken by groups of 10,000 or more limited-English speakers in California. Providing clear directions for use would result in a large health benefit for limited-English speakers.

Although CMA supports the goal of these regulations, portions of the proposed text fail to meet the clarity and consistency standards outlined by the Administrative Procedures Act. *See Government Code §11349.1*. Specifically, §1707.5(a)(1)(D) states that the purpose or condition of the drug must be listed on the prescription label if “its inclusion on the label is desired by the patient.” (Emphasis added). However, it is impossible for a pharmacy or prescriber to know whether the inclusion of the purpose or condition is “desired” by the patient if this patient never informs the prescriber of this desire. California law only imposes this requirement if the patient requests such inclusion. *See Business and Professions Code §4040 and §4076*. Requiring such labeling upon a patient’s desire is inconsistent with California law and provides no clarity to either prescribers or dispensers as to when the law applies. The current proposed language would subject individuals and entities to potential liability should it be found that such a desire existed, even if it was not explicitly requested.

Further, proposed §1707.5(a)(4) detailing the directions of use is also unclear. The proposed phrases for use in describing when a prescription medication should be consumed are too broad. Rather than using phrases such as “Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening,” as indicated in proposed §1707.5(a)(4)(J), the directions for use should instead indicate the appropriate time increments between doses. For instance, if a patient took one tablet in the late morning and another at noon - thus not allowing sufficient time to pass in between doses - the dangers of overdosing escalate. If suggested time increments between doses were also included in the directions for use, patient safety would be protected. The clarity of these directions needs to be improved so as not to affect standards of patient care.

Again, CMA applauds the efforts of the Board of Pharmacy in promulgating regulations to reduce medication errors by increasing the effectiveness of prescription labels. However, we have concerns over the clarity and consistency of the current proposed standards. For these reasons, we urge the Board of Pharmacy to amend the proposed regulations. Thank you for your consideration.

Respectfully submitted,



Veronica Ramirez  
Research Associate, Center for Medical and Regulatory Policy  
California Medical Association

**505.3 Makeup Air.** Makeup air shall be provided to replenish air exhausted by the ventilation system. Makeup-air intakes shall be located so as to avoid recirculation of contaminated air within enclosures.

**505.4 Hoods and Enclosures.** Hoods and enclosures shall be used when contaminants originate in a concentrated area. The design of the hood or enclosure shall be such that air currents created by the exhaust systems will capture the contaminants and transport them directly to the exhaust duct. The volume of air shall be sufficient to dilute explosive or flammable vapors, fumes, or dusts as set forth in Section 505.2. Hoods of steel shall have a base metal thickness not less than 0.027 inch (0.69 mm) (No. 22 gauge) for Class 1 and Class 5 metal duct systems; 0.033 inch (0.84 mm) (No. 20 gauge) for hoods serving a Class 2 duct system; 0.044 inch (1.12 mm) (No. 18 gauge) for hoods serving a Class 3 duct system; and 0.068 inch (1.73 mm) (No. 14 gauge) for hoods serving a Class 4 duct system.

Approved nonmetallic hoods and duct systems may be used for Class 5 corrosive systems when the corrosive mixture is nonflammable. Metal hoods used with Class 5 duct systems shall be protected with suitable corrosion-resistant material. Edges of hoods shall be rounded. The minimum clearance between hoods and combustible construction shall be the clearance required by the duct system.

**505.12 Pharmacies – Compounding Area of Parenteral Solutions.** *The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:*

1. *Be ventilated in a manner not interfering with laminar air flow.*

*Note: For additional pharmacy building standard requirements, see Chapter 12, California Building Code.*

**505.12.1 Pharmacies – laminar flow biological safety cabinet.** *In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar airflow hood with bag in – bag out design. The pharmacy must ensure that contaminated air plenums that are under positive air pressure are leak tight.*

*Note: For additional pharmacy building standard requirements, see Chapter 12, California Building Code.*

**505.12.2 Pharmacies Compounding Parenteral Solutions from One or More Nonsterile Ingredients.** *Any pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:*

- (a) *An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.*

(b) *An ISO class 5 cleanroom.*

(c) *A barrier isolator that provides an ISO class 5 environment for compounding.*

#### **506.0 Product-Conveying Ducts.**

**506.1 Materials.** Materials used in product-conveying duct systems shall be suitable for the intended use and shall be of metal.

##### **Exceptions:**

- (1) Asbestos-cement, concrete, clay, or ceramic materials may be used when it is shown that these materials will be equivalent to metal ducts installed in accordance with this chapter.
- (2) Ducts serving a Class 5 system may be constructed of approved nonmetallic material when the corrosive characteristics of the material being conveyed make a metal system unsuitable and when the mixture being conveyed is nonflammable.

Approved nonmetallic material shall be either a listed product having a flame-spread index of twenty-five (25) or less and a smoke-developed rating of fifty (50) or less on both inside and outside surfaces without evidence of continued progressive combustion, or shall have a flame-spread index of twenty-five (25) or less and shall be installed with an automatic fire-sprinkler protection system inside the duct.

- (3) Ducts used in central vacuum cleaning systems within a dwelling unit shall be constructed of materials in compliance with the applicable standards referenced in Chapter 17. Penetrations of fire walls or floor-ceiling or roof-ceiling assemblies shall comply with the Building Code.

Copper or ferrous pipes or conduits extending from within the separation between a garage and dwelling unit to the central vacuuming unit may be used.

Aluminum ducts shall not be used in systems conveying flammable vapors, fumes, or explosive dusts, nor in Class 2, 3, or 4 systems. Galvanized steel and aluminum ducts shall not be used when the temperature of the material being conveyed exceeds 400°F (205°C).

Metal ducts used in Class 5 systems that are not resistant to the corrosiveness of the product shall be protected with appropriate corrosion-resistant material.

**506.2 Construction.** Ducts used for conveying products shall be of substantial airtight construction



# californiapharmacistsassociation

January 4, 2010

Ms. Virginia Herold,  
Executive Officer  
California State Board of Pharmacy  
1625 N Market Blvd, N219  
Sacramento, CA 95834

RE: Proposed Regulation Title 16 Section 1707.5

Dear Ms. Herold:

The California Pharmacist Association's Long Term Care Management Council would like to take this opportunity to provide the California State Board of Pharmacy with additional language for the proposed regulation listed above. Residents of licensed health care facilities do not physically possess, control, nor do they administer, their prescribed medications. This is accomplished by the facility licensed staff. All medications are contained in secured locations and accessed only by authorized facility staff. Moreover, the Title 22 regulations do not allow patients to keep or administer their own medications.

Further, when a facility patient/resident is discharged, we propose that they be given the choice to have new discharge prescriptions dispensed to take home or the pharmacy can provide patient drug information as is currently the practice. They could also sign an opt-out letter, similar to the opt-out letters for those patients who decline child-proof vials.

The Long Term Care Management Council proposes that the following language be amended into the proposed regulation of Title 16 Section 1707.5:

"Notwithstanding any other provision of law, it is not necessary to include the requirements of 1707.5 if a pharmacist dispenses a medication for a patient in a facility licensed pursuant to Section 1250 of the Health and Safety Code."

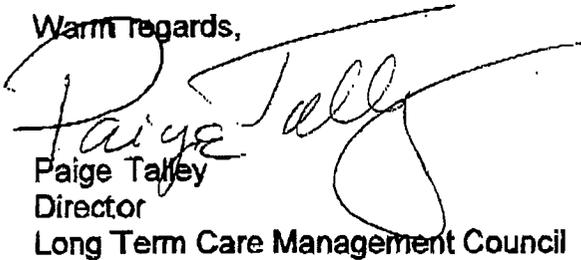
Additional language might read that "Upon discharge from a facility licensed pursuant to Section 1250 of the Health and Safety Code, a patient may choose not to have his or her medications pursuant to Title 16 Section 1707.5 by signing an opt-out waiver."

Herold 01.04.09 Page 2 of 2

The members of the Long Term Care Management Council would welcome the opportunity to discuss these amendments with you in more detail and look forward to attending the January 20 Board meeting.

Please call me if you require further information.

Warm regards,



Paige Talley  
Director  
Long Term Care Management Council



C A L I F O R N I A

RECEIVED BY CALIF BOARD OF PHARMACY

2009 DEC 28 PM 2:41

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Mexican American  
Legal Defense & Education Fund

HORACE WILLIAMS  
CA Black Health Network

December 23, 2009

Kenneth H. Schell, PharmD, President  
California Board of Pharmacy  
Attn: Carolyn Klein  
1625 N Market Blvd, N219  
Sacramento, CA 95834  
Via Fax (916) 574-8618

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Dear Dr. Schell and Members of the California Board of Pharmacy:

I am writing to you on behalf of the members of Health Access California, a statewide coalition representing consumers, seniors, people with disabilities, religious, labor, and multi-lingual/multi-cultural groups. We urge the Board of Pharmacy to adopt draft regulations implementing SB 472, California Patient Medication Safety Act (Corbett, D-San Leandro).

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a **standardized, patient-centered, prescription drug label** on all prescription medication dispensed to patients in California. This landmark legislation requires that the regulation outline requirements for drug labeling that take into account consumers' needs, particularly those of seniors and people with little medical literacy and/or limited English proficiency.

Over the last year we believe the staff of the Board of Pharmacy has done an excellent job researching the issues at hand, holding public hearings, conducting surveys, and incorporating research results into the draft regulation. We note that SB 472 underwent four revisions in the Senate and two in the Assembly before being signed into law. These revisions were largely to accommodate objections raised by the industry.

We believe the most recent draft regulations on the Board's website represent a credible start to the implementation of this statute. We are particularly supportive of the following:

- Labels should be printed in 12-point font or larger.
- The Board should provide pharmacies with standard label language in at least the 14 threshold languages delineated for language assistance in California based on population size.

ANTHONY WRIGHT  
Executive Director

ORGANIZATION LISTED  
FOR IDENTIFICATION PURPOSES

- All patients with limited English proficiency should have the right to have their prescription drug instructions orally interpreted by a health professional working within his or her field of clinical expertise.

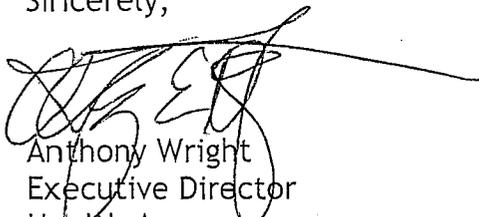
A few industry representatives testified at the Board's October public hearing regarding difficulties in implementing the proposed draft regulatory language. However, many pharmacists spoke in favor of the regulation and said that they were in large measure already adhering to key features of the law. We also listened to many consumers who offered compelling testimony regarding the necessity for swift implementation of this consumer protection law based on their inability to read the small print on the label or because of their low level English proficiency. Pharmacy board staff noted the Board's efforts to utilize external funding to support expanded translations of some of the most common phrasing used in prescription labeling. Therefore, we strongly believe that beginning the formal rule-making process is the appropriate venue to address any remaining concerns of the industry.

Consequently, we urge the Board to undertake the public review process as soon as possible. The prevalence of medical prescription errors and the lack of public comprehension of prescription labels provide a compelling and urgent rationale for this regulation. We urge strong action to implement what California's policymakers have determined is needed "to increase consumer protection and improve the health, safety, and well-being of consumers."

We believe that standardized, readable, language-accessible, prescription labels are a vital element in appropriate health care delivery. Without them we all risk injury, inappropriate care, or even death. We strongly believe these draft regulations should be adopted at the next Board meeting in January to begin this formal rulemaking process.

If you have any questions or need more information, please contact Elizabeth Abbott, Project Director at Health Access, at (916) 497-0923, ext. 201 or at [eabbott@health-access.org](mailto:eabbott@health-access.org).

Sincerely,



Anthony Wright  
Executive Director  
Health Access

1127 11<sup>th</sup> Street, Suite 234  
Sacramento, CA 95814

cc: Senator Ellen Corbett, author  
Senator Elaine Alquist (D-Santa Clara), Chair, Senate Health  
Senator Denise Ducheny (D-San Diego), Chair, Senate Budget  
Senator Negrete-McLeod (D-Chino), Chair, Senate Business, Professions, &  
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Assemblymember Mary Hayashi (D-Hayward), Chair, Assembly Business &  
Professions  
Fred Aguiar, Secretary, State and Consumer Services Agency

January 4, 2010

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**Donn Ginoza, Chair**  
California Public  
Employment  
Relations Board

Carolyn Klein  
California Board of Pharmacy  
1625 N Market Blvd, N219  
Sacramento, CA 95834  
Via Fax (916) 574-8618

**Byron Gross,**  
**Vice-Chair**  
Hooper, Lundy &  
Bookman

**Re: 16 California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Drug Labels**

**Lola FitzPatrick,**  
**Treasurer**  
Consumer  
Representative

Dear Ms. Klein:

**Elisabeth Benjamin**  
Community Service  
Society of New York

On behalf the National Health Law Program (NHeLP), we are submitting initial comments to the proposed regulations issued on November 20, 2009 and will be providing additional written comments and oral testimony at the Board of Pharmacy (Board) hearing scheduled for January 20, 2010. NHeLP is a national public interest legal organization seeking to improve health care for America's low-income population, including people of color, women, children, the elderly and people with special needs, including immigrants and limited-English proficient (LEP) individuals

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We are disappointed that the proposed regulations represent a retrenchment from the intent of SB 472 and the Board's initial proposed regulations shared with the public at the Board's July and October meetings. We have submitted comments, attended meetings, and presented testimony at several Board hearings during the last two years. We have also tried to assist the Board and have monitored the discussions and progress of the Board's research and findings. We believe that there has been ample testimony presented at the hearings that provided critical evidence about the needs of limited-English proficient (LEP) patients and clearly supported the need for translation of prescription drug labels.

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As has been noted in prior comments, SB 472 requires the Board to take into account the needs of LEP patients. The current proposed regulation does not reflect this statutory requirement. As we have noted in prior comments and testimony, there are other federal and state requirements and guidelines to ensure linguistic access to LEP patients by pharmacists in various contexts. These include the following: 1) Title VI of the 1964 Civil Rights Act (see attached NHeLP Fact Sheet), 2) U.S. Department of Health and Human Services, Office for Civil Rights, *Guidance to Federal Financial Assistance*

*Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, 68 Fed. Reg. 47311 (Aug. 8, 2000); 3) Executive Order 13166, 65 Fed. Reg. 50121 (Aug. 16, 2000); Office of Minority Health's *National Standards on Culturally and Linguistically Appropriate Services in Health Care*, 65 Fed. Reg. 80865 (Dec. 22, 2000), reprinted at: <http://www.omhrc.gov/clas>; 4) Cal. Govt. Code Section 11135 et al. and its implementing regulations, 22 Cal. Code Regs. Sections 98000 – 98413; 4) Cal. Govt. Code Section 7291 et al. (Dymally-Alatorre Act); 5) Cal Health & Safety Code Sections 1367, 1367.04 and 1367.07 and its implementing regulations, 28 Cal Code Regs. Sections 1300.67.04 & 1300.67.8; 6) Cal. Ins. Code Sections 10133.8 & 10133.9 and its implementing regulations, 10 Cal Code Regs. Sections 2538.1-2538.8; and 7) Medi-Cal and Healthy Families-related contract requirements. There are also specific regulations that require language access services: 1) for refills, the patient must be provided with written information, either on the prescription label or with the prescription container, which describes which pharmacy to contact if the patient has any questions about the prescription or medication (16 Cal. Code Regs. Section 1707.4(3)); and 2) if the patient is not in the pharmacy (including drugs shipped by mail), a pharmacy must ensure that the patient receives written notice of her right to request consultation, and a telephone number from which the patient may speak to a pharmacist (16 Cal. Code Regs. Section 1707.2(a)(2)). In order for an LEP patient to communicate with the pharmacist, he or she must have access to an interpreter or translated information.

In past comments, we have provided recommendations to strengthen access for LEP patients and seniors. We reiterate our support to expand the number of languages for the translation of standardized labels to match the Medi-Cal Managed Care threshold languages. While we continue to support section (a), including the requirement that the label be printed in 12-point, sans serif typeface, and (d), the provision of an oral language translation of the instructions, we advise the Board to adopt the following requirements, several of which were included in its originally proposed regulations: 1) to publish the translation of the directions in section (a)(4) sooner than October 2011, 2) when instructions for use specified by the prescriber do not conform to one of the items listed in subdivision (a)(4) the pharmacy shall secure its own translation, 3) for patients who cannot read or understand English but can read in another language, the pharmacy shall provide a prescription container labeled with the components specified in subdivision (a) in the language of patient, and 4) the pharmacy must offer oral interpretation of the label and/or provide an interpreter to any LEP patient and not rely on a specific request by the LEP patient.

We are also attaching some additional information regarding the need for language assistance services and some articles illustrating the existence of technology capable of performing translations into many languages, which is currently being done at many pharmacies across the country: 1) Rite Aid Now Offers Prescription Bottle Labels In 11 Different Languages (2005), [http://www.riteaid.com/company/news/news\\_details.jsf?itemNumber=728](http://www.riteaid.com/company/news/news_details.jsf?itemNumber=728); 2) Language problems at the pharmacy, Chattanooga Times Free Press, <http://www.timesfreepress.com/news/2009/apr/27/language-problems-pharmacy/>; 3) Giant Food Introduces Spanish Language Prescription Labels and Directions. (2007), <http://www.allbusiness.com/retail/retailers-food-beverage-stores-grocery-supermarkets/5330171-1.html>; 4) National Health Museum: Medical Misunderstandings, <http://www.accessexcellence.org/HHQ/qow/qow06/qow061204.php>, and 5) Language Barriers

Plague Almost Half of U.S. Drug Stores,

<http://health.usnews.com/usnews/health/healthday/070806/language-barriers-plague-almost-half-of-us-drug-stores.htm>. We hope that the Board finds the information useful.

We hope that the Board understands its key role in increasing access to pharmacy services for LEP patients and that the state continues to be a leader and model for other states to ensure that LEP residents have access to language assistance services, including translated labels on prescription drug containers. If you have any questions, please do not hesitate to contact Doreena Wong at [wong@healthlaw.org](mailto:wong@healthlaw.org) or call (310) 204-6010, ext. 107.

Sincerely,

Doreena Wong  
National Health Law Program

## LANGUAGE SERVICES IN PHARMACIES: WHAT IS REQUIRED?<sup>1</sup>

*A 10-month old girl was taken to a pediatrician's office by her parents, who spoke no English. The infant was diagnosed with iron-deficiency anemia and prescribed an iron supplement. The parents took the prescription to a local pharmacy that did not provide language services, and the prescription label on the bottle was provided in English. The pharmacist attempted to demonstrate the proper dosing and administration. The prescribed dose was 15 mg per 0.6 ml (1.2 ml) daily. Fifteen minutes after the parents administered the medication to the infant, she appeared ill and vomited twice. She was taken to the emergency room where it was discovered that the parents had administered 15 ml (a 12.5-fold overdose).<sup>2</sup>*

As this example illustrates, it is critical that pharmacists and limited English proficient (LEP) patients be able to communicate effectively. As complicated as it may be for English-speakers to understand medication instructions, the difficulties are exacerbated for LEP individuals. In a recent study, over one-quarter of LEP patients who needed, but did not get, an interpreter reported that they did not understand their medication instructions, compared with only two percent of those who either needed and received an interpreter or did not need an interpreter.<sup>3</sup>

Given that more than 4 billion prescriptions are written yearly and that 8.7% of Americans are LEP,<sup>4</sup> millions of prescriptions are likely for LEP patients. This issue brief provides an overview of existing federal laws addressing the provision of language services in the pharmacy setting.

### FEDERAL REQUIREMENTS

#### **1. Is there a federal requirement for communication assistance (also called language services) to individuals who do not speak English well?**

Yes. In 1964, Congress passed Title VI of the Civil Rights Act. This law prohibits discrimination and ensures that federal money is not used to support health care providers – including pharmacies and pharmacists – who discriminate on the basis of national origin.<sup>5</sup> Title VI says:

No person in the United States shall, on ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.<sup>6</sup>

The U.S. Department of Health and Human Services (HHS) and the courts have applied Title VI to protect national origin minorities who do not speak English well. Thus, recipients of federal

#### OTHER OFFICES

financial assistance (hereafter “federal funding”) must take reasonable steps to ensure that LEP individuals have meaningful access to their programs and services.<sup>7</sup>

## **2. Does Title VI cover pharmacies and pharmacists?**

Yes. The obligations under Title VI (and HHS’ regulations and guidance implementing Title VI, see Q. 4-5, and 12 below) apply broadly to any “program or activity” that receives federal funding, either directly or indirectly (through a contract or subcontract, for example), and without regard to the amount of funds received.<sup>8</sup> For independent and chain pharmacies and pharmacists, federal funding includes federal payments for prescription drugs (including dispensing fees or any other related payments) provided to Medicare, Medicaid and State Children’s Health Insurance Program (SCHIP) enrollees. It also applies to pharmacies providing prescription drugs to enrollees of federally-funded managed care plans (such as Medicaid managed care and Medicare Advantage plans) or Medicare Part D prescription drug plans.

Further, the Title VI protections extend to all of the operations of the organization or individual, not just that part that receives the federal funds.<sup>9</sup> So once federal funds are accepted, language services must be provided to all pharmacy patients, not just those patients participating in federally funded programs. And if a pharmacy does not take federal funds but is located in a facility that does (such as a hospital or long term care facility), Title VI still applies.

## **3. Who is “limited English proficient?”**

HHS defines individuals as “limited English proficient” if they do not speak English as their primary language and have a limited or no ability to read, write, speak, or understand English.

In determining language ability, the Census Bureau asks how well a person speaks English – the options are “very well,” “well,” “not well” or “not at all.” Due to the complex nature of health care interactions, it is generally accepted that a person who speaks English less than “very well” is likely LEP and will need language services. Nationally, over 24 million individuals speak English less than “very well.”<sup>10</sup>

## **4. How does a pharmacist know how to provide language services?**

The federal Departments of Justice and Health and Human Services (HHS) have adopted four factors for assessing how to assist LEP persons. These factors call upon the federally funded pharmacy to determine:<sup>11</sup>

- The number or proportion of LEP individuals served or encountered.<sup>12</sup>
- The frequency of contact with the program. If LEP individuals access the pharmacy on a daily or weekly basis, a recipient has greater duties than if contact is infrequent.
- The nature and importance of the program to beneficiaries. More steps must be taken if a denial or delay of services may have critical implications for daily life (e.g. medication errors that can result from a misunderstanding of prescription drug instructions).

- The resources available and cost considerations. If the number of LEP persons is limited, a small recipient with few resources may not have to take the same steps as a larger recipient. Costs are a legitimate consideration in identifying the reasonableness of particular language assistance measures.<sup>13</sup>

In balancing these factors, pharmacies and pharmacists should consider the appropriate mix of written and oral language assistance, considering which documents must be translated, when oral interpretation is needed, and whether such services should be immediately available.<sup>14</sup>

The HHS Office for Civil Rights (OCR) will apply these factors when determining whether an entity is compliance with Title VI. OCR recognizes that one size does not fit all and will determine compliance on a case-by-case basis.

#### **5. Are there specific guidelines that explain how to provide language services?**

Yes. On August 8, 2003, HHS' OCR issued guidance for federal fund recipients, including pharmacies and pharmacists participating in HHS-funded programs.<sup>15</sup> The guidance is available at <http://www.hhs.gov/ocr/lep/>. This guidance does not impose any new requirements but merely brings together all of OCR's policies for overseeing Title VI since 1965.

#### **6. How should a pharmacy offer oral language services?**

The HHS Guidance describes various options to provide oral language assistance, including the use of bilingual staff, staff interpreters, contracting for interpreters, using telephone interpreter lines,<sup>16</sup> and using community volunteers. It stresses that interpreters need to be competent, though not necessarily formally certified. A combination of oral language assistance may work best. For example, bilingual pharmacists could provide services directly in some non-English languages while other bilingual staff (including pharmacy or non-pharmacy in-store staff) may be competent to interpret between pharmacists and patients. A telephone language line can offer coverage when existing staff are unavailable. In general, all interpreters – whether staff or contract – must abide by the HIPAA (Health Insurance Portability and Accountability Act) privacy rules (see Q. 7 below).<sup>17</sup>

The HHS Guidance allows the use of a person's family members and friends to interpret but clearly states that an LEP person may not be *required* to use a family member or friend and that "extra caution" should be taken if an LEP person chooses to use a minor to interpret. Similarly, an LEP person may not be required to use unrelated individuals, such as other customers, to interpret. These untrained interpreters are often called "ad hoc" interpreters. Pharmacists should verify and monitor their competence and appropriateness of ad hoc interpreters, including the person's language and comprehension skills and awareness of confidentiality and HIPAA issues.

The HHS Guidance notes that particular care must be paid in situations involving health, safety or access to important benefits, or when credibility and accuracy are important to protect the individual – all directly relevant to pharmacy interactions. Moreover, OCR says recipients should make the LEP person aware that he or she has the "option" of having the pharmacy provide an interpreter without charge.

Patient counseling, which may be required under state pharmacy laws, is an area where

National Health Law Program, 2008.

the Guidance's emphasis on health and safety is highly relevant. Without being able to communicate with LEP patients, a pharmacist may be unable to provide information about correct dosing, drug interactions, and potential side effects. In addition to potential liability under state law, a pharmacy or pharmacist may be liable for malpractice or negligence if a patient suffers adverse harm because required information is not provided in a manner the patient understands.

The HHS Guidance's concern with access to important benefits is also implicated. For example, if a prescription coverage request is denied because the insurer refuses to cover it, the pharmacist should be able to explain the rejection codes or translate information provided about the denial. If the patient does not understand the basis for the denial, he may not understand his ability to appeal and thus is denied access to important benefits.

#### 7. **How does HIPAA impact pharmacies use of interpreters?**

HIPAA protects individuals from the release of their private (or protected) health information. Generally, those working in a pharmacy setting may not disclose a patient's protected health information except in limited circumstances and to certain entities, as defined by law. If the pharmacy discloses the information to outside sources (for example, if it uses a language agency to provide interpreters), it should have a "business associate" agreement to ensure that the outside organization also protects the patient's health information.

The HIPAA privacy rule allows others to have access to a patient's health information *with the patient's consent*. To these persons approved by the patient, the pharmacy may disclose protected health information directly relevant to the patient's care or payment if the pharmacy:

- obtains the individual's agreement; *or*
- provides the individual with the opportunity to object to the disclosure and the individual does not express an objection; *or*
- reasonably infers from the circumstances, based on the exercise of professional judgment that the individual does not object to the disclosure. (For example, when a person comes to a pharmacy to pick up a prescription on behalf of an individual he identifies by name, a pharmacist, based on professional judgment and experience with common practice, the pharmacist may allow the person to do so.<sup>18</sup>)

Under any of these circumstances, if a patient consents, a family member or friend brought by the patient to the pharmacy would be allowed to interpret and have access to a patient's protected health information. This could also include, *but only if the patient consents*, an *ad hoc* interpreter such as another patient or pharmacy customer. Because in this situation the patient has consented *and* the interpreter is neither a member of the covered entity's workforce nor a business associate, the interpreter is not bound by the privacy rule.

Before a pharmacy relies on an *ad hoc* interpreter, the pharmacy should ensure that the patient is informed of the need to provide consent; without informed consent, the pharmacy may be liable for a HIPAA violation.<sup>19</sup> The patient may ask the covered entity to provide an interpreter who would be subject to the protections of the HIPAA privacy rule.

## **WRITTEN TRANSLATED MATERIALS**

### **8. When should a pharmacist translate written materials?**

It depends on the relevant circumstances of each pharmacy based on the four factors listed above (see Q. 4). After these have been assessed, pharmacies and pharmacists should decide what reasonable steps to take to ensure meaningful access. At a minimum, the pharmacist should translate dosage instructions and warning labels to ensure that a patient fully understands the instructions for usage. Many pharmacy software programs have translation capacity built in; pharmacies and pharmacists should check with their vendors about availability.

Nothing in federal or state law prohibits the translation of prescription drug labels, instructions or inserts. While federal law requires certain information to be on the label in English,<sup>20</sup> it takes a permissive approach and allows, but does not require, the inclusion of other languages on the prescription drug label.<sup>21</sup> Posted information or handouts about patients' rights, such as the right to seek a written explanation or to appeal a denial in Medicaid or the Medicare Part D program, are also items where the importance of translated materials should be considered.

As noted, OCR will evaluate a provider's efforts on a case-by-case basis. For the translation of written materials, the HHS Guidance designates "safe harbors" that, if met, will provide strong evidence of compliance.<sup>22</sup>

## **STATE REQUIREMENTS**

### **9. In addition to federal law, do state laws require pharmacies to provide oral language services?**

It depends on the state. All states have enacted laws that address the provision of language services in healthcare settings and some of these apply to pharmacies.<sup>23</sup> In the coming months, the National Health Law Program will be conducting a 50-state survey of pharmacy laws related to language access and will provide results when available. As one example, New York pharmacy regulations include a counseling requirement when pharmacists dispense prescriptions to new pharmacy patients or dispense new medications to current patients.<sup>24</sup> The regulations do not include an exemption for LEP patients. Thus, a pharmacist will be unable to comply with the counseling requirement if language services are not provided. The pharmacist should ensure that effective communication occurs, either by using an interpreter or translating drug information handouts (however, it is unlikely that providing translated documents alone would satisfy the counseling requirement because it implies oral communication).

### **10. What about pharmacies located in hospitals, nursing homes, or other health care settings?**

For co-located pharmacies, Title VI may independently apply to both the pharmacy and host facility since both are likely recipients of federal funds. Even if the host facility does not receive federal funds, the pharmacy would still be subject to Title VI if it does. Further, additional state laws may require language access in the host facility.<sup>25</sup> For example, Massachusetts, Rhode Island and New York require hospitals to provide language services. A pharmacy located in a hospital would be subject to these laws.

The pharmacy should obtain information about the facility's policies and whether pharmacy staff can access the facility's interpreters and translated materials.<sup>26</sup>

### **ADDITIONAL INFORMATION**

#### **11. Is a pharmacy liable if it does not provide language services to LEP patients?**

Yes, it is potentially liable under both federal and state law. Under federal law, OCR investigates complaints against pharmacies and first has an obligation to seek compliance from those who fail to abide by Title VI. OCR is also available to provide ongoing technical assistance. If compliance is not obtained voluntarily, OCR may refer the issue to the Department of Justice for formal compliance proceedings that could result in suspension or termination of federal assistance.<sup>27</sup>

If a patient suffers medical harm caused by the pharmacist, the patient could initiate a malpractice or negligence claim against the pharmacy or pharmacist. And if the HIPAA privacy rules are violated, a pharmacy may be liable for fines of \$100 per violation, up to \$25,000 per year.

Depending on state law, additional liability may apply. For example, under New York law, the failure to abide by the requirements for labeling and counseling could result in a pharmacist facing misdemeanor charges with fines and possible jail time for multiple violations.<sup>28</sup>

#### **12. What if a pharmacist unintentionally discriminates against individuals?**

HHS' regulations prohibit federal fund recipients from:

- Using criteria or methods of administration that have the *effect* of discriminating against LEP patients;
- Restricting access to advantages or privileges for LEP patients that non-LEP patients receive from the same program;
- Providing services or benefits to LEP patients that are different, or provided in a different way, from those provided to non-LEP patients (NOTE: a translated document should not be considered "different" since the content is the same as the English document while being presented in a non-English language);
- Treating LEP patients differently from non-LEP patients in determining admission, enrollment, eligibility, or other requirements to receive services.<sup>29</sup>

#### **13. How can pharmacies document their language services?**

Pharmacies and pharmacists can develop a written implementation plan as a means of documenting compliance with Title VI. The Office for Civil Rights suggests five elements when designing a plan:

- Identify LEP individuals who need language assistance, using for example, language identification cards or recording patient language needs in the pharmacy's computer system.
- Describe language assistance measures, such as the types of language services available, how staff can obtain these services and respond to LEP persons, and how competency of language services can be ensured.
- Train staff, including pharmacists, pharmacy interns, and cashiers, to understand LEP policies and procedures and how to work effectively with LEP patients and interpreters (both in-person and telephonic).
- Provide notice of language services by, for example, posting signs in intake areas and other entry points, providing information in outreach brochures, working with community groups, using a telephone voice mail menu, providing notices in local non-English media sources, and making presentations in community settings.
- Monitor and update the LEP plan, considering changes in demographics, types of services, and other factors.<sup>30</sup>

#### 14. How can pharmacies pay for language services?

HHS' Centers for Medicare & Medicaid Services (CMS) recognizes that federal Medicaid and SCHIP funds can be used for language activities and services.<sup>31</sup> States can thus submit the costs of language services needed by Medicaid and SCHIP enrollees to the federal government for partial reimbursement.

Currently, twelve states plus the District of Columbia directly pay for language services in Medicaid and SCHIP. Some states have limited the reimbursement to "fee-for-service" providers so providers participating in managed care plans might not be eligible. Other states report that they currently set their reimbursement rates for all providers to include the costs of language services as part of the entity's overhead or administrative costs.<sup>32</sup>

#### 15. Where can pharmacies and pharmacists get more information?

The federal government has launched a website called "Let Everyone Participate," <http://www.lep.gov>. In addition to tracking federal activities, the website offers direct assistance to federal fund recipients and advocates. For example, fund recipients can download "I Speak" cards that allow LEP persons to identify their primary language. The presidential "Executive Order" (EO) entitled *Improving Access to Services for Persons with Limited English Proficiency*,<sup>33</sup> and OCR Guidance are also available on this website.

The "CLAS Standards" (Standards for Culturally and Linguistically Appropriate Services in health care) from the HHS Office of Minority Health, offer additional information and resources.<sup>34</sup>

<sup>1</sup> This issue brief was made possible with the generous support of the California Endowment, the New York Academy of Medicine and the Altman Foundation.  
National Health Law Program, 2008.

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<sup>2</sup> Agency for Healthcare Research and Quality, *Language Barrier: The Case*, Pediatrics (2006), at <http://www.webmm.ahrq.gov/>.

<sup>3</sup> D. Andrulis, N. Goodman, C. Pryor, *What a difference an Interpreter Can Make* (April 2002), at <http://www.accessproject.org>.

<sup>4</sup> LEP is defined as individuals who are unable to speak English "very well". See U.S. Census Bureau, "Language Spoken at Home" (Table S1601), 2006 American Community Survey, at [www.factfinder.census.gov](http://www.factfinder.census.gov).

<sup>5</sup> 100 Cong. Rec. 1658 (1964). The United States Supreme Court has treated discrimination based on language as national origin discrimination. See *Lau v. Nichols*, 414 U.S. 563 (1974). "National origin" is not defined in federal law but generally refers to the country where one is born. The U.S. Supreme Court and federal agencies have determined that language can be a proxy for national origin.

<sup>6</sup> 42 U.S.C. § 2000d. See also 45 C.F.R. § 80 app. A (listing examples of federal financial assistance, including Medicare, Medicaid, Maternal and Child Health grants).

<sup>7</sup> While some states or localities have declared English as their official language, federal fund recipients must continue to follow federal laws regarding non-discrimination. See, e.g., 42 C.F.R. §§ 438.6(f), 438.100(d).

<sup>8</sup> See 42 U.S.C. § 2000d-4a (defining "program or activity").

<sup>9</sup> *Id.*

<sup>10</sup> 2006 American Community Survey, (Tables S1601, B16001), at <http://www.factfinder.census.gov>.

<sup>11</sup> See 65 Fed. Reg. 50123 (Aug. 16, 2000). In addition to Executive Order 13166, this Guidance is authorized by 28 C.F.R. § 42.404(a), directing agencies to "publish title VI guidelines for each type of program to which they extend financial assistance, where such guidelines would be appropriate to provide detailed information on the requirements of Title VI." According to the Department of Justice, the Guidance does not create new obligations beyond those already mandated by law.

<sup>12</sup> See 67 Fed. Reg. 41459 (June 18, 2002). "But even recipients that serve LEP persons on an unpredictable or infrequent basis should use this balancing analysis to determine what to do if an LEP individual seeks services under the program in question." *Id.* at 41460.

<sup>13</sup> *Id.* at 50124-25. See also, e.g., 67 Fed. Reg. 41455, 41457 (June 18, 2002).

<sup>14</sup> See 67 Fed. Reg. 41460 (June 18, 2002).

<sup>15</sup> 68 Fed. Reg. 47311 (Aug. 8, 2003). For previous versions of this guidance, see 65 Fed. Reg. 52762 (Aug. 30, 2000).

<sup>16</sup> Previous guidance cautioned the fund recipient that telephone interpreter lines should not be the sole language assistance option, unless other options were unavailable. See 67 Fed. Reg. at 4975.

<sup>17</sup> For more information on the use of interpreters and HIPAA, see *HIPAA and Language Services in Health Care*, National Health Law Program, at <http://www.healthlaw.org>.

<sup>18</sup> HIPAA Frequently Asked Questions, Notice and Other Individual Rights, *Does the HIPAA Privacy Rule permit a doctor to discuss a patient's health status, treatment, or payment arrangements with the patient's family and friends?* at <http://www.hhs.gov/hipaafaq/notice/488.html>.

<sup>19</sup> See footnote 17.

<sup>20</sup> This information includes the date of filling; pharmacy name and address; serial number of the prescription; name of the patient; name of the prescribing practitioner; and directions for use and cautionary statements, if any contained in such prescription or required by law. 21 C.F.R. § 1306.14(a) and § 1306.24.

<sup>21</sup> 21 C.F.R. § 201.15.

<sup>22</sup> The safe harbors designate that the recipient provides written translations of "vital" documents (e.g. intake forms with the potential for important consequences, consent and complaint forms, eligibility and service notices) for each eligible LEP language group that constitutes five percent or 1,000, whichever is less, of the population of persons eligible to be served or likely to be affected or encountered. Translation of other documents, if needed, can be provided orally. Or, if there are fewer than 50 persons in a language group that reaches the five percent trigger, above, the recipient provides written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of vital written materials, free of cost. 68 Fed. Reg. at 47319.

<sup>23</sup> See J. Perkins and M. Youdelman, "Summary of State Law Requirements Addressing Language Needs in Health Care," National Health Law Program (March 2007), at [http://www.healthlaw.org/library/item.174993-Summary\\_of\\_State\\_Law\\_Requirements\\_Addressing\\_Language\\_Needs\\_in\\_Health\\_Care](http://www.healthlaw.org/library/item.174993-Summary_of_State_Law_Requirements_Addressing_Language_Needs_in_Health_Care).

<sup>24</sup> N.Y. Comp. Codes R. & Regs tit. 8, § 63.6(b)(8). Counseling can include, but is not limited to: (1) the name and description of the medication and known indications; (2) dosage form, dosage, route of administration and duration

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of drug therapy; (3) special directions and precautions for preparation, administration and use by the patient; (4) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur; (5) techniques for self-monitoring drug therapy; (6) proper storage; (7) prescription refill information; and (8) action to be taken in the event of a missed dose. Counseling requirements are also required, but adapted to the specific situations of in-pharmacy delivery to the patient, dispensing to a person authorized to act on behalf of a patient, and mail delivery of prescription drugs.

<sup>25</sup> For more information on state laws related to language access and health care, see J. Perkins and M. Youdelman, "Summary of State Law Requirements Addressing Language Needs in Health Care," National Health Law Program (March 2007), at [http://www.healthlaw.org/library/item.174993-Summary of State Law Requirements Addressing Language Needs in Health Care](http://www.healthlaw.org/library/item.174993-Summary%20of%20State%20Law%20Requirements%20Addressing%20Language%20Needs%20in%20Health%20Care).

<sup>26</sup> N.Y. Comp. Codes R. & Regs. tit. 10, § 405.7(a)(7).

<sup>27</sup> 45 C.F.R. § 80.8.

<sup>28</sup> NY CLS Educ § 6816 (1)(a). A second conviction for violation of § 6816 ("untrue labels" violation) can result in the pharmacist being fined a maximum of \$1,000 fine and/or a maximum of one year in prison. A third conviction can result in the above fines and/or jail time in addition to the individual pharmacist's license revocation.

<sup>29</sup> 45 C.F.R. § 80.3(b).

<sup>30</sup> 68 Fed. Reg. at 47319-21. Previous guidance called on recipients to develop and implement a language assistance program that addressed: (1) assessment of language needs; (2) development of a comprehensive policy on language access; (3) training of staff; and (4) vigilant monitoring. See 67 Fed. Reg. at 4971.

<sup>31</sup> See CMS, *Dear State Medicaid Director* (Aug. 31, 2000), available at <http://www.cms.hhs.gov/states/letters/smd83100.asp>.

<sup>32</sup> Of the 13 states currently using Medicaid/SCHIP funds to pay for language services, none are doing so in the pharmacy setting. However, there is no prohibition on this. For more information on this issue, see M. Youdelman, *Medicaid and SCHIP Reimbursement Models for Language Services, 2007 Update*, at <http://www.healthlaw.org>.

<sup>33</sup> See 65 Fed. Reg. 50121 (Aug. 16, 2000); see also 67 Fed. Reg. 41455 (June 18, 2002).

<sup>34</sup> See 65 Fed. Reg. 80865 (Dec. 22, 2000), at <http://www.omhrc.gov/clas>.



NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES



californiapharmacistsassociation

January 4, 2010

*Via email Carolyn\_Klein@dca.ca.gov*

Carolyn Klein  
1625 N Market Blvd, N219  
Sacramento, CA 95834

**RE: Proposed Title 16 CCR Section 1707.5 Delivery of Prescriptions**

Dear Ms. Klein:

On behalf of its members operating retail pharmacies in the State of California, the National Association of Chain Drug Stores (NACDS), the California Pharmacists Association, (CPhA), and the California Retailers Association (CRA) are writing to provide comments regarding proposed Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations, Patient Centered-Labels on Medication containers. We thank the Board of Pharmacy (“Board”) for the opportunity to submit comments on the proposed rule. We also appreciate the work of the Board in holding meetings during the development of this proposed rule. Chain and independent retail community pharmacies have worked very hard and spent significant resources to ensure that prescription labels clearly provide patients with information necessary to ensure the safe and proper use of prescription medications. We believe that we have made great strides in this area. Nonetheless, we look forward to continuing to work with the Board to find a reasonable approach for patient-centered labels for prescription medication containers.

However, as currently written, chain and independent pharmacies have numerous concerns with the proposed rule. There are other reasonable alternatives that would be equally effective for patient centered labels and less burdensome for pharmacies than this proposal. Indeed, we are concerned that the proposed regulatory requirements may hinder the use of the innovative prescription labeling for which the Board has indicated a preference.

The notice requires that the Board “must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to it’s attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to the affected private persons than the proposal described in the Notice.” Furthermore, the Board is only required to “consider” specified changes to prescription labels. The Board is not required to adopt all of the label changes currently outlined in the proposed regulation. Accordingly, we ask that the Board consider the information provided in these comments and that the Board take a less burdensome approach that would be as effective for a patient centered label. Specifically, we ask that the Board:

- Only require size 10 typeface for the patient name, prescription number, and drug name.
- Not mandate the specific directions as they are unnecessarily lengthy and repetitive and allow pharmacists to use their professional judgment if such directions are needed.
- Not mandate that certain items occupy 50% of the label

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- Allow pharmacies the flexibility to use different means to highlight information
- Allow pharmacies to provide patients with prescription container information through other means such as a separate sheet in a larger font.

***The research conducted by the Board is inadequate to support the proposed label changes***

The Board conducted significant outreach during 2008 in hopes of obtaining significant public input into the revisions of pharmacy labels. During that time period the Board received only 606 public responses. With over 30 million consumers in the State of California, dictating these label changes based on the responses of 606 consumers seems to us to be unreasonable. This conclusion is reinforced by the preliminary results of an ongoing consumer survey conducted by Western University (which has been provided to the Board) which indicates that over 75% of consumers are able to understand current prescription labels. NACDS, CPhA and CRA agree that some revision of pharmacy labels may improve patient care, but we urge the Board to consider all the research – and the weight that research should be given – in developing this regulation.

Finally, the Board should carefully consider the comments of one of the experts it consulted in this effort. In the minutes of a meeting held in Los Angeles on November 20, 2008, Michael S Wolfe, PHD, MPH is credited with stating:

“ . . . that he hopes the board does not get “bogged down” with details. He reiterated the fact that the rest of the country is watching California and looking to our state for direction. He pointed out that decisions will need to be made that best represent the majority of the public, and that it is not feasible to accommodate all requests given. He noted that too much detail can also create distraction, which causes more harm than good.”

***The underlying legislation does not require many of the requirements in the proposed regulation***

SB472 added CA B&P Code section 4076.5, which requires regulations to require a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California. Subsection (c) of the statute details several factors the board “shall consider” in developing the regulatory requirements. The statute does not *require* that those factors be addressed in the regulation, only that they be *considered*. In fact, two of the factors, “directions for use” and “font types and sizes,” both of which are key components of the proposed regulation, include specific language in the statute that they “improve” current practices. As noted below, we have serious concerns about the use of the standardized directions for use proposed in the regulation. We likewise have concerns about whether use of a standard font type is justified in light of the cost associated with that change. Further, as noted below, we do not believe that other components in the proposed regulation will result in an improvement of patient understanding of their medications and their use.

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While the Board is required to consider many factors in developing this regulation, you are not required to incorporate any or all of them. What factors are included in the final regulation, and what weight each should be given, should be a function of what will truly improve prescription labels and patient understanding of their medications. In addition, the regulation should avoid the "too much detail" identified by Dr. Wolf in order to avoid more harm than good.

***Pharmacies face burdensome costs to implement the requirements***

The requirements in the proposed rule will be extremely burdensome for pharmacies to implement. In accord with the implementing statute, we ask that the Board consider the large number of technology changes that pharmacies would face. Pharmacies will need to make extensive changes to their software and hardware systems resulting in overwhelming costs for pharmacies. Pharmacy costs are expected to be in the millions of dollars due to the need for computer changes, new printers, new larger labels, and switching all prescriptions to much larger prescription vials to accommodate the larger labels. The result will be large prescription container labels that must be placed on large vials which consumers will find unworkable. Many if not most pharmacies now use automated systems for prescription dispensing, use centralized filling services, and also fill prescriptions for patients in other states with their own different labeling requirements. Imposing California's specific requirements in such a diverse environment will result in pharmacies incurring extensive costs to comply with both California and the other states' requirements. Pharmacies cannot easily switch their systems and prescription labeling back and forth from one state to another, nor can they afford the costs of implementing a California labeling system and another for other states.

Chain pharmacies have estimated that many prescriptions currently dispensed in much smaller vials will have to be dispensed in much larger vials - possibly up to 40 dram vials - to accommodate the larger labels and that they will not be able to use the drug manufacturer unit of use containers that are helpful for patients. Moreover, patients will likely be dissatisfied with the vials that are several times larger than what they are used to. Patients may easily decide to take their medications out of the larger vials and put them in smaller vials that are unlabeled to avoid the larger vials.

In addition, the increased size of prescription container vials that would be required due to the use of much larger labels will result in shipping, storage, and handling problems. More shipments will be needed to ship the much larger vials, with increased costs for pharmacies from the increased number of shipments and trucking miles and resulting increased carbon emissions.

***The requirements for a specific type size, use of 50% of the label space, and the specified directions language are unreasonable due to limited label space.***

The requirement for pharmacies to use 12 point sans serif for the specified four items and to use 50% of the label for these items is burdensome and unworkable in view of the other information that must be on the label and the limited label space. Business & Professions Code § 4076 also requires that the label include the prescriber's name, date, name and address of the pharmacy, prescription number, quantity, expiration date of the drug's effectiveness, and the physical description of the medication including its color, shape, and any identification code. In addition,

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the purpose for the prescription must be placed on the prescription if requested on the prescription. Pharmacies also put other information that patients want on the label such as the number of refills remaining and the deadline date for using the remaining refills. All of this information must be on the label. Accordingly, mandating that only 50% of the remaining label be set aside for all of these other items is not feasible and would likely make the information too small creating other problems and patient complaints. Patients are unlikely to want the huge vials which would be necessary to accommodate the label that would result from this regulation.

There are other reasonable alternatives for these mandates that would be equally effective and less burdensome for pharmacies. Size 10 typeface could be used for the patient name, prescription number, and drug name. Pharmacies could provide patients with a separate sheet in a larger font with the prescription information along with the labeled prescription container.

The text for the specific directions should not be mandated as they are unnecessarily lengthy and repetitive. Pharmacists should be permitted to use their professional judgment to determine if such directions are needed for the patient. In addition, there should not be a mandate that certain items occupy 50% of the label. Pharmacists should have the professional flexibility to use different means to highlight the information such as bolding or highlighting with a different color.

### ***Language Translations***

For limited English proficiency patients, pharmacies can provide translation services through language assistance services. This will assist patients who need such services.

For written translation services, pharmacies are limited by the technology available. As discussed above, we ask that the Board take into consideration the technological issues. Pharmacies have the ability to translate into some other languages. However, the only languages available for drug information translation today are French and Spanish. The ability to translate consumer medicine information and MedGuides into other languages is limited. Such services are generally not available, printers lack the capability, and written translations are not available on demand.

### ***Other recommendations***

We have several suggestions for additional content the Board should consider in order to achieve its goal of improving consumer understanding of their medications:

- Subsection (b) of 4076.5 requires the Board to hold public meetings to “ensure maximum public comment.” There is nothing in the statute that restricts that effort to a specific time period. We believe the Board should make a commitment as part of this regulation to continued public outreach regarding prescription labels and to use that outreach to enhance public understanding of their medications. A prescription label with improved design and appearance is of little use to a consumer who doesn’t understand his or her medication. While pharmacies and pharmacists play a key role in improving consumer understanding, there is a corresponding responsibility on consumers to ask questions and seek information when they do not understand how or why to use dangerous drugs. The Board, as a consumer

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protection agency, should commit to an effort to improve patient literacy in this area. This regulation is a perfect vehicle for such a commitment by the Board.

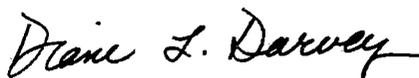
- For several years now the organizations represented here and the Board have been pursued efforts to improve medication safety and medication use. That goal should be seen as the primary focus of this regulatory effort. To enhance that effort, the Board should include language in the regulation that excludes violations of this section from its Citation and Fine program without first giving the pharmacy and involved pharmacists the opportunity to correct any violations. By doing so, the Board will emphasize its focus on meeting the needs of consumers rather than enforcing technical violations of the law and it will avoid any perception by those it regulates that any new label requirements are merely another unfunded mandate intended to victimize licensees who have difficulty meeting the new requirements.

Chain and independent pharmacies wish to continue to work to improve patient safety and patient compliance when taking their prescription medications. However, we wish to accomplish this objective in a manner that does not create new problems and is not unreasonably burdensome. In view of the huge cost impact on pharmacies and reasonable alternatives, we ask that the proposed regulation be amended and look forward to continued work with the Board. We thank you for consideration of our comments. Please do not hesitate to contact us with any questions.

Sincerely,



Missy Johnson  
CRA



Diane L. Darvey, Pharm.D., JD  
NACDS



Lynn Rolston  
CPhA

January 4, 2010

Ms. Carolyn Klein  
Manager, Legislation and Regulations  
California State Board of Pharmacy  
1625 N. Market Blvd., N219  
Sacramento, CA 95834  
*Via email Carolyn\_Klein@dca.ca.gov*

**RE: Patient-Centered Prescription Labels (16 Cal.Code Reg. §1707.5)**

Dear Ms. Klein:

On behalf of the California Grocers Association (CGA), I write to provide comments in response to proposed regulations 16 Cal. Code Reg. §1707.5. These regulations are intended to specify how prescription drug information is to be placed on the prescription drug container label and clarify what interpretive services are required to be provided by pharmacies in compliance with Section 4076.6 of the Business and Professions Code.

CGA is a non-profit, statewide trade association representing the retail food industry since 1898. CGA represents approximately 500 retail members operating over 6,000 food stores in California and Nevada, and approximately 300 grocery supplier companies. Retail membership includes chain and independent supermarkets, convenience stores and mass merchandisers. Many of our member grocery companies operate full service pharmacies inside some or all of their stores.

While patient protection is the top priority of pharmacies, for our member companies to comply with these new regulations the requirements must be cost effective, feasible and practical for all pharmacy retailers. If requirements become too costly or unworkable, no patient benefit will be achieved. Unfortunately, the current regulatory draft does not meet intended objectives.

While pharmacies are aware of the potential for improvements in prescription medication labeling and counseling to improve health literacy and patient safety, physicians, pharmacists, and patients also have responsibilities in ensuring appropriate medication use. Specifically, patients have the responsibility to request information from their physicians, and if they need additional information, from their pharmacists. Although simplifying drug labels sounds like an easy task, more evidence is needed on how to make labels more comprehensible yet manageable.

The proposed regulations provide a list of items which must be clustered into one area of the label that comprises at least 50 percent of the label and requires each item be printed in at LEAST 12-point, Sans Serif typeface. The standard Rx label



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is 2 inches tall and 3 1/8 inch long. This accommodates a 13 dram vial with 2 warning labels (may cause drowsiness, do not drive, etc.)

The 12-point font requirement limits the amount of space needed on a prescription bottle to effectively list all the directions or inclusions of the drug indication (purpose or condition). For example, increasing the font size will not only limit the necessary information from being placed on the bottle, it may prevent the patient's full name from being displayed. In order to comply, pharmacies would be required, as a minimum vial size to use a 20 dram vial. This means added cost and more plastic in the environment.

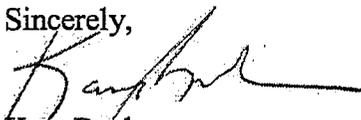
In addition to the labeling requirement, the proposed regulations state that a pharmacy shall provide an oral language translation of the prescription contents if requested by the patient. Although some pharmacies already provide this service to patients with limited English proficiency, not all are able to provide this service without economic impact. In addition, this regulation presents legal concerns for pharmacies that would be held liable if medication information was misinterpreted in translation---once again this service does not come without an economic impact to the pharmacies.

Although there has been some research conducted on how to improve labels, more analysis is needed to determine what changes can be made to fulfill the statutory requirements without causing such a significant impact on the pharmacies. Furthermore, there is no strong evidence to demonstrate that changing the label, as defined in the proposed regulations, will lead to better adherence, fewer adverse consequences, or better patient outcomes.

While we recognize solutions to this issue are not easily constructed, we would like to stress the need for additional collaboration with our Association in an effort to develop regulations that are cost effective, feasible and practical to implement. We would be happy to work with you to develop alternatives to achieve the mandates required by the statute.

If we can provide you with any additional information, please contact Kara Bush, Manager, Government Relations at 916.448.3545. Thank you.

Sincerely,



Kara Bush  
Manager, Government Relations



Carolyn Klein  
California State Board of Pharmacy  
[Carolyn\\_Klein@dca.ca.gov](mailto:Carolyn_Klein@dca.ca.gov)

January 4, 2010

Dear Ms. Klein,

These comments are submitted to the California State Board of Pharmacy pursuant to the Board's invitation to comment on the proposed Patient-Centered Prescription Label Regulations (proposed Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations) and in connection with the hearing on said matter to take place on January 20, 2010. In particular, these comments pertain to paragraph 1705.5.b of the proposed regulations concerning the translation of Directions for Use (SIGs) into several languages other than English.

1. There are several private companies in the U.S. that directly (over 1,800 U.S. translation agencies indirectly) offer the service of providing on-demand translated Directions for Use (SIGs) in over a dozen languages. RxTran (see [www.rxtran.com/translation-of-patient-instructions.html](http://www.rxtran.com/translation-of-patient-instructions.html)) is one of them, and, in the interest of fairness, Polyglot Systems (see [www.pgsi.com/Products/Medication.aspx](http://www.pgsi.com/Products/Medication.aspx)) is another.

RxTran's prices are quite affordable even for small independent pharmacies: they can be as low as \$50 per month for the equivalent translation of hundreds of thousands of SIGs per month via our online catalog into any 11 languages. This cost is less than that of a typical cell phone or cable bill for a pharmacy. Therefore we are not certain why the Board feels it needs to provide some of these translations for free on its website as opposed to involving private sector vendors. Our concern is that the published translations will be available not only to California pharmacies but to all our potential customers across the world.

At the very least, we would hope that if the Board goes ahead with providing some translations for free to the California pharmacies, it would publish along with the translations the list of private sector vendors who offer to provide on-demand catalog translations of hundreds of thousands of SIGs into a wide variety of languages at reasonable cost.

2. Regardless of point 1 above, if the Board decides to implement the proposed Rule as published, we will be happy to provide the Board with the translation of the Instructions for Use listed in 1705.5.a.4 into any 5 languages the Board chooses free of charge as a public service.

I invite any interested Board member to contact me for more information.

Sincerely yours,

Brian Kratt  
Chief Executive Officer  
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