California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

BOARD OF PHARMACY PATIENT-CENTERED LABEL FORUM

MEETING MATERIALS AND DETAILS

Thursday, July 31, 2014

1. FOR INFORMATION: Text of the Patient-Centered Label Regulations

Attachment 1

Attachment 1 includes Section 1707.5 of the Code of Regulations for the requirements for patient-centered labels for prescription drug containers with the approved changes to require the patient-centered portion of the label to be in 12-point font (these changes are pending administrative review.) Section 1707.6, the Notice to Consumers, is also included in the attachment. This regulation requires all pharmacies to post materials informing patients of their rights and that interpreter services are available to them, at no cost, upon request.

2. FOR INFORMATION: 2010 Board of Pharmacy Report to the Legislature on Prescription Drug Labeling Requirements

Attachment 2

The report in **Attachment 2** summarizes the Board of Pharmacy's initial efforts to develop the standardized, patient-centered prescription drug container requirements.

3. FOR INFORMATION: National Recommendations For Patient-Centered Labels

Attachment 3

Attachment 3 contains recommendations from various organizations on patient-centered prescription labels. Representatives from all but one of these organizations will speak during the forum.

a. USP

In 2012, U.S. Pharmacopeial Convention (USP) developed standards for prescription container label standards to promote patient understanding. The standards recommend that a prescription container label must be able to fulfill the professional obligations of physicians and pharmacists to give the patient the most essential information needed to understand how to safely and appropriately use the medication.

b. ISMP

In 2010, the Institute for Safe Medication Practices (ISMP) developed principles for medication labeling for community and mail order pharmacy prescription packages.

c. NABP

A 2009 report is included in the attachment describing the work of the task force that developed NAPB's Uniform Prescription Labeling Requirements.

d. NCPDP Universal Medication Schedule White Paper

The National Council for Prescription Drug Programs (NCPDP), in 2013, developed the *Universal Medication Schedule White Paper,* which supports the standardized directions in the board's regulation at 16 CCR Section 1707.5. The goal of these standardized directions is to increase patient understanding and adherence to medication instructions by standardizing the phrasing of directions, thereby improving health outcomes.

e. NCPDP White Paper on Liquid Dosing

The National Council for Prescription Drug Programs in March 2014 released liquid dosing instructions to provide recommendations and guidance for standardizing the dosing designation (the amount and volumetric units) used on prescription container labels of oral liquid medications dispensed from community pharmacies. The goal is to improve patient safety and outcomes by decreasing the potential for error when patients and caregivers take and administer these medications.

A recent AP article is also included which discusses the results of a recent study of dosing instruments and problems associated with incorrect dosage.

The board's existing regulation is silent on liquid dosing instructions.

f. Documents Pertaining to New York Prescription Labeling

4. <u>FOR INFORMATION: Surveys Conducted by Board of Pharmacy</u>

Attachment 4

The Board of Pharmacy conducted various surveys involving prescription labels, which are found in **Attachment 4**.

a. 2013 Survey: Translated labels in use in California pharmacies, surveys conducted by board inspectors
b. 2012 Survey: Readability of new prescription drug container labels

c. 2009 Survey: Open-ended questions in English and Spanish, surveys conducted at consumer public outreach events.
d. 2009 Radio Survey: Online surveys conducted with the Pharmacy Foundation of California.
e. 2008 AARP Survey: Survey on AARP website asking about importance, understandability and changes recommended for prescription medication labels.
f. 2008 Consumer Survey: Survey of attendees at public forum and consumers on readability, importance of information and suggested changes on prescription labels.

5. <u>FOR INFORMATION: Confirmed Presenters</u>

- Donna Bohannan, RPh, Scientific Liaison with USP
- Donna Horn, RPh, DPh, Director of Patient Safety - Community Pharmacy with ISMP
- Larry Mokhiber, MS, RPh, Executive Secretary of the New York Board of Pharmacy
- Mike Wolf, PhD, MPH, with Northwestern University School of Medicine
- William Shrank, MD, MSHS, with CVS Caremark Corporation
- Maureen Schanck, PharmD, Professional Affairs Manager with NABP
- Michelle Tenerelli, Clinical Director West Coast with Rite Aid
- Anandi Law, B.Pharm, PhD, Department Chair, Professor of Pharmacy Practice and Administration at Western University of Health Sciences
- Linda Neuhauser, DrPH, MPH, Clinical Professor, Community Health and Human Development, and Co-Principal Investigator, Health Research for Action at University of California, Berkeley
- Sarah De Guia, Director of Government Affairs with California Pan-Ethnic Health Network

6. <u>Public Comment from Non-scheduled Speakers</u>

7. <u>FOR DISCUSSION: Cross Cutting Issues</u>

a. Should Section 1707.5(a)(1)(B) Require Listing of the Manufacturer's Name in the Patient-Centered Clustered Area of the Label When a Generic Drug Is Dispensed?
b. When a Generic Drug Is Dispensed, Should the Brand Name of the Generic Equivalent Be Included on the Label Phrased as "Generic for _____"?
c. Should Purpose or Condition Be a General Requirement for Labels?
d. Should the Existing Requirements for "Added Emphasis" in the Patient-Centered Area of the Prescription Label Be Modified?
e. Translations on Labels:
    1. Translated Directions for Use Are Available on the Board's Website. Should the Board Require Use of Them to Aid Patients with Limited English Proficiency?
    2. Should There Be a Specific Requirement for Labels to Be Translated? If So, What Components Are Needed (e.g., Also printed in English, Only Directions, and Exemption from Liability for Translation Errors)?
f. Should the Board Adopt Liquid Measurement Standards as recommended by NCPDP?

g. Should the Board Consider Technology Standards to Enhance the Patient- Centered Requirements?

Patient-Centered Prescription Label Forum: Speaker Schedule

Note: All times listed are Pacific Standard Time

10:10 a.m. - Donna Bohannan, RPh – U.S. Pharmacopeia

10:35 a.m. - Donna Horn, RPh, DPh – Institute for Safe Medicaiton Practices

11:00 a.m. - Larry Mokhiber, MS, MSHS - New York Board of Pharmacy

11:25 a.m. - Mike Wolf, PhD - Northwestern University School of Medicine

11:50 a.m. - William Shrank, MD, MSHS – CVS Caremark Corporation

12:15 p.m. - Maureen Schanck, PharmD – National Association of Boards of Pharmacy

12:40 p.m. - Lunch

1:15 p.m. - Michelle Tenerelli - Rite Aid

1:40 p.m. -Anandi Law, BPharm, PhD - Western University of Health Sciences

2:05 p.m. - Linda Neuhauser, DrPH, PhD - Universtiy of California, Berkeley

2:30 p.m. - Sarah De Guia – California Pan-Ethnic Health Network

3:00 p.m - Public Comment

Attachment 1

Attachment 1 Regulation

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four 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 ~~10-point sans serif typeface or, if requested by the consumer, 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 of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] 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) 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) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(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.

(f) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet.

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

NOTICE TO CONSUMERS

1707.6 Notice to Consumers

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

California law requires a pharmacist to speak with you every time you get a new prescription.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese. Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

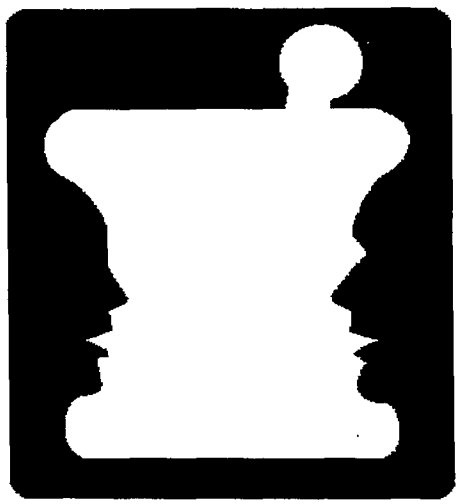
Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

Attachment 2

State of California

Board of Pharmacy

Report to the Legislature



Prescription Drugs: Labeling Requirements

January 2010

Arnold Schwarzenegger, Governor
Kenneth H. Schell, PharmD, President, Board of Pharmacy
Virginia Herold, Executive Officer, Board of Pharmacy

Summary

The California Patient Medication Safety Act (Chapter 470, Statutes 2007) requires the Board of Pharmacy 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. This Act further requires the board to report to the Legislature by January 1, 2010, on its progress in implementing these regulations.

This report summarizes the Board of Pharmacy's efforts to establish a standardized, patient-centered prescription drug label.

After approximately 18 months of public discussion regarding a standardized, patient-centered prescription label and gathering information at public forums, hearings, board and committee meetings, and conducting patient surveys, the board issued on November 20, 2009 proposed regulatory text to add section 1707.5 to Title 16 of the California Code of Regulations. This proposed section contains California's requirements for patient-centered prescription labels. The board will take action on this proposed regulation at its next scheduled meeting scheduled in January of 2010.

Background

In 2005, Senator Jackie Speier authored Senate Concurrent Resolution 49 (SCR 49), Chapter 123 Statutes of 2005, to create a multidisciplinary 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. The report reflected improvements, additions or changes which would reduce errors associated with the delivery of prescription and over-the-counter medications to consumers.

One bill was pursued based on the recommendations of the SCR 49 panel's report. Senator Ellen Corbett authored SB 472, resulting in enactment of the California Patient Medication Safety Act (Chapter 470, Statutes of 2007), Business and Professions Code section 4076.5. Therein, the Legislature stated the importance of reducing medication-related errors and increasing health care literacy regarding prescription drugs and prescription container labeling—which could 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 to identify and encourage the adoption of structural safeguards related to prescription drug container labels. To further these objectives, the Legislature mandated that the Board of Pharmacy adopt regulations to implement a standardized, "patient-centered" prescription drug container label in California.

SB 472 Medication Label Subcommittee

Legislation required that the board initiate public hearings to collect information from the public to facilitate the development of a regulatory proposal. The Board of Pharmacy president appointed a SB 472 Medication Label Subcommittee in January of 2008 to conduct public forums and to work with organizations and individuals to develop recommendations to implement the provisions of SB 472 to establish a patient-centered prescription drug label.

The SB 472 Medication Label Subcommittee held public forums on the following dates, apart from regularly-scheduled board meetings.

April 12, 2008	January 27, 2009
November 20, 2008	March 12, 2009

Agendas for these meetings are provided in Attachment 1.

At these public forums and at other board and board sub-committee meetings, as directed by the SB 472 Label Subcommittee, the board considered testimony and information provided from the public, the pharmaceutical industry, pharmacy professionals and literacy subject matter experts 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. Board members were also provided with research

articles on designing patient-centered labels. The information and data received helped frame draft regulatory text to implement the provisions of SB 472.

Public and Community Outreach / Survey

Responding to minimal public input regarding the public's concerns about the current medication prescription labels that are used, the board developed a survey (Attachment 2) that could be provided and/or conducted one-on-one with participants at public outreach events, such as health fairs, where the board provides consumer information. This survey was provided in English and in Spanish. The survey was posted on the board's public Web site from May 2008 through November 2009. Survey questions were open-ended, allowing participants to provide as little or as much information as desired, but the questions did not direct participants to pre-defined responses. Survey results were provided to the board at SB 472 Subcommittee meetings, and also at regularly-scheduled board meetings.

Attachment 3 lists those organizations and individuals to which the survey was distributed to solicit input. Attachment 3 also contains a list of public outreach events at which board staff interviewed consumers and provided printed surveys to solicit input.

At public outreach events and at board and committee meetings, the public was provided with fact sheets entitled "Do you understand the directions on your Rx medicine label?" (Attachment 4) and demonstrated samples of faux prescription labels serving as visual aids.

The board also worked with the Pharmacy Foundation of California to develop a multi-choice survey of four questions that were available via a radio-sponsored survey. The goal was to identify key attitudes, knowledge and behaviors of California consumers related to prescription drug labels. The survey was conducted via Entercom Broadcasting and was made available in January 2009 on radio station Web sites that stream their audio. Results of this survey were provided to the SB 472 Medication Label Subcommittee at its meeting held March 12, 2009.

Proposed Regulatory Text

To implement the provisions of Business and Professions Code section 4076.5 (the California Medical Safety Practice Act) the board proposed text to add section 1707.5 to Title 16 of the California Code of Regulations (Attachment 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.

Specifically, the regulatory language proposed on November 20, 2009, specifies the following:

- What components of a prescription label are considered "patient-centered"
- The font type, font size, wording and placement of specified components of a prescription label
- The Board will publish on its Web site by October 2011 translations of specified directions for use into at least five (5) languages other than English
- The Board will publish on its Web site by October 2010 examples of prescription labels that conform to the requirements of the regulation
- A pharmacy, upon request of a patient, shall provide oral interpretive services of the "patient-centered" elements of the prescription label, and
- The Board will re-evaluate the requirements of the regulation by December 2013 to ensure optimal conformance with the California Patient Medication Safety Act (Business and Professions Code section 4076.5)

Contained within the provisions of the proposed regulation, the board will publish on its Web site by October 2011 translations of the "directions for use" as specified in the proposed regulations, into at least five (5) languages other than English. The board will work with research health care advocates to develop these translations.

To assist those with limited English proficiency, and upon request by a patient, the proposed regulations will require a pharmacy to provide an oral language translation of the "patient-

centered" components of a prescription label, as specified in the proposed regulatory language. At its board meeting held October 20, 2009, representatives from chain and retail pharmacy representatives stated that their existing oral language translation services provided to insured patients would be extended to cover all non-English speaking patients, if requested, with no further economic impact on their industry. The board commends the pharmacy industry for recognizing this significant component of delivering prescription drugs, and for meeting the needs of these patients.

Finally, the board included in its proposed regulations a requirement that it will re-evaluate the requirements of the regulations by December 2013 to ensure the effectiveness of the regulation in light of the factors contained in the California Patient Safety Medication Act (e.g., new developments in technology).

Regulation Schedule

The board issued proposed regulatory text on November 20, 2009. A 45-day comment period will close on January 4, 2010.

In addition, the board has scheduled a regulation hearing for January 20, 2010, in Sacramento. At that time, the board will accept written and verbal testimony and comments concerning the draft proposal. This hearing will be conducted prior to its regularly scheduled public Board Meeting that

same day and the board, at that time, may take action to adopt, amend, or to not move forward with the proposed regulation.

The board also scheduled a public Board Meeting for February 17, 2010, in anticipation of the need for a 15-day comment period of modified text following the regulation hearing and Board Meeting.

The board believes this regulation schedule will allow industry approximately ten months to prepare for the implementation of new regulatory requirements. The board also believes its current Board Meeting schedule will allow it to address the needs of industry and the public, and provide for the required reviews prior to implementing a regulation by the January 2011 mandate contained in SB 472.

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting
April 12, 2008

Wally Pond Irvington Community Center
41885 Blacow Road
Fremont, CA

10 a.m. – 2 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Leech at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the Board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order **10 a.m.**

1. Invitation to Participate in the Redesign of Prescription Container Labels
   Committee Chair Ken Schell, PharmD

2. Opening Remarks
   The Honorable Ellen Corbett, California Senator, District 10

3. Presentation of SCR 49 findings, and the need for patients to understand their drug therapy as a source of reducing medication errors.
   Michael Negrete, PharmD

4. Requests for Public Comment on the Following: What works on prescription container labels? What does not? How can prescription container labels be improved to make them patient-centered?

5. Timeline for Project

6. Future Meeting Dates

Adjournment **2 p.m.**

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF PUBLIC BOARD MEETING OF THE CALIFORNIA STATE BOARD OF PHARMACY

FORUM ON DESIGNING PATIENT-CENTERED PRESCRIPTION LABELS
November 20, 2008
1:30 p.m. - 4:30 p.m.

The Westin Los Angeles Airport Hotel
5400 West Century Boulevard
Lindberg A and B Meeting Rooms
Los Angeles, CA 90045

Contact: Virginia Herold
(916) 574-7911

This forum is hosted by the California State Board of Pharmacy as part of the board's efforts to develop standards for prescription labels by 2011 that will be patient-centered, and to implement the California Medication Safety Act (SB 472, Corbett, Chapter 470, Statutes of 2007). The goal is to foster better patient understanding of the information on a label as a means to reduce medication errors, and improved patient well-being. The public is invited to attend.

This meeting is open to the public (no pre-registration is required) and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Gallagher at (916) 574-7912, at least five working days prior to the meeting. Opportunities are provided to the public to address the board on each open agenda item. Action may be taken on any item on the agenda by the Board of Pharmacy. All times are approximate and subject to change.

---

1. **Welcoming Remarks** 1:30 p.m.
   Kenneth Schell, PharmD, President, California State Board of Pharmacy
2. **Improving Prescription Container Labels – What is the Status of the Research**
   Michael S. Wolf, PhD, MPH, Feinberg School of Medicine, Northwestern University
   Stacy Cooper Bailey, MPH, Feinberg School of Medicine, Northwestern University
3. **Patient Health Literacy in the U.S. and its Impact on Health**
   Michael Villaire, MSLM, Director Programs and Operations, Institute for Healthcare Advancement
4. **Perspective of the Latino Coalition for a Healthy California to Improve Prescription Container Labeling**
   Vanessa Cajina, Director, Regional Networks Coordinator, Latino Coalition for a Healthy California
5. **Perspective of California's Seniors to Improve Prescription Container Labeling**
6. **Summary of Patient Surveys Collected During 2008 by the California State Board of Pharmacy**
   Virginia Herold, Executive Officer, California State Board of Pharmacy
7. Next Steps
8. Public Comments for Items Not on the Agenda
9. Adjournment 4:30 p.m.

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting
January 27, 2009

Sheraton Hotel - Mission Valley
1433 Camino Del Rio South
San Diego, CA, 92108
(619) 260-0111

1 – 5 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tess Fraga at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order **1 p.m.**

1. Welcoming Remarks
   Subcommittee Chair Ken Schell, PharmD
2. Review of Consumer Surveys Conducted by the Board of Pharmacy
3. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy
4. Review of California's Requirements for Prescription Container Labels (California Business and Professions Code Section 4076
5. Timelines for Project Deliverables
6. Public Comment
7. Future Meeting Dates

Adjournment **5 p.m.**

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting

March 12, 2009

Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834
(916) 574-7900
6 - 9 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tess Fraga at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order **6 p.m.**

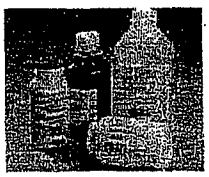
1. Welcoming Remarks
2. Review of SB 472 and the Charge to the Board in Developing Patient-Centered Labels
3. Overview of SB 853 (Escutia, Chapter 713, Statutes of 2003) Health Care Language Assistance
4. Review of Consumer Surveys Conducted by the Board of Pharmacy for SB 472
5. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy for SB 472
6. Patient-Focused Elements of Prescription Container Labels (California Business and Professions Code Section 4076)
7. Legislative Proposal to Add "Purpose" to Prescription Container Labels
8. Public Comment for Items Not on the Agenda
   (Note: the committee may not discuss or take action on any matter raised during the Public Comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))

Adjournment **9 p.m.**

CONSUMERS – we want to hear from you!

Do you have suggestions to improve prescription container labels? The California State Board of Pharmacy welcomes your feedback to make labels more patient-friendly with directions that are easier to read and understand.

Examples of warning labels



Examples of different container shapes and sizes requiring different types of labels

What information on the label is most important to you?

_____

_____

Do you understand the directions?

_____

_____

What would you change on the label?

_____

_____

What would make the label easier to read?

_____

_____

Other suggestions:

_____

_____

City: _____ Date: _____

Printed information in different colors

Directions for use or how to take the drug

THANK YOU for your feedback.
Please return your completed form to:

Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834

CONSUMIDORES – ¡Queremos oír de usted!

¿Tiene usted sugerencias para mejorar las etiquetas del envase de recetas? La Junta de Farmacia del Estado de California da la bienvenida a su reacción para hacer etiquetas más-paciente amistosas con las indicaciones que son más fáciles de leer y comprender. Gracias por su reacción.

¿Qué información en la etiqueta de la receta es más importante para usted?

¿Comprende usted las instrucciones en la etiqueta de la receta?

¿Qué cambiaría usted en la etiqueta de la receta?

¿Qué haría la etiqueta de la receta más fácil de leer?

Ciudad: _____ **Fecha:** _____

Vuelva por favor su forma completada a: Virginia Herold, California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834

CONSUMIDORES – ¡Queremos oír de usted!

¿Tiene usted sugerencias para mejorar las etiquetas del envase de recetas? La Junta de Farmacia del Estado de California da la bienvenida a su reacción para hacer etiquetas más-paciente amistosas con las indicaciones que son más fáciles de leer y comprender. Gracias por su reacción.

¿Qué información en la etiqueta de la receta es más importante para usted?

¿Comprende usted las instrucciones en la etiqueta de la receta?

¿Qué cambiaría usted en la etiqueta de la receta?

¿Qué haría la etiqueta de la receta más fácil de leer?

Ciudad: _____ **Fecha:** _____

Vuelva por favor su forma completada a: Virginia Herold, California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834

California State Board of Pharmacy Prescription Label Survey

OBJECTIVE: To elicit feedback from consumers in California regarding development of patient-centered prescription drug labels pursuant to Senate Bill 472 (Chapter 470, Statutes of 2007)

METHODOLOGY: A survey was developed by the California State Board of Pharmacy (Board) 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 website 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.

RESULTS: A total of 622 surveys were received as of March 3, 2009. The majority of respondents provided one or more answers to the first two questions, but did not always provide answers to subsequent questions. Respondents gave similar answers to multiple questions within a survey (i.e., request for large print). Attached graphs reflect detailed responses; most frequent responses summarized below.

When asked what information on the prescription label was most important, the top responses were:

Directions for use (224 of 1,207 responses = 18.6%)
Name of drug; if generic, state generic name AND brand name (222 of 1,207 responses = 18.4%)
Dosage prescribed (213 of 1,207 responses = 17.6%)
Side effects/warnings/interactions/contraindications (122 of 1,207 responses = 10.1%)
Purpose of drug – state what condition medication is prescribed to treat (84 of 1,207 responses = 7%)

When asked what to change on the prescription label, the top responses were:

Print should be larger or darker (170 of 568 responses = 30%)
Nothing needs to be changed on the label (139 of 568 responses = 24.5%)
Include purpose of drug – state what condition medication is intended to treat (69 of 568 responses = 12.1%)

When asked what would make prescription labels easier to read, the top response was:

Larger or bolder print (314 of 522 responses = 60%)

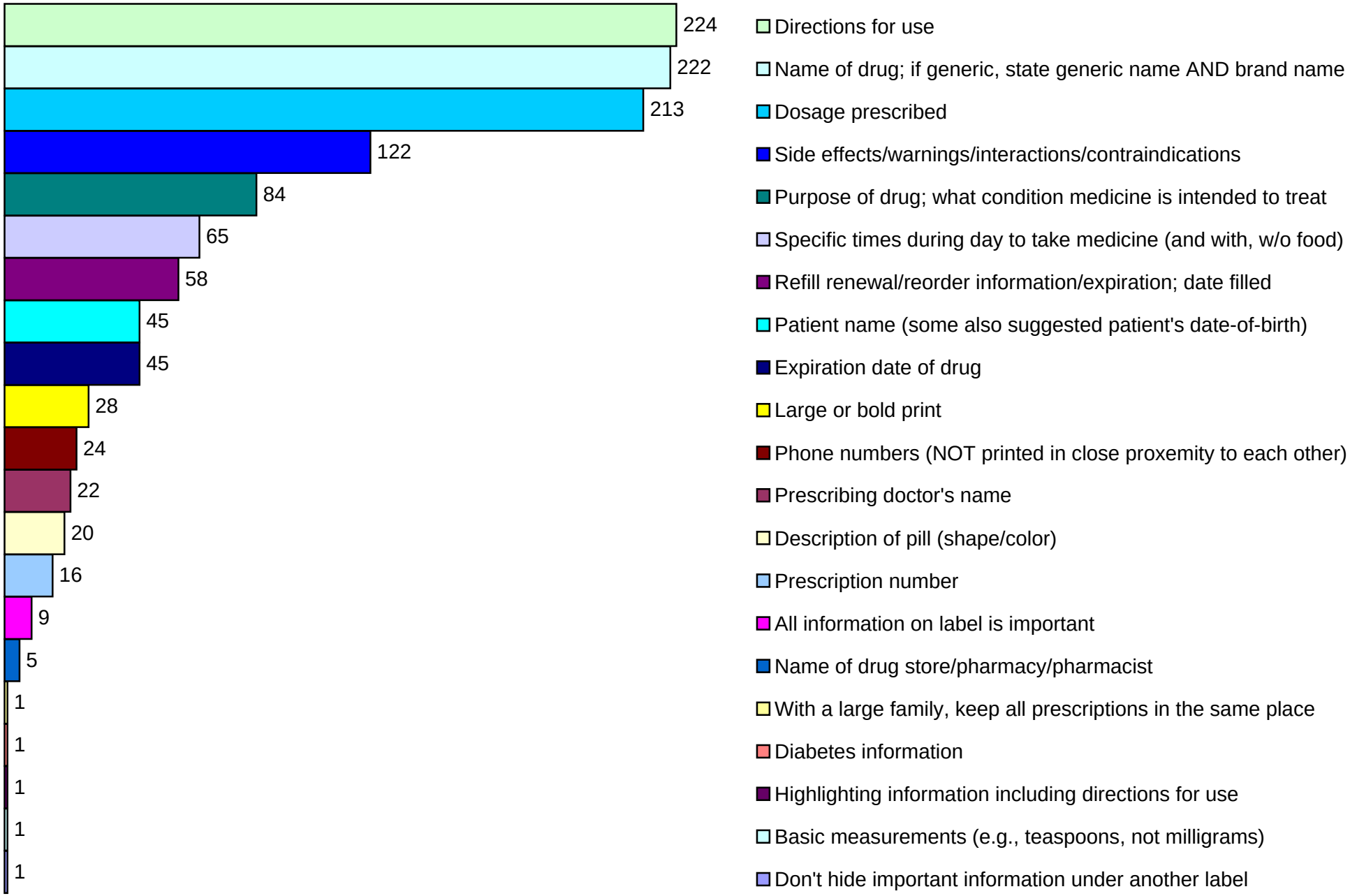
When asked for other suggestions, the top responses were:

Easy-open lids/packages should be used; no child-proof caps for seniors (20 of 134 responses = 14.9%)
Include purpose of drug - state what condition medication is intended to treat (17 of 134 responses = 12.7%)

CONCLUSIONS: Most consumers participating in this survey requested larger/bolder type font on prescription labels to increase readability. Many participants suggested that if a generic drug is provided, the prescription label should state the name of the generic drug name AND the brand-name it is generic for. They also noted that color printing and highlighting on labels brings attention to important information. Some participants suggested that the labels themselves be color-coded to help differentiate between multiple medications and family members. Many consumers want to know 'what the drug is for' and suggested that 'purpose of drug' be printed directly on prescription labels.

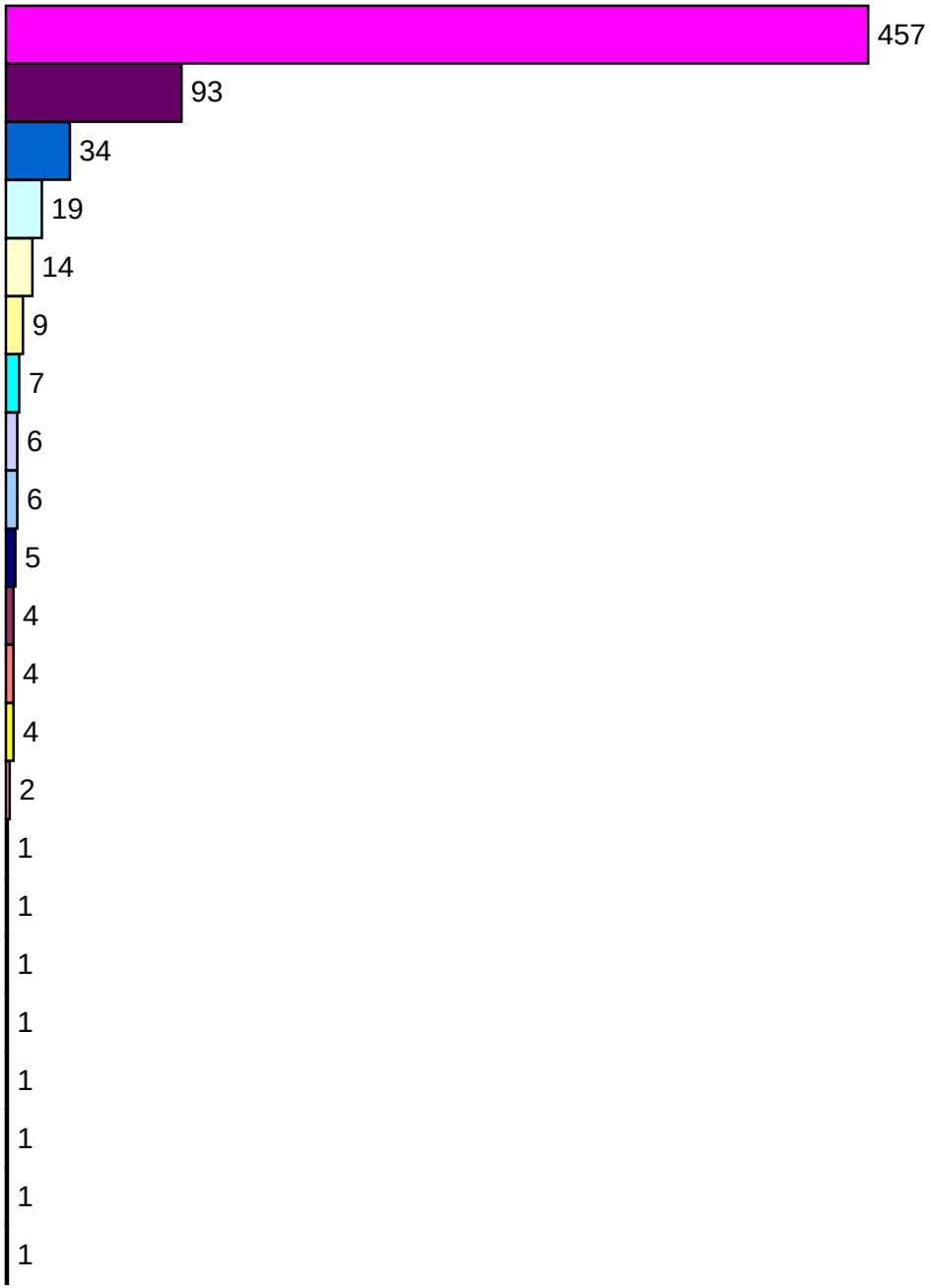
QUESTION #1: What information on the label is most important to you?

622 surveys returned (1,207 responses to Question #1) as of March 3, 2009



QUESTION #2: Do you understand the directions on the prescription label?

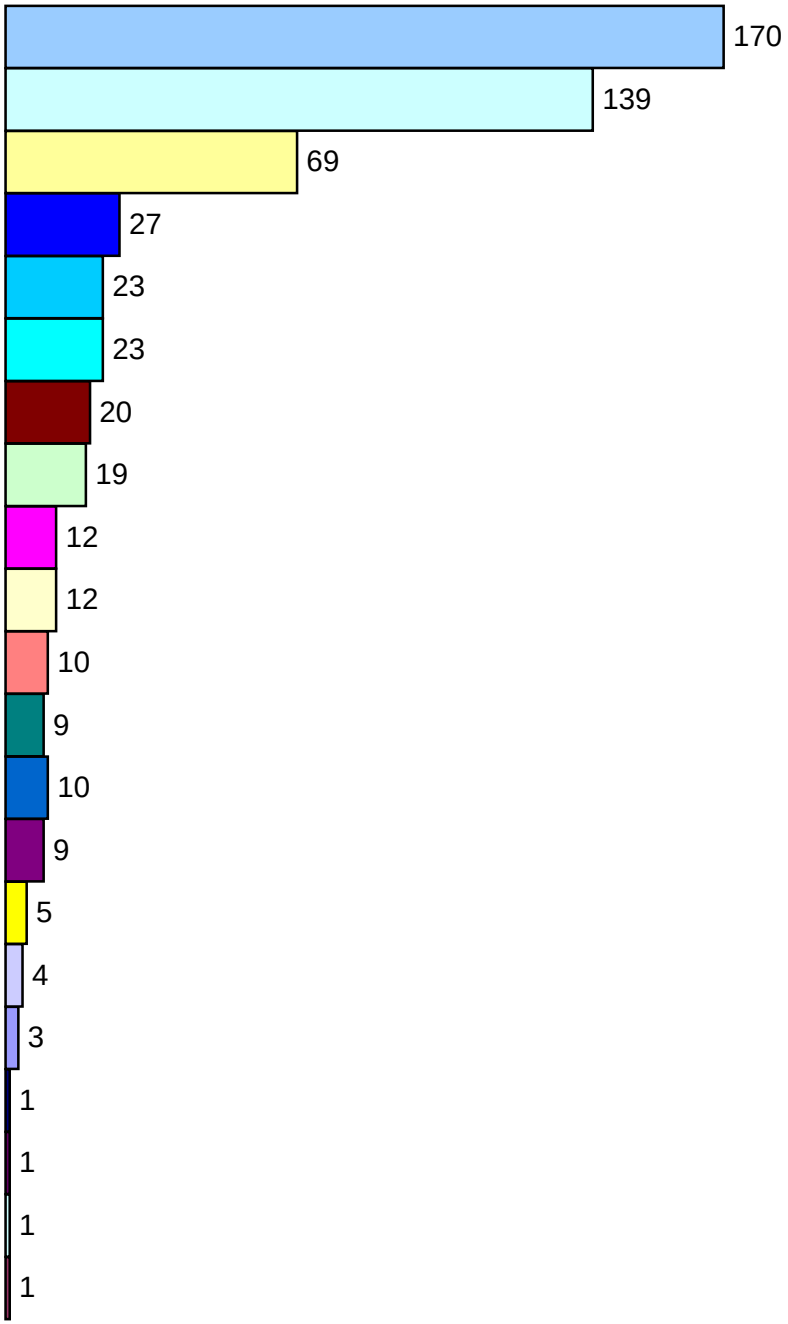
622 surveys returned (672 responses to Question #2) as of March 3, 2009



- Yes
- Usually (though print may be too small, directions/warnings unclear)
- Sometimes
- No (i.e., trouble understanding or not enough space for directions)
- Directions should state what time(s) to take medicine and how much
- Would be helpful to know whether to take with or without food
- I understand because I'm RN, Dr, health worker, have biology degree
- Not when there is a language barrier
- What does 2x (or 3x, or 4x) a day mean?
- Directions need clarity (2 pills = 1 pill twice/day or 2 pills twice/day?)
- Instructions should be in English and Spanish
- Instructions should be in English and Spanish
- Abbreviations should be eliminated
- I do not understand directions that only say "Take as directed"
- No long paragraphs on prescription label
- Label from Kaiser understandable, label from Rite Aid not as clear
- Bullets and spacing on label would be helpful
- Handout should be more readable
- Accompanying paper shouldn't be complicated - use bullets/spacing
- When I don't understand the directions, I ask the pharmacist
- Pharmacist's directions are vague during consultation
- The directions often conflict with the doctor's orders

QUESTION #3: What would you change on the prescription label?

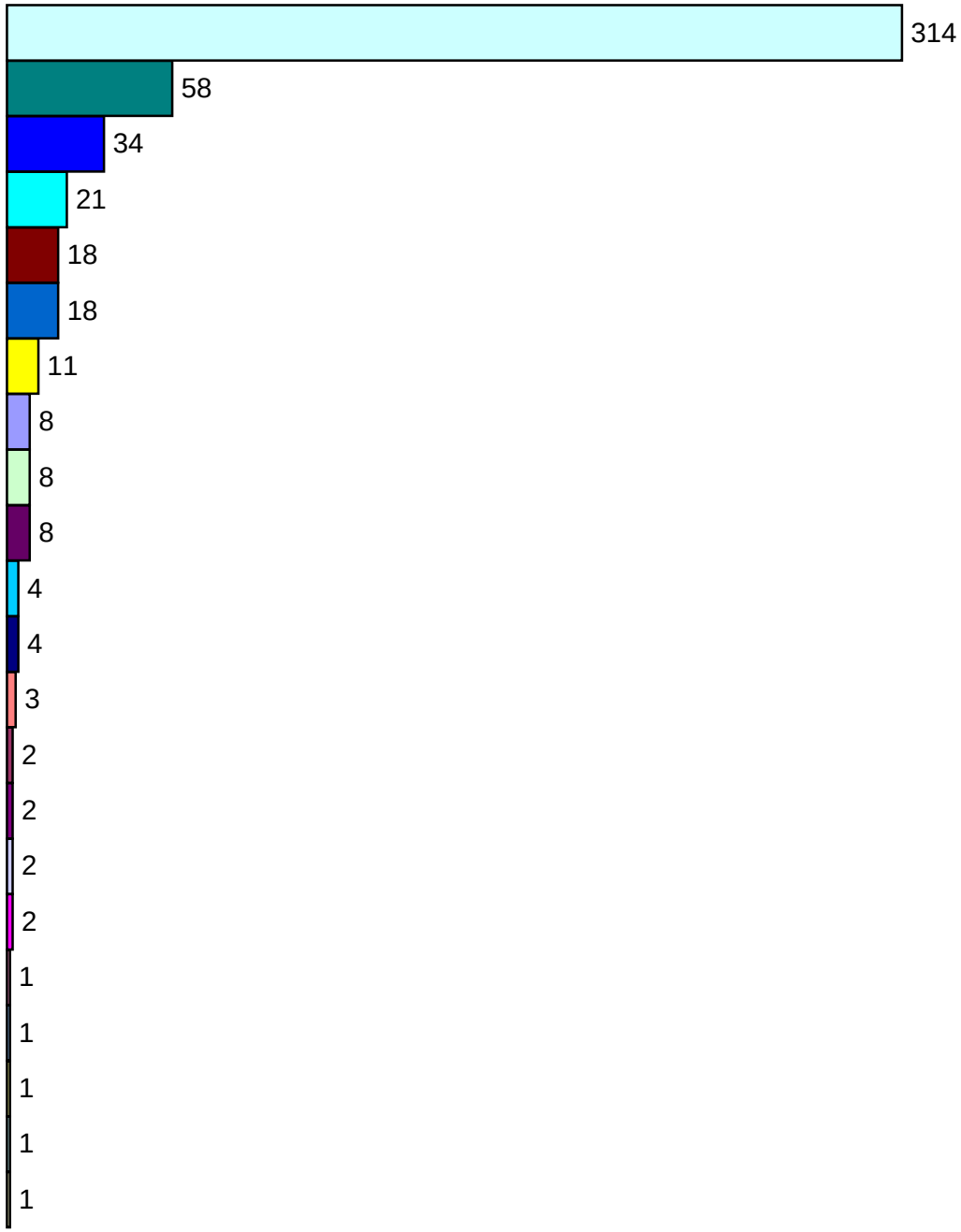
622 surveys returned (568 responses to Question #3) as of March 3, 2009



- Print should be larger or darker (legibility)
- Nothing needs to be changed (some referred to Kaiser, Target, Raley's, CVS)
- Include purpose of drug - state what condition medication is intended to treat
- Information printed should be understandable for all ages; layman's terms
- Use bold or highlighted print or capital letters; red/blue ink for warning labels
- Use different colors for different medicines, strengths/doses, family members
- Directions should include specific times (or morning/night) to take medicine
- Make warning labels easier to read or print directly on label instead of auxilliary
- Name of drug; if generic, state generic name AND brand name
- Refill info (i.e., date to reorder or if no refills remain, state "0 refills remain")
- Include direct phone numbers for easier communication with doctor/pharmacy
- Print in patient's primary language; bilingual wording
- Standardize location of info; uniform label; show information in same order
- Delete unneeded info (i.e., don't say take tab "by mouth" or show address)
- Should be less advertising on label; remove unnecessary information
- Use ink that does not disappear, fade, rub off, or smudge
- Make "fold-out" label or "lift-open flap" stating side effects or purpose of drug
- If more than 1 label, show as "label #1" and "label #2"
- Use only one color on label
- More than one name for medicine is confusing at times
- Label should not refer patient to internet web site

QUESTION #4: What would make the prescription label easier to read?

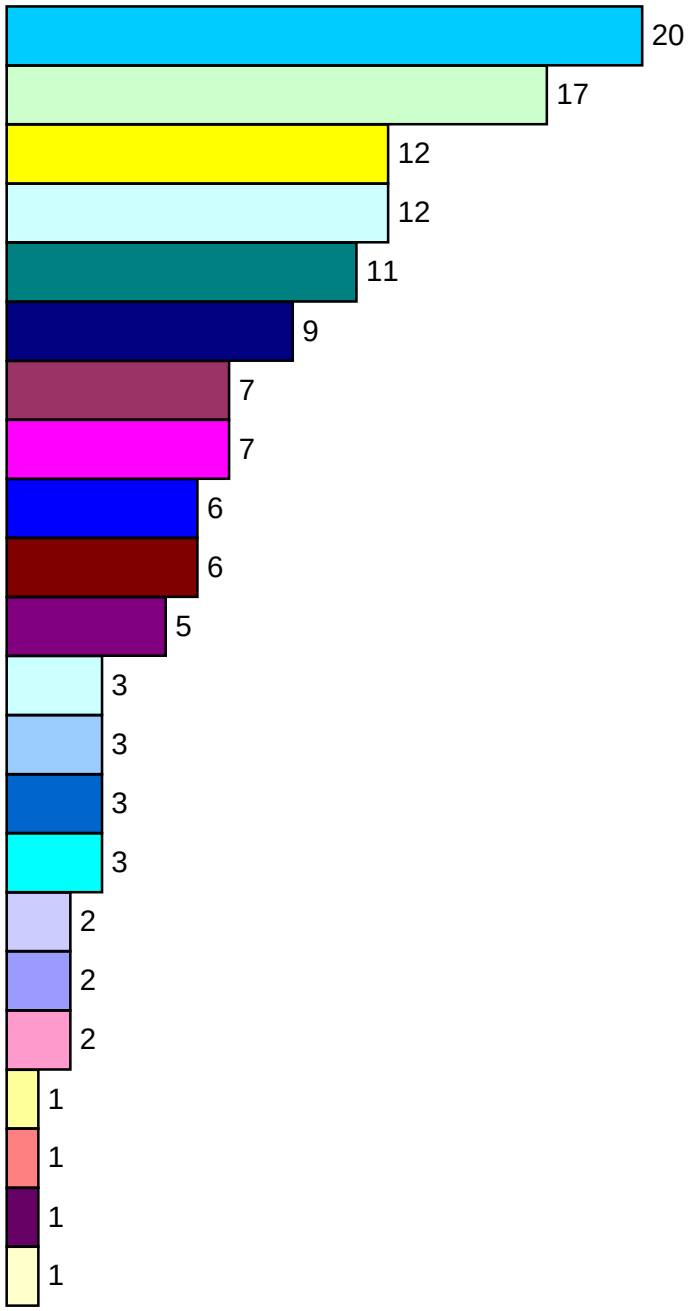
622 surveys returned (522 responses to Question #4) as of March 3, 2009



- Larger print (or bolder print)
- Highlighting directions & other info in colors (or color-coded label)
- Nothing
- Info should be in layman's terms; easy wording; don't abbreviate
- Bilingual wording
- Better description of directions (how/when to take; interactions)
- Refill renewal information including renewal expiration date
- Increase container size so large labels can have large print
- Eliminate clutter (i.e., multiple colors, icons, logos, name of PIC)
- Standard labeling for all pharmacies; standard placement of info
- Underline info or separate directions for use into different lines
- Drawings would help or symbols (or chart of meds & time to take)
- Dark background with light/flourescent print (or glow-in-the-dark)
- Print on label with ink that does not fade or disappear
- Yellow or white warning labels are easier to read than red
- Directions could be printed in all CAPS or bold
- Information on label should NOT be written by hand
- Lower and higher case letters are easier to read than ALL CAPS
- Beige background is easier for seniors to read than white
- List emergency phone number on label
- Standard placement of drug expiration date
- Print in braille for visually-imparied patients

QUESTION #5: Other suggestions?

622 surveys returned (134 responses to Question #5) as of March 3, 2009



- Easy-open lids/packages should be used; no child-proof caps for seniors
- Include purpose of drug - state what condition medication is intended to treat
- Bigger or darker font (i.e., drug expiration date, directions for use, warnings)
- Use different color for printing some info (i.e., directions for use, pharmacy phone #)
- Make directions simple/clear/understandable; print in patient's primary language
- Make bottles rectangular or square w/flat surface and directions printed on long side
- Put picture of pill on label or photo of pill or description of pill
- Side effects/interactions should be stated (i.e., dry mouth may cause dental caries)
- Different colored bottles or caps would help identify medications
- Standardize location of info so all prescriptions show information in same order
- Make label easy to remove (to recycle bottle or for privacy/security when discarding)
- Note on label when the manufacturer of the medicine changes
- Show where to return outdated meds or option to dispose via phamacy
- Don't cover prescription number with warning labels; use symbols as warnings
- Bottles should be in travel/airplane size; large bottles are clumsy and take up space
- Use top of lid for info; containers opening at bottom leave room for larger label
- Note change in size, color, shape of pills, so won't be perceived as medication error
- State what to do if you miss a dose
- Allow NP's name to appear on Rx bottle when submitting electronic prescriptions
- Labels should be waterproof
- Don't allow label to completely cover bottle; leave space to see medication remains
- Include a plan w/multiple meds (i.e., interactions, don't take with Calcium, etc.)

Attachment 3

COMMUNITY ORGANIZATIONS AND OTHER ENTITIES PROVIDED WITH BOP PRESCRIPTION LABEL SURVEYS 2008/09

The organizations and individual entities listed below were provided with English and Spanish versions of the California State Board of Pharmacy Prescription Label Survey during 2008/09.

1. Casey Young
   AARP State Legislative Director
   1415 L Street, #960
   Sacramento, CA 95814
   (916) 556-3018
   cyoung@aarp.org

2. Sam Totah
   Kaiser Permanente
   10990 San Diego Mission Road
   San Diego, CA 92108
   sammy.r.totah@kp.org

3. Vanessa Cajina
   Latino Coalition for a Healthy California
   1225 8th Street, Suite 500
   Sacramento, CA 95814
   (916) 448-3234
   vcajina@lchc.org

4. Nancy Kawahara, PharmD
   Associate Professor of Pharmaceutical Sciences
   11262 Campus St, West Hall, Room 1334
   Loma Linda, CA 92350
   nkawahara@llu.edu

5. Barry Goggin, President
   Better Business Bureau of Sacramento Valley
   400 S Street
   Sacramento, CA 95814
   (916) 443-6843 info@necal.bbb.org

6. Lu Molberg
   Ca. Assn. of Area Agencies on Aging
   980 9th Street, Suite 2200
   Sacramento, CA 95814
   (916) 443-2800
   C4a@pacbell.net

7. Sandra Fitzpatrick, Director
   California Commission on Aging
   1300 National Drive, Suite #173
   Sacramento, CA 95834
   (916) 419-7591
   sfitzpatrick@ccoa.ca.gov

8. Steve Blackledge
   CalPIRG
   1107 9th Street, Suite #601
   Sacramento, CA 95814
   (916) 448-4516
   Sblackledge@calpirg.org

9. Betty Williams, Executive Director
   Network for Elders
   1555 Burke Avenue, Suite A
   San Francisco, CA 94123
   (415) 647-5353
   bwilliams@networkforelders.org

10. Julia Ling, Executive Director
    Chinese Newcomers Foundation
    777 Stockton Street, #104
    San Francisco, CA 94108
    (415) 421-2111
    julialing@msn.com
    cnsc@chinesenewcomers.org

11. Gary Passmoore, Legislative Coordinator
    Congress of California Seniors
    1228 N Street, #29
    Sacramento, CA 95814
    (916) 442-4474 GaryP@seniors.org

12. Joe Ridout, Consumer Advice Counselor
    Consumer Action
    221 Main Street, Suite #480
    San Francisco, CA 94105
    (415) 777-9648

jridout@consumer-action.org

13. Kathy Li, Director
National Consumer Resource Center
221 Main Street, Suite #480
San Francisco, CA 94105
(415) 777-9648
kathy.li@consumer-action.org

14. Jason Wimbley
Special Programs Manager
Dept. of Community Services & Development
700 N. 10th Street, Room #258
Sacramento, CA 95814
(916) 341-4200
jwimbley@csd.ca.gov

15. Ed Mendoza
Office of Patient Advocacy
980 9th Street, Suite #550
Sacramento, CA 95814
(916) 342-6407
Emendoza@dmhc.ca.gov

16. Laurel Pallock, Investigator
Consumer & Environmental Protection Unit
District Attorney's Office
732 Brannan Street
San Francisco, CA 94103
(415) 551-9575
consumer.mediation@sfgov.org

17. Brad Chibos
Santa Clara County Commission on Consumer Affairs
540 Bird Avenue, #200
San Jose, CA 95125
(408) 998-1694 Chibos@aol.com

18. Marina Community Center
Senior Services Office
15301 Wicks Blvd.
San Leandro, CA 94579

19. Lavender Seniors of the East Bay
1395 Bancroft Avenue
San Leandro, CA 94577

20. East Bay Services for the Developmentally Disabled
797 Montague Ave.
San Leandro, CA 94577

21. Evergreen Senior Program/Wisdom Path
985 Suerro Street
Hayward, CA 94541

22. Hayward Area Senior Center
22325 N. 3rd Street
Hayward, CA 94546-6969

23. Kenneth Aitken Senior & Community Center
17800 Redwood Road
Castro Valley, CA 94546

24. Ralph & Mary Ruggieri Senior Center
33997 Alvarado-Niles Road
Union City, CA 94587

25. Newark Senior Center
7401 Enterprise Drive
Newark, CA 94560

26. Fremont Multi-Service Senior Center
40086 Paseo Padre Parkway
Fremont, CA 94538

27. Barbara Lee Senior Center
540 S. Abel Street
Milpitas, CA 95035

28. Shauna McKeever
Safeway Pharmacy #2707
6445 N. Pacific Avenue
Stockton, CA 95207

29. Fred S. Mayer, RPh, MPH
President, PPSI
101 Lucas Valley Road, #384
San Rafael, CA 94903

30. Chris Oliva, PharmD
Pharmacy Services Manager
Kaiser Permanente Santa Clara
Medical Center
710 Lawrence Expressway,
Department #194
Santa Clara, CA 95051

31. Jennifer Hall
8041 Belgian Court
Sacramento, CA 95830

32. Suzy Hackworth
11144 Traditions Court
Riverside, CA 92503

33. Kathy Besinque, PharmD
USC School of Pharmacy
1985 Zonal Avenue, #301
Los Angeles, CA 90033

34. Tony Yee, PharmD
1220 Broadway Street
Placerville, CA 95667

35. RoseAnn L. Jankowski, PharmD
Memorial Health Services
17360 Brookhurst Street
Fountain Valley, CA 92708

36. Doris Cheng
6481 Atlantic Avenue, Apt. #120
Long Beach, CA 90805

37. Dawn Bronsema
9026 Bushman Avenue
Downey, CA 90240

38. Doreena P. Wong, Staff Attorney
NHelp - National Health Law Program
2639 S. La Cienega Blvd.
Los Angeles, CA 90034

39. Anita Hong-Ha Le
Program Director, PALS for Health
605 W. Olympic Blvd., #600
Los Angeles, CA 90015

40. Michael Villaire, MSLM
Director, Programs & Operations
Institute for Healthcare Advancement
501 S. Idaho Street, Suite #300
La Habra, CA 90631

41. Brian Hui, Program Coordinator
Tongan Community Service Center
14112 S. Kingsley Drive
Gardena, CA 90249

42. Tina Tarsitano, RPh, MBA
Pharmacy Supervisor, Walgreen Co.
711 W. Kimberly Avenue, Suite #200
Placentia, CA 92870

43. Margie Metzler, Executive Director
Gray Panthers
1121 Wayland Avenue
Sacramento, CA 95825

44. Frank Whitney, President
Better Business Bureau of Mid-Counties,
Inc.
11 S. San Joaquin Street, Suite #803
Stockton, CA 95202
(209) 948-4880

45. Michael Winter
UCSF Department of Clinical Pharmacy
winterm@pharmacy.ucsf.edu

46. Eunice Chung, Associate Professor
Western University
echung@westernu.edu

47. Helen Park
helen.park@va.gov

PUBLIC OUTREACH EVENTS WHERE BOP STAFF INTERVIEWED ATTENDEES AND COMPLETED BOP PRESCRIPTION LABEL SURVEYS

1. Meet The Pharmacist – San Diego – May 2008
2. Senior Day in The Park – Elk Grove – May 2008
3. Better Business Bureau Community Alliance Day – Merced – June 2008
4. Eddie Smith Senior Center – Riverside – June 2008
5. Safetyville Family Safety Expo – Sacramento – June 2008
6. Lotus Festival – Los Angeles – July 2008
7. California State Fair – Sacramento – August 2008
8. Celebrando Nuestra Salud – Sacramento – October 2008
9. Evans Community Adult School Consumer Fair – Los Angeles – March 2009

CALIFORNIA STATE BOARD OF PHARMACY

Do you understand the directions on your Rx medicine label?

Approximately 46% of American adults do not.

A prescription label says to "Take two tablets by mouth twice daily." Sounds simple, doesn't it?

But patients have understood this to mean:

- Take it every 8 hours
- Take it every day
- Take one every 12 hours

Better directions might be "Take 2 tablets by mouth at 8 in the morning, and take 2 tablets at 9 at night."

FACT: Six out of 10 people have taken their medicines incorrectly, due to:

- confusing directions on the container label,
- poor health literacy (the ability to read, understand, and act on healthcare information), and
- inability to read and/or understand directions written in English of those whose first language is not English.

FACT: Medicine errors are among the most common medical errors, harming at least 1.5 million people every year. More than one third of these take place outside a hospital in a home setting, costing close to $1 billion annually.

FACT: Up to one-half of all medicines are taken incorrectly or mixed with other medicines that can cause dangerous reactions that can lead to injury and death.

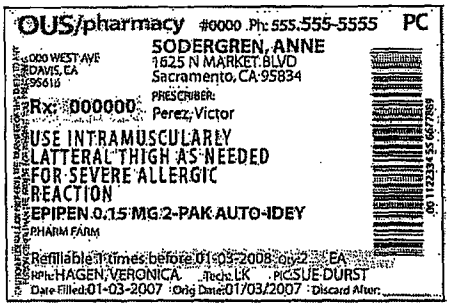
Medicine-related errors must be reduced. One way to begin is by providing patients with easy to read and understand prescription container labeling. This can be a giant step toward increasing consumer protection and improving the health, safety, and well-being of consumers.

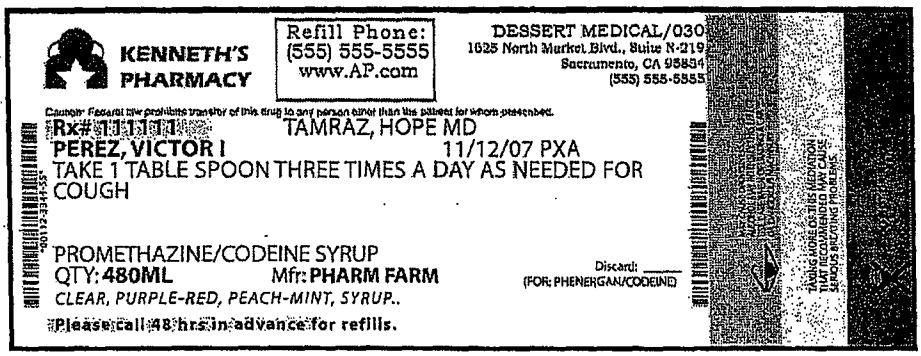
California recognizes the importance of improving medicine container labels. In 2007, the Legislature and Governor Schwarzenegger enacted Senate Bill 472, mandating the Board of Pharmacy to develop requirements for standardized, patient-centered, prescription drug labels on all prescription medicine dispensed to patients in California.

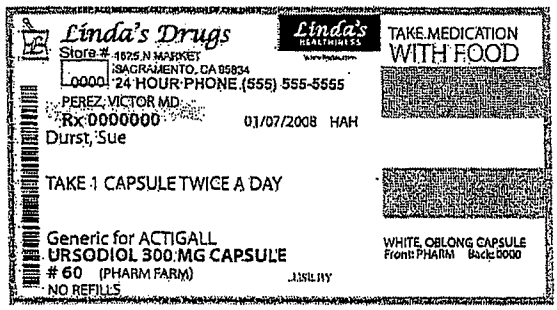
In 2008, the Board will hold statewide public meetings to consult with patients and health providers to improve prescription container labels. The meetings will focus on improving directions for the drug's use, using better type fonts and sizes, and placement of information that is patient-centered. The needs of senior citizens and patients with limited English reading skills also will be identified.

(916) 574-7900
WWW.PHARMACY.CA.GOV
1625 N. MARKET BLVD.
SUITE N-219
SACRAMENTO, CA 95834

sample prescription labels


OUS/pharmacy #0000 Ph: 555.555-5555 PC
1000 WEST AVE
DAVIS, CA
95616
SODERGREN, ANNE
1625 N MARKET BLVD
Sacramento, CA 95834
Rx: 000000
PRESCRIBER:
Perez, Victor
USE INTRAMUSCULARLY
LATTERAL THIGH AS NEEDED
FOR SEVERE ALLERGIC
REACTION
EPIPEN 0.15 MG/2-PAK AUTO-IDEY
PHARM FARM
Refillable 1 times before 01-03-2008 qty:2 EA
Rph: HAGEN, VERONICA Techs: LK PICSUE DURST
Date Filled: 01-03-2007 Orig Date: 01/03/2007 Discard After:


KENNETH'S PHARMACY
Refill Phone: (555) 555-5555 www.AP.com
DESSERT MEDICAL/030
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834
(555) 555-5555
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed.
Rx# 111111 TAMRAZ, HOPE MD
PEREZ, VICTOR I 11/12/07 PXA
TAKE 1 TABLE SPOON THREE TIMES A DAY AS NEEDED FOR COUGH
PROMETHAZINE/CODEINE SYRUP
QTY: 480ML Mfr: PHARM FARM
CLEAR, PURPLE-RED, PEACH-MINT, SYRUP..
Please call 48 hrs in advance for refills.
Discard: ____
(FOR: PHENERGAN/CODEINE)


Linda's Drugs
Store #
1625 N MARKET
SACRAMENTO, CA 95834
0000 24 HOUR PHONE (555) 555-5555
Linda's HEALTHINESS
TAKE MEDICATION WITH FOOD
PEREZ, VICTOR MD
Rx 0000000 01/07/2008 HAH
Durst, Sue
TAKE 1 CAPSULE TWICE A DAY
Generic for ACTIGALL
URSODIOL 300 MG CAPSULE
60 (PHARM FARM)
NO REFILLS
WHITE, OBLONG CAPSULE
Front: PHARM Back: 0000

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.

Attachment 3

U.S. PHARMACOPEIA
The Standard of Quality℠

Patient-centered Labeling

Recommendations from USP's Health Literacy and Prescription Container Labeling Advisory Panel

Co-chairs: Gerald McEvoy and Joanne Schwartzberg

FDA Public Workshop on Naming, Labeling, and Packaging Practices to Minimize Medications Errors
June 24, 2010 College Park, MD

Charge to the Panel

- Determine optimal prescription label content and format to promote safe medication use by **critically reviewing factors that promote or distract from patient understanding** of prescription medication instructions

- Create universal prescription label standards for **format/appearance** and **content/language**

- Sponsoring USP Expert Committee: Safe Medication Use (SMU)

Summary of the Issue

- Medication misuse results in over 1 million ADE/yr (IOM 2007)
- The patient's best source (and often only source) of information is the Rx container label
- The Rx container label must be able to fulfill the professional obligations of physicians and pharmacists to give the patient the most **essential information** needed to understand how **to safely & appropriately use the medication**

Recommendations for Universal Standards

- USP assumed role of developing standards for content & format of Rx container labeling following **IOM Roundtable on Health Literacy** workshop October 2007
- USP Advisory Panel with four subcommittees studied issues for over a year
- Safe Medication Use Expert Committee adopted report and recommendations in November 2009
- Currently preparing **General Chapter <17> for *USP-NF***, which will include applicable standards

Guiding Principles

- Focus on clarity & readability
- Use unambiguous, simple language
- Emphasize most critical content; minimize distractions
- Only employ visual cues that are evidence based
- Employ instructions that are readily understandable and explicit rather than implicit
- Develop dosing instructions that reinforce patient understanding over broad range of literacy levels; develop evidence-based standard SIGs

Universal Standards: Principles

- ***Organize the Prescription Label in a Patient-centered Manner***
  - Patient-directed information must be organized in a way that best reflects how most patients seek out and understand medication instructions
  - Prescription container labeling should feature only the most important patient information needed for safe and effective understanding and use

Universal Standards: Format/Readability

- ***Patient-directed Instructional Content***
  - Will be at the top of the label; the patient's name, drug name, and explicit clear directions for use in simple language should be displayed with greatest prominence
  - Other less critical but important content (e.g., pharmacy name and phone number, prescriber name, fill date, refill information, expiration date, prescription number, drug quantity, product description, and evidence-based auxiliary information) should not supersede critical patient information

Universal Standards: Format/Readability

- ***Improve Readability***
  - Critical information for patients must appear on the prescription label in a simple, uncondensed, familiar, large font size that is in sentence case
  - Use numeric rather than alphabetical characters
  - Use horizontal text
  - Minimize need to turn container

Universal Standards: Format/Readability

- ***Optimize Typography***
  - Use high contrast print (e.g., black print on white background)
  - Use simple, familiar fonts with sufficient space within letters and between letters; use effective fonts such as serif Times Roman or sans serif Arial
  - Use large print 12-14 point font for critical information and do not use smaller than 10 point font for important information
  - Bolding & highlighting (with light color only) should preserve readability and be reserved for critical information

Universal Standards: Format/Readability

- ***Optimize White Space***
  - Use adequate white space between lines of text (25-30%)
  - Use white space to distinguish sections on the label such as directions for use vs pharmacy information

Universal Standards: Language/Content

- ***Simplify Language***
  - Language on the label should be clear, simplified, concise, and familiar and used in a standardized manner
  - Only common terms and sentences should be used. Use of unfamiliar words (including Latin terms) and unclarified medical jargon should be avoided
  - Whenever available and appropriate to the patient context, standardized patient-centered translations of common prescribing directions to patients (SIG) should be used

Universal Standards: Language/Content

- ***Use Explicit Text to Describe Dosage/Interval Instructions***
  - Instructions for use must clearly separate the dose from the timing of each dose, so as to explicitly convey the number of dosage units to be taken and the timing of such (e.g., specific time periods each day such as morning and evening or at breakfast and dinner)
  - Instructions for use should contain numeric rather than alphabetic characters for numbers (e.g., “Take 2 tablets in the morning and 2 tablets in the evening” rather than “Take two tablets by mouth twice daily”)

Universal Standards: Language/Content

- ***Include Purpose for Use***
  - Patient preferences in sharing such information on the label must be the paramount consideration
  - Confidentiality and FDA approval for intended use (e.g., labeled vs off-label use) may limit inclusion of indications on prescription container labels
  - Current evidence supports inclusion of purpose-for-use language in clear, simple terms (e.g. for high blood pressure versus hypertension)

Universal Standards: Language/Content

- ***Auxiliary information***
  - Auxiliary information on the prescription container label should be minimized and limited to **evidence-based critical information** regarding safe use
  - The information should be presented in a standardized manner and should be essential for patient understanding (e.g., warnings and critical administration alerts)
  - Use of icons should be limited to those for which evidence demonstrates enhancement of interpretation and clarity about use

Add the following:

▲⟨17 PRESCRIPTION CONTAINER LABELING

INTRODUCTION

Medication misuse has resulted in more than 1 million adverse drug events per year in the United States. Patients' best source (and often only source) of information regarding the medications they have been prescribed is on the prescription container label. Although other written information and oral counseling sometimes may be available, the prescription container label must fulfill the professional obligations of the prescriber and pharmacist. These obligations include giving the patient the most essential information needed to understand how to safely and appropriately use the medication and to adhere to the prescribed medication regimen.

Inadequate understanding of prescription directions for use and auxiliary information on dispensed containers is widespread. Studies have found that 46% of patients misunderstood one or more dosage instructions, and 56% misunderstood one or more auxiliary warnings. The problem of misunderstanding is particularly troublesome in patients with low or marginal literacy and in patients receiving multiple medications that are scheduled for administration using unnecessarily complex, nonstandardized time periods. In one study, patients with low literacy were 34 times more likely to misinterpret prescription medication warning labels. However, even patients with adequate literacy often misunderstand common prescription directions and warnings. In addition, there is great variability in the actual auxiliary warning and supplemental instructional information applied by individual practitioners to the same prescription. The specific evidence to support a given auxiliary statement often is unclear, and patients often ignore such information. The essential need for, and benefit of, auxiliary label information (both text and icons) in improving patient understanding about safe and appropriate use of their medications vs. explicit simplified language alone require further study.

Lack of universal standards for labeling on dispensed prescription containers is a root cause for patient misunderstanding, nonadherence, and medication errors. On May 18, 2007, the USP Safe Medication Use Expert Committee established an Advisory Panel to: 1) determine optimal prescription label content and format to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription medication instructions and 2) create universal prescription label standards for format/appearance and content/language.

In November 2009, the Health Literacy and Prescription Container Labeling Advisory Panel presented its recommendations to the Safe Medication Use Expert Committee, which then requested that USP develop patient-centered label standards for the format, appearance, content, and language of prescription medication instructions to promote patient understanding. These recommendations form the basis of this general chapter.

Note—These standards do not apply when a prescription drug will be administered to a patient by licensed personnel who are acting within their scope of practice.

PRESCRIPTION CONTAINER LABEL STANDARDS TO PROMOTE PATIENT UNDERSTANDING

Organize the prescription label in a patient-centered manner: Information shall be organized in a way that best reflects how most patients seek out and understand medication instructions. Prescription container labeling should feature only the most important patient information needed for safe and effective understanding and use.

Emphasize instructions and other information important to patients: Prominently display information that is critical for patients' safe and effective use of the medicine. At the top of the label specify the patient's name, drug name (spell out full generic and brand name) and strength, and explicit clear directions for use in simple language.

The prescription directions should follow a standard format so the patient can expect that each element will be in a regimented order each time a prescription is received.

Other less critical but important content (e.g., pharmacy name and phone number, prescriber name, fill date, refill information, expiration date, prescription number, drug quantity, physical description, and evidence-based auxiliary information) should not supersede critical patient information. Such less critical information should be placed away from dosing instructions (e.g., at the bottom of the label or in another less prominent location) because it distracts patients, which can impair their recognition and understanding.

Simplify language: Language on the label should be clear, simplified, concise, and familiar, and should be used in a standardized manner. Only common terms and sentences should be used. Do not use unfamiliar words (including Latin terms) or medical jargon.

Use of readability formulas and software is not recommended to simplify short excerpts of text like those on prescription labels. Instead, use simplified, standardized sentences that have been developed to ensure ease of understanding the instructions correctly (by seeking feedback from samples of diverse consumers).

Give explicit instructions: Instructions for use (i.e., the SIG or signatur) should clearly separate the dose itself from the timing of each dose in order to explicitly convey the number of dosage units to be taken and when (e.g., specific time periods each day such as morning, noon, evening, and bedtime). Instructions shall include specifics on time periods. Do not use alphabetic characters for numbers. For example, write "Take 2 tablets in the morning and 2 tablets in the evening" rather than "Take two tablets twice daily").

Whenever available, use standardized directions (e.g., write "Take 1 tablet in the morning and 1 tablet in the evening" if the prescription reads b.i.d.). Vague instructions based on dosing intervals such as twice daily or 3 times daily, or hourly intervals such as every 12 hours, generally should be avoided because such instructions are implicit rather than explicit, they may involve numeracy skills, and patient interpretation may vary from prescriber intent. Although instructions that use specific hourly times (e.g., 8 a.m. and 10 p.m.) may seem to be more easily understood than implicit vague instructions, recommending dosing by precise hours of the day is less readily understood and may present greater adherence issues due to individual lifestyle patterns, e.g., shift work, than more general time frames such as in the morning, in the evening, after breakfast, with lunch, or at bedtime. Consistent use of the same terms should help avoid patient confusion.

Ambiguous directions such as "take as directed" should be avoided unless clear and unambiguous supplemental instructions and counseling are provided (e.g., directions for use that will not fit on the prescription container label). A clear statement referring the patient to such supplemental materials should be included on the container label.

Include purpose for use: If the purpose of the medication is included on the prescription, it should be included on the prescription container label unless the patient prefers that it not appear. Always ask patients their preference when prescriptions are submitted for filling. Confidentiality and FDA approval for intended use (e.g., labeled vs. off-label use) may limit inclusion of the purpose on labels. Current evidence supports inclusion of purpose-for-use language in clear, simple terms (e.g., "for high blood pressure" rather than "for hypertension").

Limit auxiliary information: Auxiliary information on the prescription container label should be evidence-based in simple explicit language that is minimized to avoid distracting patients with nonessential information. Most patients, particularly those with low literacy, pay little attention to auxiliary information. The information should be presented in a standardized manner and should be critical for patient understanding and safe medication use (e.g., warnings and critical administration alerts). Icons are frequently misunderstood by patients. In addition, icons that provide abstract imagery for messages that are difficult to visually depict may be ineffective at improving understanding compared with simplified text alone. Use only icons for which there is adequate evidence, through consumer testing, that they improve patient understanding about correct use. Evidence-based auxiliary information, both text and icons, should be standardized so that it is applied consistently and does not depend on individual practitioner choice.

Address limited English proficiency: Whenever possible, the directions for use on a prescription container label should be provided in the patient's preferred language. Otherwise there is a risk of misinterpretation of instructions by patients with limited English proficiency, which could lead to medication errors and adverse health outcomes. Additionally, whenever possible, directions for use should appear in English as well, to facilitate counseling; the drug name shall be in English so that emergency personnel and other intermediaries can have quick access to the information.

Translations of prescription medication labels should be produced using a high-quality translation process. An example of a high-quality translation process is:

- Translation by a trained translator who is a native speaker of the target language
- Review of the translation by a second trained translator and reconciliation of any differences
- Review of the translation by a pharmacist who is a native speaker of the target language and reconciliation of any differences
- Testing of comprehension with target audience

If a high-quality translation process cannot be provided, labels should be printed in English and trained interpreter services used whenever possible to ensure patient comprehension. The use of computer-generated translations should be limited to programs with demonstrated quality because dosage instructions can be inconsistent and potentially hazardous. Standardized translated instructions and technology advances are needed to ensure the accuracy and safety of prescription container labeling for patients with low English proficiency.

Improve readability: Labels should be designed and formatted so they are easy to read. Currently no strong evidence supports the superiority in legibility of serif vs. sans serif typefaces, so simple uncondensed fonts of either type can be used.

Optimize typography by using the following techniques:

- High-contrast print (e.g., black print on white background).
- Simple, uncondensed familiar fonts with sufficient space within letters and between letters (e.g., Times Roman or Arial).
- Sentence case (i.e., punctuated like a sentence in English: initial capital followed by lower-case words except proper nouns).
- Large font size (e.g., minimum 12-point Times Roman or 11-point Arial) for critical information. Note that point size is not the actual size of the letter, so 2 fonts with the same nominal point size can have different actual letter sizes. X-height, the height of the lower-case x in typeface, has been used as a more accurate indicator of apparent size than point size. For example, for a given point size, the x-height and apparent size of Arial are actually bigger than those for Times Roman. Do not use type smaller than 10-point Times Roman or equivalent size of another font. Older adults, in particular, have difficulty reading small print.
- Adequate white space between lines of text (25%–30% of the point size).
- White space to distinguish sections on the label such as directions for use vs. pharmacy information.
- Horizontal text only.

Other measures that can also improve readability:

- If possible, minimize the need to turn the container in order to read lines of text.
- Never truncate or abbreviate critical information.
- Highlighting, bolding, and other typographical cues should preserve readability (e.g., high-contrast print and light color for highlighting) and should emphasize patient-centric information or information that facilitates adherence (e.g., refill ordering).
- Limit the number of colors used for highlighting (e.g., no more than one or two).
- Use of separate lines to distinguish when each dose should be taken.

Address visual impairment:

- Provide alternative access for visually impaired patients (e.g., tactile, auditory, or enhanced visual systems that may employ advanced mechanics of assistive technology).

▲ *USP36*

PRINCIPLES OF DESIGNING A MEDICATION LABEL FOR COMMUNITY AND MAIL ORDER PHARMACY PRESCRIPTION PACKAGES

Institute for Safe Medication Practices

a nonprofit organization

200 Lakeside Drive, Suite 200
Horsham, PA 19044
www.ismp.org
215-947-7797

There is an ever-present risk of medication errors in community pharmacy and ambulatory care practice, but this risk is even greater when pharmacy labels, which are provided to assist in patient care, are poorly designed. Standardized, and well thought drug labeling practices need to be a part of an overall strategy to improve medication adherence and reduce inadvertent medication errors. Based on ISMP's ongoing analysis of actual medication errors reported and a review of pharmacy-generated labels produced by a number of systems including a sample BPOC system, ISMP offers the following recommendations as a basic approach toward the prevention of errors related to label misinterpretation:

1. **Label formats should include larger fonts, lists, headers, whitespace, simple language, and logical organization to improve readability and comprehension.[1]**

   a) Minimum font size for patient name, generic drug name, and patient-specific dose should be 12 point or equivalent.[2] (A 1994 study of adults and seniors found more self-administration medication errors with 9 vs. 12 or 14 point font and `Courier` vs. Helvetica fonts.)

   b) Use standardized font styles such as: Arial, Verdana, or their equivalent for all text and numbers. To improve typography, use larger, sans serif font. Do not use italic, oblique, narrow, or condensed type fonts.

   c) When applicable, use numeric vs. alphabetic characters when describing drug doses, concentrations, or frequencies.

   d) Use typographic cues (bolding and highlighting) for patient content only.

   e) Allow for horizontal text only.

   f) Maximize the amount of white space while managing the readability of the text. White space is often perceived by older patients as having greater readability.[3]

   g) Use thicker, denser lined letters where appropriate as they are easier to read.

   h) Consider enhancing the line spacing, making pharmacy labels easier to read.

This material is the property of the Institute for Safe Medication Practices. This material may not be copied in any format or used for any purpose without permission of the Institute for Safe Medication Practices. © ISMP 2010

i) Use a white background color for labels for better visualization of text and bar codes (when applicable).

j) Use black ink for all bar codes.

k) Organize the label content in a patient-centered manner, as below:

- Group text into separate, conceptually-related sections (chunking) to facilitate search and acquisition of information for the patient.

- All provider directed content (Pharmacy logo, number, address, and phone number) should be placed away from dosage instructions and separated at the bottom of the label.[4]

- Provide pharmacy applied auxiliary labels in a consistent location for patient routine expectation.

2. Provide explicit instruction to improve patient comprehension, such as using -paced reading (see a-e below).[5]

a) Directions must contain specific dosing /interval times; ex: 'Take 2 tablets in the morning and take 2 tablets in the evening' NOT 'Take two tablets twice a day.'

b) Use numbers instead of text.

c) Avoid awkward terms such as 'twice'; instead use 'two' or '2.'

d) Use mixed case (upper and lower case letters).

e) Ensure that the application and printer support both upper and lower case fonts and any characters which drop below the lower line (example lower case y and g). This would include the ability to use mixed case fonts within a line or a format to support tall man lettering, when indicated. See http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm164587.htm.

f) Avoid use of dangerous drug name, dosage instruction, or unit of measure abbreviations.

- To avoid confusion, never abbreviate drug names. Each drug field should contain a sufficient number of characters to prevent truncating drug names, whether single entity or multi-ingredient product. (The rise in acute liver toxicity has been attributed to patient inadvertent overdosing of acetaminophen.[6] Consumers may be unaware that prescription labels indicating the drug abbreviation, APAP, is actually acetaminophen.)

This material is the property of the Institute for Safe Medication Practices. This material may not be copied in any format or used for any purpose without permission of the Institute for Safe Medication Practices. © ISMP 2010

- Avoid the use of all potentially dangerous abbreviations and dose expressions (see www.ismp.org/Tools/errorproneabbreviations.pdf) including the following:

    i. Do not use trailing zeros (e.g., 5 mg, never 5.0 mg).

    ii. Use leading zeros for doses less than a whole number (e.g., 0.3 mg, never.3 mg)

    iii. Spell out the word Units. Never use U, which easily can be mistaken as a zero, causing a 10-fold overdose

    iv. Abbreviate International Units as “units”

    v. Include properly spaced commas for dose numbers expressed in thousands (e.g., 5,000 units).

    vi. Do not use M as an abbreviation for thousands (e.g., 5 M units), which has been mistaken as million. Use the word thousand for larger doses in the hundreds of thousands (e.g., 150 thousand rather than 150,000). Use the word million for doses expressed in millions (e.g., 1 million units) to avoid possible misplacement of commas and misreading the dose if the commas are not seen correctly with such large numbers.

    vii. Use standard metric abbreviations as follows:

> **m** (lower case) = meter
>
> **kg** = kilogram
>
> **g** = gram
>
> **mg** = milligram
>
> **mcg** = microgram
> (do not use the Greek letter μ as as μg which has been misread as mg)
>
> **L** (upper case) = liter
>
> **mL** (lower/upper case) = milliliter
> (do not use cc which has been misread as U or the number 4)
>
> **mEq** = milliequivalent
>
> **mmol** = millimole

g) Simplify the language, avoiding unfamiliar words/medical jargon.

This material is the property of the Institute for Safe Medication Practices. This material may not be copied in any format or used for any purpose without permission of the Institute for Safe Medication Practices. © ISMP 2010

3. Drug names on label should be separate and distinct from all other information.

a) List all generic names using lower-case letters as the primary drug nomenclature (unless employing tall man letters as a safety strategy), ensuring that each matches FDA-approved nomenclature. As appropriate, list associated brand names in a requisite field using all upper case letters (e,g., LASIX) to differentiate them from generic names. Trademark symbols (e.g., ™ or ®) should not be used.

b) When the drug name, strength, dosage form, and dosage units appear together, avoid confusion by providing a space between them (e.g., propranolol20 mg has been misread as 120 mg and 10Units has been misread as 100 Units).

c) Do not include the salt of the chemical when expressing a generic name unless there are multiple salts available (e.g., hydroxyzine hydrochloride and hydroxyzine pamoate). If the salt is listed as part of the name (e.g., USP approved abbreviations such as K, Na, HBr, and HCl), it should follow the drug name, not precede it (e.g., hydroxyzine HCl not HCl hydroxyzine).

d) Include both the brand name and the generic name on the label. If state law prohibits printing the BRAND name when the specific BRAND is not dispensed then the term "used for" may be inserted before the BRAND name.

e) All combination products should include the BRAND name on the label. If a product contains two ingredients they should both appear in the generic name field. If the product contains greater than two generic ingredients then the two primary ingredients should be placed in the generic field accompanied by the phrase "and others" at the end of the 2 generic names. If one of the ingredients is acetaminophen, consider applying an auxiliary label that states; 'This product contains acetaminophen.'

f) Do not include an abbreviation of the manufacturer's name as part of the drug name on the same line of text (e.g., tramadol hcl acetaminophen par, where PAR is the name of the manufacturer, not an additional ingredient or drug-name suffix)

g) Should be written as:

tramadol 37.5 mg acetaminophen 325 mg
manuf: Par used for ULTRACET

4. Include the condition for which the drug was prescribed if requested by the patient and if the condition is indicated on the prescription.

5. Label should include a clearly-visible second patient identifier, preferably their date of birth, but also could use the current address.

6. Provide a written description of medication and picture of medication, if possible.

This material is the property of the Institute for Safe Medication Practices. This material may not be copied in any format or used for any purpose without permission of the Institute for Safe Medication Practices. © ISMP 2010

ISMP ADDITIONAL/FUTURE RECOMMENDATIONS

1. **Use a standard icon system for signaling and organizing auxiliary warnings and instructions.**

   a) Consider well placed sparing use of easily understood pictograms to increase likelihood of reading.

   b) Ensure that warnings and alerts are applied consistently and not practitioner dependent.

2. **The purchase receipt should include the second patient identifier, preferably date of birth, and/or patient address.**

3. **When affixing labels to a manufacturer-supplied bottle, do not cover medication name and strength on original label.**

4. **If a picture of medication can not be included on the label, refer patient to Web sites that provide pictures of medications, such as: www.mypillbox.org/mypillbox.php; www.healthline.com; www.webmd.com.**

5. **Use the largest font size label will allow, minimum of 18-point type for people with low vision.[7] Most standard prescription label size will not accommodate the required labeling information in 18-point type. Therefore, the American Foundation for the Blind recommends that pharmacies:[7]**

   a) Provide "duplicate labels" (prescription and auxiliary) printed in a minimum of 18-point type on paper stock.

   b) If pictograms are used, these should also be provided in "large print" format and high contrast (saturated black on white background).

   c) The "duplicate labels" should be matched in some way to the prescription container, such as by using a large-print number or colored sticker on both the duplicate label and the corresponding medication container.

   d) Use sans serif, standard font (not narrow or condensed), such as Arial, Verdana, or obtain APHont™ (pronounced Ay'-font). APHont™ was developed specifically for low vision readers and embodies characteristics that have been shown to enhance reading speed, comprehension, and comfort for large print users. Available free at: www.aph.org/products/aphont.html.

   e) If the pharmacy offers prescription label information in large print, this should be prominently posted at the prescription counter or communicated directly to each patient.

This material is the property of the Institute for Safe Medication Practices. This material may not be copied in any format or used for any purpose without permission of the Institute for Safe Medication Practices. © ISMP 2010

6. **Use "tall man" letters (e.g., hydrOXYzine and hydrALAZINE) to help distinguish look-alike products on screens to minimize the risk of selecting the wrong product when medication names appear alphabetically in drug profiles. Establish and disseminate a list of products for which tall man letters are used, specifying which letters are affected, to ensure standard application for all uses. http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm164587.htm.**

REFERENCES

1. Shrank W, Avorn J, Rolon C, et al. Effect of content and format of prescription drug labels on readability, understanding, and medication use: a systematic review. Ann Pharmacother. 2007;41:783-801.

2. Shrank WH, Agnew-Blais J, Choudhry NK, et al. The variability and quality of medication container labels. Arch Intern Med. 2007;167:1760-1765.

3. Wogalter M., Vigilante W. Effects of label format on knowledge acquisition and perceived readability by younger and older adults. Ergonomics. 2003;46(4):327-344.

4. Cohen MR, ed. Medication Errors. 2nd ed. Washington DC: American Pharmacists Association. 2007. 222-223.

5. Wolf M, Davis T, Shrank W, et al. To err is human: Patient misinterpretations of prescription drug label instructions. Patient Education and Counseling. 2007;67(3):293-300.

6. Larson AM, Polson J, Fontana RJ, et al. Acetaminophen-induced acute liver failure: results of a United States multicenter, prospective study. Hepatology. 2005;42:1364-1372. Available on the Intranet at: http://www3.interscience.wiley.com/cgi-bin/fulltext/112161379/HTMLSTART. Accessed 24 Nov 2008.

7. American Society of Consultant Pharmacists Foundation/American Foundation for the Blind. Guidelines for prescription labeling and consumer medication information for people with vision loss. 2008. Available on the Intranet at: http://www.afb.org/Section.asp?SectionID=3&TopicID=329&DocumentID=4064. Accessed 24 Nov 2008.

This material is the property of the Institute for Safe Medication Practices. This material may not be copied in any format or used for any purpose without permission of the Institute for Safe Medication Practices. © ISMP 2010

Report of the Task Force on Uniform Prescription Labeling Requirements

Members Present:

Michael J. Romano (PA), *chair*; Barry J. Boudreaux (NV); Karen DiStefano (RI); Patricia Donato (NY); Virginia Herold (CA); Ronald Huether (SD); William Prather (GA); Leo H. Ross (VA)

Others Present:

Karen M. Ryle, *executive committee liaison*; Carmen Catizone, Melissa Madigan, Larissa Doucette, *NABP staff*

Guests:

Colleen Brennan, *United States Pharmacopeia*; Darren K. Townzen, *National Council for Prescription Drug Programs*

The Task Force on Uniform Prescription Labeling Requirements met December 6, 2008 at the JW Marriott Starr Pass Hotel, Tucson, AZ.

This task force was established in response to Resolution 104-3-08, Task Force on Uniform Prescription Labeling Requirements, which was approved by the NABP membership at the Association's 104th Annual Meeting in May 2008.

Review of the Task Force Charge

Task force members reviewed their charge and accepted it as follows:

1. Evaluate current state and federal laws and regulations addressing prescription label format and content.
2. Review the results of the findings of both state and federal studies regarding prescription labeling.
3. Study the feasibility of implementing standardized state requirements for prescription label format and content and for patient medication information.
4. Recommend revisions, if necessary, to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (*Model Act)* addressing these issues so as to increase readability and comprehension of labels by patients.

Recommendation 1: Endorse and disseminate statement on prescription labeling.

The task force recommends that the NABP Executive Committee endorse the following statement on the issue of prescription labeling and disseminate it to all interested stakeholders:

> The purpose of the prescription label is to provide critical information to the patient so that he or she may use the medication appropriately and comply with the medication regimen. The label should be patient-centered. The label should not be used as an audit mechanism by third-party payers, nor should it be used for promotional purposes by dispensing pharmacies. Further, the label should not be used as a sole means to determine compliance with pharmacy laws and regulations by pharmacy regulators.
> The prescription label cannot and should not replace critical pharmacist care responsibilities, such as appropriately identifying the patient at the time of dispensing and providing patient counseling.

Background:

Upon review and discussion of the issue of prescription labeling and concerns related to patients' understanding of such labeling, the task force determined it is important to clearly identify for what purposes prescription labels should and should not be used. As stated above, members felt that labels should be used solely to provide patients with important information about medication use. They agreed that prescription labels should not replace critical pharmacist care responsibilities. Identified were two such primary responsibilities: patient identification and patient counseling. On these issues, the task force stated the following:

1. Patient Identification – Patient data elements, such as address, are important identifiers but do not warrant inclusion on the label; instead, such information should be contained in other patient identification systems upon which a pharmacist relies to ensure that the patient receives his or her medication and to avoid confusion among patients with similar names or whose names may bear suffixes such as "Jr" or "Sr" within a family group.
2. Patient Counseling – The single most effective component to increase and improve patient compliance and avoid medication errors, as documented in numerous studies, is appropriate patient counseling. The prescription label is designed to supplement this critical pharmacist responsibility and not replace it in any way. Pharmacists cannot avoid their legal and professional responsibilities by deferring counseling activities to the prescription label. Further, boards of pharmacy cannot regulate counseling activities through the prescription label.

Recommendation 2: Amend the NABP Model Act language addressing prescription drug labeling.

The task force recommends that NABP Executive Committee approve amendments to the *Model Act* that will ensure prescription labels are organized in a patient-centered manner and that mandate the following data elements appear on the prescription label. The task force has consciously removed some data elements historically included on prescription labels to make room for the most critical patient information.

A. Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif (such as "arial"), minimum 12-point

font, and in "sentence case." Field size and font size may be increased in the best interest of patient care. Critical information text should never be truncated.

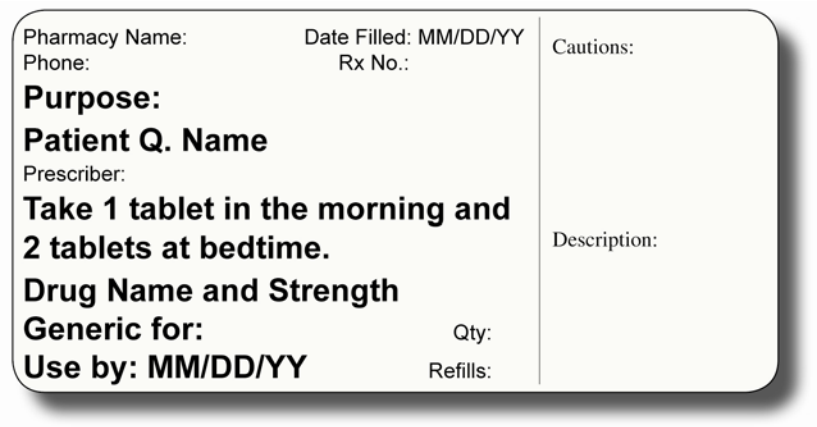
a. Patient name.
    i. Legal name of the patient. If patient is an animal, include the last name of the owner, name of the animal, and animal species.
b. Directions for use.
    i. The directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order.
        1. Boards of pharmacy and licensees should recognize that "take as directed" may not provide sufficient information for the appropriate use of the medication. "Take as directed" is appropriate when specific directions are included on a unit-of-use package or dispensed package or in situations when directions are not able to be included on the label and the pharmacist presents directions to the patient and documents that such directions were given. "Take as directed' should not be used in lieu of patient counseling.
        2. It is understood that prescription drug orders often do not include the indication for use.
    ii. Language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.
c. Drug name.
    i. Name of the drug.
    ii. If written for a brand name and a generic drug is dispensed, include phrase "Generic for [brand name]."
    iii. If a fixed combination generic product is dispensed, use the United States Pharmacopeia (USP) publication of Pharmacy Equivalent Names (PEN) abbreviation. If no PEN has been officially issued by the USP, label the medication secundum artem.
    iv. Include drug name suffixes, such as CD, SR, XL, XR, etc.
d. Drug strength.
    i. Strength of the drug.
e. "Use by" date.
    i. Date by which medication should be used; not expiration date of medication or expiration date of prescription.
    ii. Format as: "Use by: MM/DD/YY."

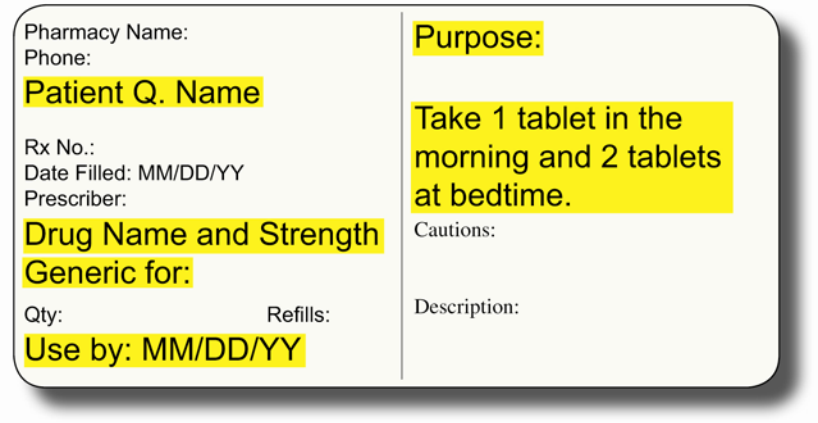
B. Important Information for Patients – Must appear on the label but should not supersede Critical Information for Patients.

a. Pharmacy name.
    i. Name of the dispensing pharmacy. Boards of pharmacy should recognize that some pharmacies "do business as" a name other than the corporate name.
b. Pharmacy telephone number.
    i. Phone number of the dispensing pharmacy. Recognizing that a central fill pharmacy may be involved in the filling process, boards of pharmacy should not require more than one telephone number on the label.

c. Prescriber name.
    i. Name of the prescriber.
    ii. Format – "Prescriber: [prescriber name]."
d. "Fill date."
    i. Date the prescription is dispensed, which will change with each subsequent refill. Format – "Date filled: MM/DD/YY."
    ii. The "fill date" and "use by" date should be the only dates appearing on the prescription label. Other dates often found on labels, such as the original and expiration dates of the prescription drug order can be misunderstood by patients and clutter the label with unnecessary information.
    iii. The term "fill date" should be defined in the *Model Act*.
e. Prescription number.
    i. Identifies the number of the pharmacy record under which the prescription information is recorded.
f. Drug quantity.
    i. Quantity of drug dispensed.
    ii. Format – "Qty: [number]."
g. Number of refills.
    i. Number of remaining refills.
    ii. Format – "Refills: [number remaining]" or "No refills," using whole numbers only and managing partial fills through the pharmacy recordkeeping system.
h. Product description.
    i. Written or graphic description of medication dosage form.
i. Auxiliary information.
    i. Auxiliary labels – information should be evidence based, standardized, and demonstrated to complement the prescription label.

Examples of compliant labels include the following:





Recommendation 3:

The task force recommends that NABP work with federal and state agencies and pharmacy stakeholders to advocate for and ultimately achieve changes in state or federal laws and regulations and industry standards to support a patient-centered label.

Background:

The task force recognized that Recommendation 2 represents a significant change in the philosophy of what defines a prescription label and the purpose of the prescription label. In some situations, this recommendation will be contrary to existing federal and state laws and regulations and industry standards. The *Model Act* cannot and is not intended to contravene state and/or federal laws or regulations. The task force understands this and supports NABP working with relevant agencies and organizations to allow the use of a patient-centered label.

Recommendation 4:

The task force recommends that the NABP Executive Committee approve amendments to the *Model Act* to note that the following additional data elements may appear on the prescription label:

- Bar codes
- Pharmacy address
- Pharmacy store number

Background:

The task force wanted to give states the option to allow pharmacies to include these elements on the label if they felt they were necessary.

Recommendation 5:

The task force recommends that NABP work with relevant organizations, including the American Medical Association, the Federation of State Medical Boards, and the Centers for Medicare and Medicaid Services (CMS), to require that medication indications be included on all prescriptions including but not limited to written and electronic prescription drug orders.

Background:

Task force members agreed that this item of information is vital for appropriate medication counseling. It was felt that this was a good time to approach CMS about the possibility of requiring prescribers to include such information in order to be reimbursed for their services.

Universal Medication Schedule White Paper

April 2Ø13

National Council for Prescription Drug Programs
924Ø East Raintree Drive
Scottsdale, AZ 8526Ø

Phone: (48Ø) 477-1ØØØ
Fax (48Ø) 767-1Ø42

NCPDP is a not-for-profit ANSI-accredited Standards Development Organization consisting of members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry. NCPDP standards have been named in HIPAA, MMA, and many other regulations.

Universal Medication Schedule White Paper
Version 1.Ø

NCPDP recognizes the confidentiality of certain information exchanged electronically through the use of its standards. Users should be familiar with the federal, state, and local laws, regulations and codes requiring confidentiality of this information and should utilize the standards accordingly.

NOTICE: In addition, this NCPDP Standard contains certain data fields and elements that may be completed by users with the proprietary information of third parties. The use and distribution of third parties' proprietary information without such third parties' consent, or the execution of a license or other agreement with such third party, could subject the user to numerous legal claims. **All users are encouraged to contact such third parties to determine whether such information is proprietary and if necessary, to consult with legal counsel to make arrangements for the use and distribution of such proprietary information**.

Published by:
National Council for Prescription Drug Programs

Publication History:
Version 1.Ø 2Ø13
Copyright © 2Ø13

All rights reserved.
Permission is hereby granted to any organization to copy and distribute this material as long as the copies are not sold.
National Council for Prescription Drug Programs
924Ø E. Raintree Drive
Scottsdale, AZ 8526Ø
(48Ø) 477-1ØØØ
ncpdp@ncpdp.org

Acknowledgements

The National Council for Prescription Drug Programs Work Group (WG 10) Professional Pharmacy Services and its Universal Medication Schedule Task Group would like to acknowledge and thank the Task Group members and other stakeholders that participated in the creation and review of this White Paper, including representatives from all facets of the pharmacy industry and regulatory bodies. For a listing of contributors, please see "*Appendix G. Contributors to this White Paper."*

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

TABLE OF CONTENTS

1. EXECUTIVE SUMMARY 6

2. PURPOSE 7

3. OVERVIEW 8

4. UMS RESEARCH 12

5. DISCUSSION 16

5.1 OPERATING ASSUMPTIONS/SCOPE 16
5.2 BACKGROUND OF LABEL INFORMATION 17
5.3 WHAT ARE THE BENEFITS AND CONSIDERATIONS OF USING UMS? 19
5.4 FORMAT AND TERMINOLOGY 21
5.5 TRANSLATION INTO OTHER LANGUAGES 22
5.6 CHALLENGES IN ADOPTION AND IMPLEMENTATION 25
5.7 ADOPTION AND IMPLEMENTATION RECOMMENDATIONS AND CONSIDERATIONS 25

6. CONCLUSION 27

APPENDIX A. MODEL STATE PHARMACY ACT AND MODEL RULES OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY AUGUST 2011 28

APPENDIX B. CALIFORNIA STATUTE 34

APPENDIX C. BEST PRACTICE RESEARCH 37

APPENDIX D. TARGET CLEARRX IMPLEMENTATION 42

FEATURES OF CLEARRX 43

APPENDIX E. NABP RESOLUTION 44

APPENDIX F. IMAGERY EXAMPLES 46

APPENDIX G. CONTRIBUTORS 49

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

Disclaimer

This document is Copyright © 2013 by the National Council for Prescription Drug Programs (NCPDP). It may be freely redistributed in its entirety provided that this copyright notice is not removed. It may not be sold for profit or used in commercial documents without the written permission of the copyright holders. This document is provided “as is” without any express or implied warranty.

While all information in this document is believed to be correct at the time of writing; the writers of this paper may review and possibly update their recommendations should any significant changes occur. This document is for educational and awareness purposes only and does not purport to provide legal advice. If you require legal advice, you should consult with an attorney. The information provided here is for reference use only and does not constitute the rendering of legal, financial, or other professional advice or recommendations by NCPDP. The listing of an organization does not imply any sort of endorsement and the NCPDP takes no responsibility for the products or tools.

The existence of a link or organizational reference in any of the following materials should not be assumed as an endorsement by the NCPDP.

1. EXECUTIVE SUMMARY

Universal Medication Schedule (UMS) is a methodology that simplifies medication administration instructions for the patient and / or their caregiver. The goal of UMS is to increase patient understanding and adherence of their medication instructions, thus resulting in improved health outcomes.

Two considerations were ever present in the development of this paper. One, the reason for moving to UMS is for the patient – to reduce potential errors and improve outcomes. Two, there is a limited ability to measure a hard return on investment. No studies have been done that have isolated the financial impact of UMS.

Currently, prescription administration instructions appear on the label in an inconsistent manner. Depending on the prescriber and the pharmacist, any of the following may be used, either as interpretation of "1 qd" or as a direct representation of what the prescriber communicated to the pharmacist:

- Take one tablet once daily.
- Take 1 tablet 1 time per day.
- Take one tablet each morning.
- Take one tablet every 24 hours.

Administration instructions using UMS are standardized to provide explicit timing with standard intervals (morning, noon, evening, bedtime):

- Take 1 pill in the morning.

The simplification of medication administration instructions should provide many benefits to patients, caregivers and healthcare providers, including increase in adherence and health for the patient, and efficiencies in the prescribing and dispensing of medications.

The authors researched best practices in the industry, the state of health literacy in the United States, prescription label requirements in individual states, recommendations from the National Association of Boards of Pharmacy, federal government requirements, chain pharmacy initiatives and published research concerning medication compliance and medication scheduling.

The authors have also taken into consideration the discussion that will inevitably surround the implementation of UMS into daily workflows of prescribers and pharmacists and attempted to practicably address those associated items.

The use of UMS will benefit the provider and the patient. NCPDP supports the use of UMS in all applicable situations.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

2. PURPOSE

This paper will introduce the concept of Universal Medication Schedule and discuss how it can be implemented, and ultimately presented to the patient, using NCPDP standards. The Universal Medication Schedule (UMS) is intended as an optimal way to convey prescription directions for use to the patient. NCPDP's electronic prescribing standard, the SCRIPT standard, will support the transmission of the UMS through the use of the Sig segment when an electronic prescription is sent from a prescriber to a pharmacy. The consistent and widespread use of these standards will assist patients in understanding and adhering to their medication regimen. As an example, instructions that indicate "take one pill in the morning and take one pill in the evening" are clearer than "take twice a day".

Understanding how patients use their prescription labels illustrates the need for additional clarity. A study performed by the VA National Center for Patient Safety found that only 56% of veterans surveyed confirmed their name on the prescription label and 55% confirmed the directions prior to each use.

The information contained in this paper will address the concept of "best practice", a history of UMS, a snapshot of health literacy in the United States, and an overview of prescription container label requirements. Also included are the benefits and considerations associated with the implementation of UMS.

The audience for this paper is health care providers; pharmacists; system/software vendors; informaticists; oversight bodies, such as boards of pharmacy and medicine; and patient advocates. NCPDP hopes these stakeholders, and others, acknowledge the importance of health literacy and the role that the UMS can play in improving medication adherence for all patients. In addition, it is envisioned that these stakeholders will eagerly and actively implement UMS into their operations and practices.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

3. OVERVIEW

Through its collaborative efforts with many organizations that are addressing issues of health literacy and patient safety, NCPDP has determined that the use of the Universal Medication Schedule (UMS) to convey Sig instructions for solid dosage forms has been convincingly shown to significantly improve an individual's ability to understand prescription instructions, properly dose medicines, and organize multi-drug regimens. Early evidence supports initial gains in medication adherence. Given the amount of evidence already available, NCPDP therefore recommends the UMS be adopted as a best practice when appropriate, regardless of dosage form.

"Best practice" is a term that does not yet have a standardized definition or legal set of qualifications related to patient-centered prescription labeling or the UMS concept. Most of the literature on the topic of best practices in the healthcare industry points to a relatively common idea that a best practice is one that has repeatedly demonstrated outcomes superior to any other comparable method. This practice or behavior should persist across settings or populations.

This definition is supported by the work of a number of different organizations. Examples include:

- The Department of Health and Human Services has said that a best practice demonstrates evidence of effectiveness and can be generalized to other populations and settings. [i]
- The National Registry of Evidence-Based Programs and Practices require a demonstration of positive outcomes in at least one experimental study which has been published in a peer-reviewed journal. [ii]
- The California Reducing Disparities Project identifies best practices by those that demonstrate both positive results and community consensus. [iii]
- The National Resource Center defines a Research Validated Best Practice as "a program, activity or strategy that has the highest degree of proven effectiveness supported by objective and comprehensive research and evaluation". [iv]

Despite the lack of official standards, some efforts have been made towards defining best practices in prescription labeling. In 2007, a research team led by faculty from Northwestern University devised the UMS to standardize and simplify medication instructions to support safe and effective prescription drug use. The UMS was reviewed and highlighted by both the Institute of Medicine (IOM) and the U.S. Pharmacopeia (USP) as a health literacy 'best practice', and the state of California passed legislation recommending the use of the UMS with drug labeling. Simply put, the UMS standardizes the prescribing and dispensing of medicine by using health literacy principles and more explicit times to describe when to take medicine (morning, noon, evening, bedtime). This eliminates variability found in the way prescriptions are written by prescribers and transcribed by pharmacists onto prescription container labels.

The *Journal of Young Pharmacists* stated that evidence-based best practices for prescription container labeling exist, and that they include a Universal Medication Schedule. The U.S. Pharmacopeial Convention has released standards surrounding prescription container labeling which include a patient-centered, low health literacy

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

perspective. The UMS concept itself was vetted, and a pending recommendation has been issued by the USP Drug Labeling Advisory Panel to incorporate it as recent studies are summarized.

According to the article in the *Journal of Young Pharmacists* in 2010: [v]

> "There is evidence available to detail "best practices" for improving dosage or usage instructions written by the prescribing physician and the format and content of prescription medication container labels designed by the dispensing pharmacy. [1] The use of standard and more explicit dosage or usage instructions can improve patients' functional understanding of how and when to take a medicine. Evidences are available for best practices in labeling format and content, such as increasing font size, using clear and simple language, using headers, and placing a more appropriate emphasis on organizing label content around what is most important for patients such as drug name, dose, dosage or usage instructions, patient name, doctor name, quantity, refill information, and provider content such as pharmacy name, logo and national drug code number should be in optimal font size. A complete list of evidence-based, recommended standards for format, content, and instruction is as follows:
>
> - Use explicit text to describe dosage and interval in instructions.
> - **Use a universal medication schedule (UMS) to convey and simplify dosage and use instructions.**
> - Organize labels in a patient-centered manner.
> - According to need, include indication for use.
> - Simplify language, avoiding unfamiliar words or medical jargon.
> - Improve typography, use larger, sans serif font.
> - When applicable, use numeric versus alphabet characters.
> - Use typographic cues (bolding and highlighting) for patient content only.
> - Use horizontal text only.
> - Use a standard icon system for signaling and organizing auxiliary warnings and instructions."

There are increased efforts to simplify language in a variety of settings. Many of these initiatives are related to health care and will likely have profound impact on the US health care system.

- The Department of Health and Human Services' 2010 National Action Plan to Improve Health Literacy, which is grounded on two principles; that all people are entitled to health information that helps them make informed decisions; and, that healthcare must be provided in a way that is easy to understand and promotes health. [vi]

- The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (NABP Model Act) identify critical and important information for patients that must appear as well as additional information that may appear

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

on all prescription labels. [vii] See "*Appendix A. Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy August 2011"*.

- The Joint Commission has begun considering certain new "Patient-Centered Communication Standards & EPs" as part of its accreditation process. Among other things, these standards may require hospitals to identify and meet their patients' need for plain language communication. (see, e.g., Standard PC.02.01.21) [viii]

- Under the "Value Based Purchasing" regulations promulgated by CMS pursuant to the 2010 Patient Protection and Affordable Care Act (ACA), providers' reimbursement levels are adjusted according to the quality of care they provide. Quality is measured in a variety of ways, including patients' subjective assessment of the quality of the communication they receive from providers. This provides an incentive to use plain language for effective communication. [ix], [x]

- HealthyPeople 2020 is the continuation of efforts begun several decades ago to improve the health of all Americans. The project looks at over three dozen different areas of health. Of particular interest is the goal related to health literacy.

  HC/HIT-1: (Developmental) Improve the health literacy of the population.

  - HC/HIT–1.1 Increase the proportion of persons who report their health care provider always gave them easy-to-understand instructions about what to do to take care of their illness or health condition. [xi], [xii]

- The National Patient Safety Foundation indicates that studies show that people who understand health instructions make fewer mistakes when they take their medicine or prepare for a medical procedure. They may also get well sooner or be able to better manage a chronic health condition.[xiii]

- The VA National Center for Patient Safety (NCPS) conducted a study that identified safety vulnerabilities with prescription labels used at the VA. A key finding was that there was a discrepancy in the placement of information deemed important to the patient as opposed to what the pharmacist felt was important. As a result of their study, a new patient-centric label design will likely be introduced nationally in 2013. [xiv]

Although the above do not establish mandatory requirements for every pharmacist and provider, they make it clear that the importance of plain language has been accepted by policy makers at the highest levels. This is further reflected in an article recently published, which was authored by senior federal policy makers:

> "According to the Affordable Care Act of 2010, health literacy is the capacity to obtain, communicate, process, and understand basic health information and services to make appropriate health decisions. An increasing body of research links health literacy with health outcomes. In particular, limited health literacy

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

> leads to a cascade of suboptimal outcomes, including reduced ability to interpret labels and health messages*, limited ability to take medications appropriately* (emphasis added), lower likelihood of receiving preventive care, more hospitalizations, greater use of emergency care, and—among elderly people—worse overall health status and higher mortality rates. [xv]

Please see "*Appendix C. BEST "* for more information regarding best practices.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

4. UMS RESEARCH

In a recent clinical trial led by Northwestern University's Feinberg School of Medicine (PI: Michael Wolf, PhD MPH), the UMS was randomly administered to a cohort of 425 patients from eight community health centers outside of Washington, D.C. – all of whom had Type 2 diabetes and hypertension. [xvi] Patients' ability to correctly demonstrate proper, safe use of their medications significantly increased over nine months compared to a usual-care arm that received medicines with instructions that followed a typical standard from a national pharmacy chain. At three months, those receiving the UMS had significantly greater adherence to their regimen as measured by pill count.

The Universal Medication Schedule (UMS)

In the context of ambulatory care, patients assume primary responsibility for safely and appropriately administering prescription regimens. Yet the expectations placed on patients by the healthcare system for medication-related tasks are considerable.[21] Multiple steps need to occur for patients to gain the benefits of drug therapy while minimizing the risks of adverse drug events. This includes: 1) having a functional understanding of medications and their proper dosing, 2) consolidating the regimen to the most efficient daily schedule, 3) problem-solving around regimen use as changes occur, and 4) repeating the behaviors over time.

Studies have repeatedly documented that patients have problems performing these routine tasks.[7,12,13,24] This is alarming, as adults are being prescribed increasingly complex medication regimens.[25] Over the past decade, the percentage of Americans who take 5 or more prescription drugs has almost doubled; nearly 40% of older adults use at least 5 prescription medications.[25] While long-term adherence is essential to reap health benefits, all forms of non-adherence - failure to fill new prescriptions, incomplete use, and premature discontinuation - are common.[26-31] Non-adherence has been linked to greater morbidity and mortality from chronic conditions. Complex drug regimens also raise the risk for errors and adverse drug events, of which many are either preventable or ameliorable.[32-37] The 2006 IOM report, *Preventing Medication Errors*, suggests 1.5 million preventable adverse drug events occur annually, with a third occurring in outpatient settings.[21]

In the Veterans Administration study, 446 veterans were asked how many tablets per day they would take when given a prescription with the directions to "Take one tablet daily with meals". Only 42% of the respondents identified the correct answer. The VA NCPS has received numerous reports of medication mishaps caused by a lack of understanding by veterans on how to accurately adhere to the medication regimen as prescribed by their prescriber.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

Figure 1. Examples of Patients Dosing a 7 drug regimen.

Hour	UMS* Regimen	Patient #1	Patient #2	Patient #3	Patient #4
5:00 AM					
6:00 AM					
7:00 AM					
8:00 AM					
9:00 AM					
10:00 AM					
11:00 AM					
12:00 PM					
1:00 PM					
2:00 PM					
3:00 PM					
4:00 PM					
5:00 PM					
6:00 PM					
7:00 PM					
8:00 PM					
9:00 PM					
10:00 PM					
11:00 PM					
Doses	**4**	**8**	**10**	**12**	**14**

Drug A = ; Drug B = ; Drug C = ; Drug D = ; Drug E = ; Drug F = ; Drug G =

Limited Literacy. Numerous studies have found limited literacy to be significantly associated with patients' poorer recall of medication names and indications, inadequate understanding and demonstrated use of prescription instructions and precautions.[11-13,38-42] The study team at Northwestern recently found that patients also may overcomplicate multi-drug regimens by taking medicine more times a day than necessary.[7] Lower literate patients were at greater risk for not consolidating medications [M=6.1 times/daily (SD=1.8); adequate literacy M=5.8 (SD=1.6) vs. low literacy M=6.5 (SD=2.4), p=0.03; see **Figure 1** for examples]. While studies have been inconclusive as to whether lower literacy is associated with non-adherence,[43-46] the evidence clearly suggests that patients with lower literacy are more likely to misunderstand prescription instructions, putting them at greater risk for poor adherence.[24,47]

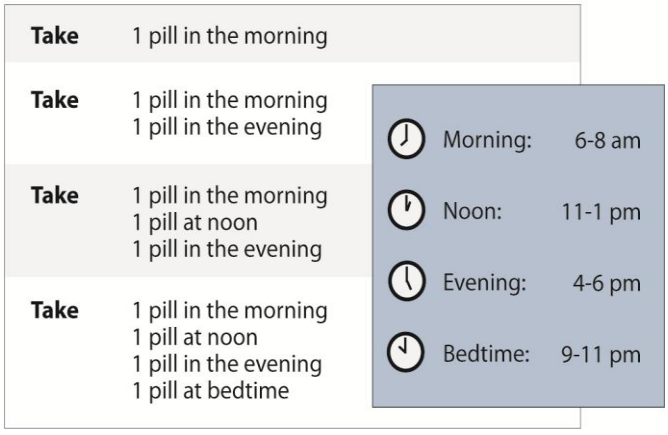
Limited English Proficiency. Limited English Proficiency (LEP) is common in the US.[48] Research on language access in healthcare indicates serious barriers exist.[48-53] Interpreters are rarely available to aid prescribers and pharmacists in counseling LEP patients on safe prescription use, instructions are frequently unavailable in non-English languages, and multilingual materials are often inaccurate and poorly translated.[54-57] These barriers have been shown to have a deleterious effect on LEP patients' prescription use.[14,15,58] Wilson, *et al*. conducted a survey among 1,200 LEP adults speaking one of 11 languages in California.[15] In this study, more than one-third of LEP

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

adults reported confusion about how to take medication, 42% stated that they encountered difficulties interpreting prescription container labels, and 16% reported experiencing an adverse reaction due to this confusion. Similarly, Sleath *et al*. conducted interviews with Spanish-speaking, Latino adults in North Carolina and found that 58% reported difficulty understanding English prescription instructions as a primary barrier to safe use.[59] This study found that less than a third of LEP Latinos consistently received prescription labels, verbal counseling, or print materials in Spanish.

Health System Barriers. Individual barriers to proper prescription use, such as limited literacy and LEP, are exacerbated (if not the result of) health system barriers.[60] For instance, multiple studies have shown prescribers often fail to discuss with patients basic information around the safe use of prescribed medicines, let alone other relevant concerns (i.e. cost of medications).[61-65] Furthermore, print prescription information is rarely distributed at the point of prescribing. Evidence also suggests that pharmacists equally fail to counsel patients on safe and appropriate prescription use.[61,63,64] While print materials (prescription labels, warning stickers, Medication Guides, patient leaflets) are provided by pharmacies, these materials are often poorly written and confusing.[66-69] In addition, considerable variability has been identified across this process.[4,5,70] Bailey et al. found prescription instructions written by prescribers to be highly variable,[4] and Wolf et al. reviewed prescription instructions printed by multiple pharmacies and also found that pharmacy translations often deviated from prescribers' instructions.[5] *An individual's ability to organize and properly dose out multiple medications becomes increasingly complex when factoring in such variability and poor quality in how prescriptions are written by prescribers and translated by pharmacies.*

Figure 2. Universal Medication Schedule (UMS)



The IOM 2008 report *Standardizing Medication Labels* recognized the need for setting standards within prescribing and dispensing practices to promote safe and accurate medication use for patients.[2] Members of the Northwestern research team presented the concept of the universal medication schedule (UMS) in this report. As approximately 90% of prescriptions are taken four times a day or less, the UMS was specifically

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

proposed to establish four standard time intervals (morning, noon, evening, bedtime) for the prescribing and dispensing of medicine. This would remove the current variability found in the manner in which prescriptions are written by prescribers and transcribed by pharmacists.[4,5,70] All prescriptions would instruct patients to take their medicine at one or more of these specified times, and this would be described in a single, standardized fashion (**Figure 2**). Beyond standard times, UMS instructions also use simplified text, numeric characters instead of words to detail dose (i.e. 1 instead of 'one'), and 'carriage returns' to place each dose on a separate line to clearly identify every time period a medicine is to be taken.[7]

There is strong evidence supporting the UMS.[2,7,9,10] Among a multi-site sample of 500 primary care patients, Wolf *et al*. found those receiving UMS instructions versus a current standard were 33% more likely to accurately interpret prescription instructions.[10] Lower literate adults were also more likely to correctly comprehend the UMS instructions. These findings were replicated among 94 patients in Cork, Ireland, and also among 203 LEP patients in Chicago and San Francisco.[71,72] Earlier studies also found the use of more explicit time intervals such as those used in the UMS approach improved patient understanding and reduced medication errors.[10,73]

Our team's most recent efficacy trial of the UMS also found that those receiving UMS instructions were significantly more likely to consolidate prescription regimens to fewer times per day compared to those receiving standard instructions.[74] We have early evidence from our ongoing AHRQ/NIH-funded trial (885 English and Spanish-Speaking patients currently enrolled) testing the UMS at the point of pharmacy practice that patients may prefer UMS instructions.[16] *In reviewing the body of evidence on the UMS, The IOM issued favorable findings on the concept, the USP and American College of Physicians Foundation have recommended it as a standard, and the state of California passed legislation stating the UMS as a best practice for drug labeling.*[1-3]

Limitations of UMS: What is known and not known

At present, repeated studies among diverse patient populations have demonstrated *efficacy* and *effectiveness* to the outcomes of improved comprehension, consolidation of regimens, and early evidence also highlights a two-fold improved rate of adherence as measured by pill count among diabetic patients receiving care at safety net settings (personal correspondence, Michael Wolf, August 2012). Whether or not improvements can be documented towards clinical outcomes is not known, yet that also should not be necessary. The UMS is meant to more clearly state instructions for multi-drug regimens, and benefits to adherence might be expected, however longer-term benefits and improvements in biomarkers are subject to many other barriers to proper self-care behaviors.

What remains to be tested, to complete the UMS concept, is further testing of the UMS for non-pill form drugs (liquids, inhalers, injectables, etc.) This work is under way with support from The California Healthcare Foundation. The current UMS has already been translated from English to Spanish, Chinese, Korean, Vietnamese, and Russian. Further language translations should be explored, for all instructions.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

5. DISCUSSION

5.1 OPERATING ASSUMPTIONS/SCOPE

The focus of this paper is the information presented to the patient as a result of the prescription sent by the prescriber and received by the pharmacy. If UMS is used in the transmission of the electronic prescription, it must be displayed to both the sender and the receiver. The NCPDP Universal Medication Schedule Task Group acknowledges there may be confusion if the patient has additional information (monographs, auxiliary labels, previous prescription containers, etc.) that contain information that does not exactly align with the UMS. There will be a known transition period during implementation where prescribers and pharmacists must be prepared to address any questions or confusion with their patients.

While there does not appear to be any reason to believe that the UMS concept cannot be successfully applied to other dosage forms, research has not yet been published that specifically addresses the use of UMS on non-solid dosage forms and non-daily frequencies.

The simplicity of UMS can be augmented with additional instructions, such as “take with meals”. The use of UMS will still require review by providers to handle unique situations, such as non-traditional work/sleep schedules; i.e. those patients who may work overnight.

The UMS offers more explicit patient-centric dosing times and better consolidated regimens and should be incorporated into medication therapy management and counseling. Drug interactions **within** a regimen need to be addressed by the provider.

While UMS is focused on the Sig, the task group recognizes that a transition to UMS should occur in concert with the development of a patient-centric label. Operational issues regarding the size and format of any new label design in addition to the practical aspects of implementing it will need to be addressed.

Legislation enacted in California in 2008 required the California State Board of Pharmacy to develop requirements for patient-centered labels to aid patient adherence to their prescribed medication therapy. Over a period of two years, the board surveyed consumers, pharmacists and others as well as convened hearings to develop the requirements, which took effect in January 2011. These requirements, establishing parameters for the first patient-centered labels in the US, specify that at least 50% of every prescription container label be dedicated exclusively to only the following elements: patient name, drug name and strength, directions for use, and if on the prescription document, the purpose of the medication. This information was deemed most important to patients. The dedicated section must be printed in at least a 10 point, sans serif font, but must be provided to the patient upon request in a 12 point font. The label must present all other required information on the label outside this dedicated space in a manner that does not detract from the patient-centered and clustered information.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

Within one year after implementation, surveys of the labels in use conducted by the Board of Pharmacy during inspections indicated that 60% of all labels were being printed directly in 12 point font, with another 25% of the labels being printed in both 10 point and 12 point fonts, and only 15% being printed (at least initially) in 10 point font.

Other elements of California's requirements establish standardized directions for use to be printed on the label "when appropriate" based on the pharmacist's judgment. These standardized directions, developed by UMS researchers Dr. Mike Wolf and Dr. Stacey Bailey, conform to UMS principles to maximize patient comprehension. The standardized directions have been translated into five languages to permit widespread availability of translations on prescription containers to limited English speaking patients.

5.2 BACKGROUND OF LABEL INFORMATION

What is perhaps not widely known or well understood is the process that results in the information printed on a prescription container label.

The information below, based on the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* (*Model Act*) does not provide greater specificity regarding "Directions for Use", such as how the medication is to be administered, or the timing associated with the medication. As such, there is as much variety in "directions for use" as there are prescribers. See "*Appendix A. Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy August 2011"*.

The state of California has added language in support of standardized directions to provide consistent directions for the patient and to enable accurate translation of the directions into the patient's preferred language. See "*APPENDIX B. California Statute*".

Additional requirements can be found in the Federal Food, Drug and Cosmetic Act, Subchapter V, Part A, Sections 352 and 353. Requirements specific to prescriptions containing controlled substances can be found in § 290.2. [xvii]

Laws vary from state to state, but generally, the following information is required on each prescription label.

- **Patient Name***
- **Directions for use - *directions for use as indicated by the prescriber****
- **Drug Name***
- **Drug Strength***
- "use by" date
- Important information for patients
    - pharmacy name;
    - pharmacy telephone number;
    - prescriber name;
    - "fill date;"
    - prescription number;
    - drug quantity;

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

- number of remaining refills;
- written or graphic product description;
- auxiliary information;
- any cautions and other provisions which may be required by federal or state law.

The following additional information for Patients – may appear on the label:

- bar codes;
- pharmacy address; and
- store number.

*** Items** that are considered critical information by the US Pharmacopeial Convention:

Emphasize instructions and other information important to patients. Prominently display information that is critical for patients' safe and effective use of the medicine. At the top of the label specify the patient's name, drug name (spell out full generic and brand name) and strength, and explicit clear directions for use in simple language.

The prescription directions should follow a standard format so the patient can expect that each element will be in a regimented order each time a prescription is received. Other less critical but important content (e.g., pharmacy name and phone number, prescriber name, fill date, refill information, expiration date, prescription number, drug quantity, physical description, and evidence-based auxiliary information) should not supersede critical patient information. Such less critical information should be placed away from dosing instructions (e.g., at the bottom of the label or in another less prominent location) because it distracts patients, which can impair their recognition and understanding."

Simplify language. Language on the label should be clear, simplified, concise, and familiar and should be used in a standardized manner.

Give explicit instructions. Instructions for use (i.e., the SIG or signatura) should clearly separate the dose itself from the timing of each dose in order to explicitly convey the number of dosage units to be taken and when (e.g., specific time periods each day such as morning, noon, evening, and bedtime). Instructions shall include specifics on time periods. Do not use alphabetic characters for numbers. For example, write, "Take 2 tablets in the morning and 2 tablets in the evening" rather than "Take two tablets twice daily."

Address limited English proficiency. Whenever possible, the directions for use on a prescription container label should be provided in the patient's preferred language.

In November 2012, USP published a new General Chapter <17> Prescription Container Labeling in USP 36–NF 31. [xviii] The standard provides, for the first time, a universal approach to the format, appearance, content and language of instructions for medicines in containers dispensed by pharmacists. The new USP general chapter offers specific

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

direction to label manufacturers, pharmacies and prescribers on how prescription labels should be organized in a "patient-centered" manner that reflects how most patients seek out and understand medication instructions.

Patients' best (and often only) source of information regarding the medications they have been prescribed is on the prescription container label. Although other written information and oral counseling sometimes may be available, the prescription container label must fulfill the professional obligations of the prescriber and pharmacist. These obligations include giving the patient the most essential information needed to understand how to use the medication safely and appropriately and to adhere to the prescribed medication regimen.

The USP effort to create these new standards developed from an Institute of Medicine (IOM)-led initiative to improve health literacy, which is defined as the degree to which people can obtain, process and understand the basic health information and services they need to make appropriate health decisions. According to IOM, 77 million Americans have limited health literacy, and a majority of Americans have difficulty understanding and using currently available health information and services. At a 2007 IOM workshop on Standardizing Medication Labels: Confusing Patients Less, USP Chief Executive Officer Roger L. Williams pledged that the organization would initiate work on a standardized prescription container label. The resulting standard was finalized by the USP Nomenclature, Safety, and Labeling Expert Committee, which is chaired by Thomas Reinders, Pharm.D. The standard was developed by experts in patient safety, health literacy, pharmacy, medicine, human factors research and labeling technology. Key areas covered in General Chapter <17> include organizing the label in a patient-friendly way, using explicit language to describe dosages and intervals, improving readability with clear formatting, including "purpose for use" (e.g., "for high blood pressure") and addressing those with visual impairments and those with limited English comprehension.

Enforcement of the standard will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations—similar to USP standards for sterile and non-sterile pharmaceutical compounding, both of which are widely recognized by states. At its 2012 annual meeting, the National Association of Boards of Pharmacy passed a resolution supporting state boards in requiring a standardized prescription container label. [xix]

The efforts of USP and NABP are intended to provide a standard patient centered prescription label that will be consistently applied nationally. More information is available at "*Appendix E. NABP Resolution".*

5.3 WHAT ARE THE BENEFITS AND CONSIDERATIONS OF USING UMS?

It is anticipated that the use of UMS will not interfere with existing professional practice or communications.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

Impact to the patient/caregiver:

- Increases understanding by simplifying the medication regimen.
- Simplifies the use of multiple medications.
- Inherent assumption that simplification and increased understanding will improve adherence and health outcomes.
- Provides additional opportunities for prescribers and pharmacists to communicate with the patient about the patient's regimen.

Impact to the pharmacist/pharmacy team:

- Improves productivity, accuracy and workflow efficiencies due to standardization.
- Provides additional opportunities for counseling (as a result of staff availability from increased productivity/improved workflows) which may increase patient loyalty.
- Standardized content may ease translations to other languages.
- Increases interoperability when exchanging information across systems.
- Greater patient adherence likely leads to more consistent and regular refill schedule.
- Continued ability to exercise professional judgment when communicating prescriber's instructions or intent to the patient/caregiver. This includes the ability to support medication administration schedules in facilities.
- Greater clarity in the Sig (as received from the prescriber) may reduce the need for additional verification.

Impact to the Prescriber:

- Reduces calls to the prescriber for clarification based on improved patient understanding of medication.
- While all patients can benefit from the use of UMS, there are care settings that may see greater impact such as federally qualified health centers, community clinics, geriatric practices, etc.
- Increases productivity efficiencies by using UMS rather than adding clarification to Sig.
- Impacts a variety of quality of care programs that affect prescribers including the Physician Quality Reporting System of CMS (Centers for Medicare & Medicaid Services). The measures reported by prescribers can impact reimbursement levels and patient satisfaction scores. As stated above, the Value Based Purchasing Regulations allow for provider reimbursement levels to be adjusted based upon the quality of care provided.
- Offers support for patient engagement measures under Meaningful Use Stage 2 by creating and transmitting prescription instructions using UMS and making that available to patients.
- New reimbursement models in the private sector, such as Accountable Care Organizations (ACO) also consider quality of care and patient outcomes measures when determining reimbursement agreements.
- Increases interoperability when exchanging information across systems.
- System modifications to support UMS or convert existing Sig "favorites" may require additional financial investment.
- May have to change prescribing practices depending on level of system modification that is completed. (i.e., user interface and practice).

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

While the industry does not consistently track who actually picks up a prescription, there are various reports indicating that anywhere from 20%-60% of prescriptions are delivered to someone other than the patient. Given this, having easily understandable dosing information included on the prescription is incredibly important. As the industry considers the changing demographics of the American population, it is reasonable to presume that there will be more and more situations where there is an intermediary between the pharmacy and the patient.

With adoption and implementation of UMS, it is possible that EMRs and pharmacy systems will be able to view a patient's chronic medication regimens by day/week/month, rather than by medication. Such a view can assist with patient counseling and medication reconciliation resulting in improved adherence and outcomes.

The National Consumers League has launched a medication adherence campaign, "Script Your Future", to assist patients with managing their medication regimens. The campaign focuses on providing tools to assist patients in remembering to take their medications as instructed. [xx]

5.4 FORMAT AND TERMINOLOGY

Implementing UMS forces the industry to revisit discussions and decisions related to the format and terminology used on patient prescription labels. The state of California has been at the forefront of moving to a patient-centric label, requiring many of the elements outlined as part of the Model Act and adding additional requirements.

Patients are comfortable with the term "pill", yet many containers are labeled with "tablet", "tab", "capsule", "cap". While prescriptions may specify the actual dose form, the pharmacist should continue to have the discretion to provide the patient with the information that is most readily understood.

Because everyone processes information differently, there is likely value in adding visual images to the label to improve patient understanding. A study published in 2008 found a significant reduction in medication dosage errors when pictograms were used. [xxi]

> "Medication counseling using a plain language, pictogram-based intervention resulted in fewer medication-dosage errors (5.4 percent versus 47.8 percent) and greater adherence, compared to standard medication counseling (38 percent versus 9.3 percent)".

According to the International Pharmaceutical Federation, "pictograms give health professionals a means of communicating medication instructions to people with no common language and/or who may be illiterate. Pictograms may also be used for those who have slight cognitive impairment or difficulties seeing such as the elderly."

The same type of simple imagery could be added to prescription labels. See "*Appendix F. Imagery Examples*".

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

Using icons (and pictograms) is recommended only when proven through testing to improve consumer and patient understanding beyond simple explicit text alone.

Research shows that "not all of the patient-centered icons were effective at improving comprehension beyond the revised text. In particular, a few of the icons provided abstract imagery for messages that were more difficult to visually depict in such a small size. Given the limited space for content on prescription drug containers, it would be helpful to include only those icons that have been shown in consumer testing to significantly improve comprehension beyond simplified text alone." [xxii]

Another recommendation from the research suggests that patients better understand how to take their medicine when the information is separated with each timing segment on a separate line.

As an example, instead of "Take two tablets three times daily":

Take 2 pills in the morning,
2 pills at noon, and
2 pills in the evening.

5.5 TRANSLATION INTO OTHER LANGUAGES

Health literacy, especially among those with limited English proficiency (LEP), is a widely documented issue. Providing oral and/or written information in a patient's primary language is more likely to lead to greater comprehension, especially for those with limited health literacy . Improved comprehension can result in more successful adherence to medication regimens.

According to the 2010 Census,[xxiii] LEP individuals accounted for 25.2 million, or nine percent, of the US population over age 5. This reflects a growth of 80 percent in the prior 20 years. Of all people who speak a language other than English at home, about 66 percent speak Spanish. In 2010, five languages – Spanish, Chinese, Vietnamese, Korean and Tagalog – were spoken by 79 percent of all LEP individuals.

Given that approximately four billion prescriptions are filled each year, nearly 360 million are filled by those with LEP. Using the information presented earlier regarding LEP, it can be extrapolated that for approximately 120 million prescriptions, there is confusion about how to take the medication; that for approximately 50 million prescriptions, there is difficulty in interpreting the container label and over 19 million patients experienced an adverse reaction due to this confusion.

Providing consistent, structured terminology for patient instructions will likely ease translation efforts. Some translations using UMS are available in Chinese, Korean, Russian, Spanish and Vietnamese through the California Board of Pharmacy. [xxiv] More information on translation guidelines can be found in the "Toolkit for Making Written Material Clear and Effective", as published by CMS. [xxv]

It should be noted that several states have requirements related to translations of prescription labels, and other items. Translations can occur via printed materials or with

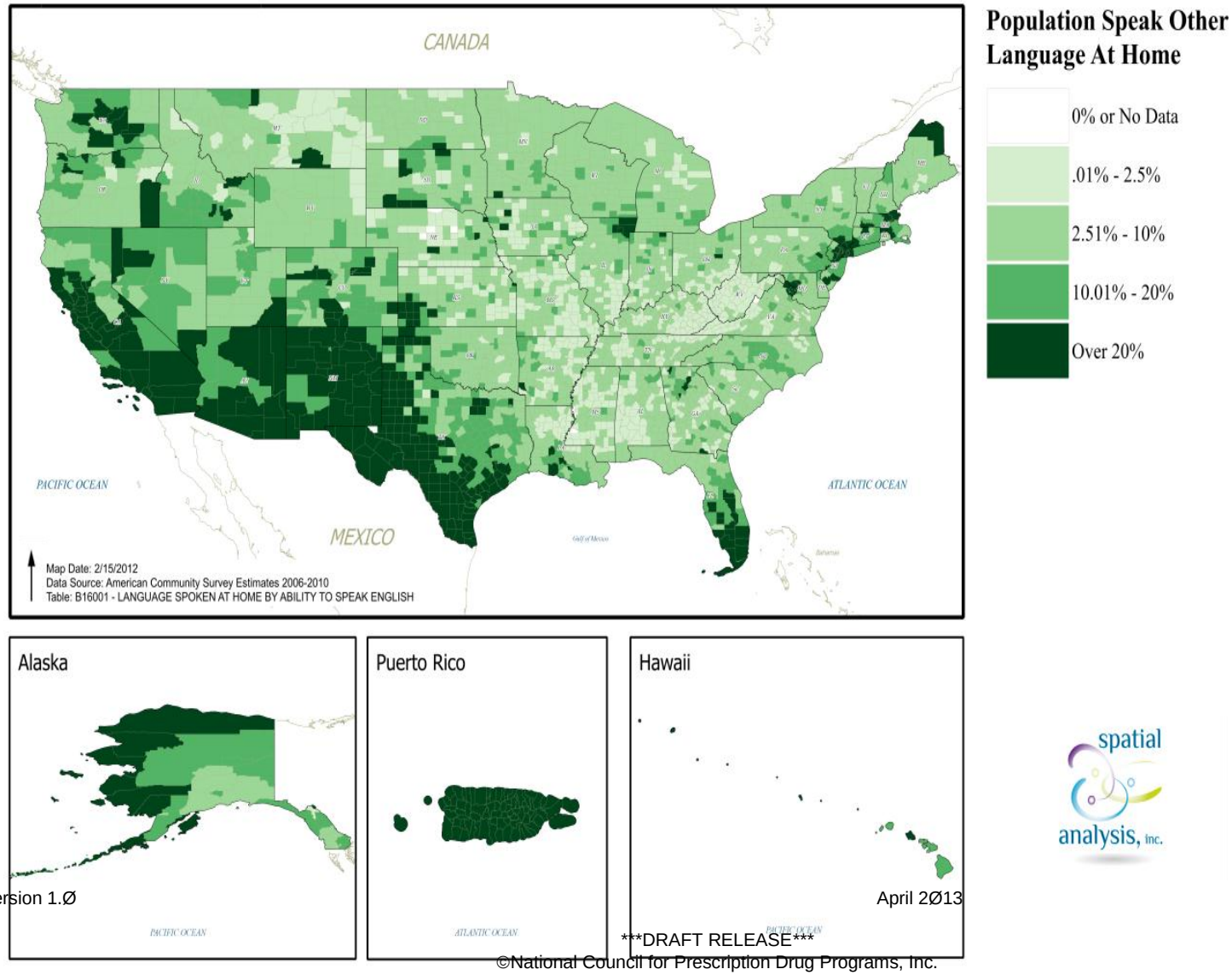
DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

the use of interpreters. New York's requirements, as an example, are specific to pharmacies with a minimum of eight locations. The law requires that pharmacies provide free interpretation and translation services to customers with limited English proficiency (LEP) who request the services or fill a prescription that indicates that the customer is LEP. [xxvi]

The National Conference of State Legislatures has tracked initiatives at the state level to address medication errors. [xxvii]

The map below provides an illustration of the US population who speak a language other than English at home.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.



DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

5.6 CHALLENGES IN ADOPTION AND IMPLEMENTATION

As with any change, adoption and implementation of UMS will present stakeholders with challenges. Among the challenges to be considered are:

- Capacity of industry to implement in light of other activities, i.e. new and existing regulatory requirements, corporate initiatives, etc.
- Timing of implementation by trading partners – how is patient impacted?
- Changes in workflow process.
- Enabling the technology to support consistent execution and delivery.
- Role of professional organizations, state boards (pharmacy, medical, dental, etc.).
- Cost effectiveness.

5.7 ADOPTION AND IMPLEMENTATION RECOMMENDATIONS AND CONSIDERATIONS

Prescribers and dispensers are highly encouraged to begin incorporating UMS into their practices. With the industry's transition to NCPDP SCRIPT version 10.6 for electronic prescribing, the use of UMS can be easily accomplished by leveraging the features that are included.

Adopting the use of UMS concurrently with the adoption of SCRIPT 10.6 will allow users to leverage the efforts already planned to achieve the additional benefit of UMS. If users will be including the Structured Sig in their 10.6 implementation, then incorporating UMS can be readily accomplished. Even if users are not planning to use the Structured Sig, existing Sig strings in EMR or pharmacy management systems can be mapped to UMS.

Items to consider when implementing UMS:

- Community collaboration – ensuring that all community stakeholders (prescribers, pharmacies and payers) understand the timing of the upcoming changes and the implications for all involved.
    - The general consensus among the task group is that the "rip the bandage" approach may be the most effective, as the change would be made overnight, not in phases. This may or may not work for all stakeholders, depending upon their service area, and the readiness of their trading partners.
    - Identify opportunities to share implementation experiences with others.
- Communication plans, for internal (employee) and external (patient/customer/caregiver) recipients.
    - Opportunity to increase professional satisfaction via enhanced patient communication tools.
    - One chain saw great success with the use of counter mats when they introduced a new bottle and label design. The mat allowed for easy, comprehensive reference when pharmacists were counseling patients.
- Other related changes that will be visible to the patient

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

  - Conversion from APAP to acetaminophen
  - Recommendations from USP Chapter 17
- Contractual impacts
  - Review trading partner agreements to determine if:
    - Amendments are needed to support use of UMS.
    - Transition to UMS is included in vendor system support.
    - Notice is required to be given to third party payers.
  - Identify opportunities to share implementation experiences with others.
- Workflow changes – as with any system enhancement, project teams will need to consider associated workflow changes.
  - Patient education opportunities at the prescriber's office or pharmacy.
  - Increased automation of label generation at the point of dispensing.
- Measurement – items that might be measured to demonstrate the impact of implementing and using UMS. Depending on what information is currently measured, isolating the impact of UMS may be difficult.
  - Patient/employee satisfaction scores
  - Call volume/clarification contacts
  - Errors
  - Adherence rates
  - Outcomes; perhaps even re-admission rates
  - Opportunities to improve (identified during implementation)

Throughout its discussions, the task group acknowledged two considerations. One, the reason for moving to UMS is for the patient – to improve outcomes and reduce potential errors. Two, the ability to measure a hard return on investment is limited. No studies have been done that have isolated the financial impact of UMS.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

6. CONCLUSION

This paper explains the case for the industry to adopt the Universal Medication Schedule (UMS), a methodology that simplifies medication administration instructions for the patient and / or their caregiver, as a best practice. Use of UMS has the potential to improve patient care and increase positive outcomes. A recent study showed that patients receiving UMS instructions were 33% more likely to accurately interpret prescription instructions.

Use of UMS provides many benefits to patients/caregivers, pharmacists and prescribers, including:

- Increase in consistent patient understanding of and adherence to medication regimens.
- Simplification of the dosing regimen when using multiple medications.
- Standardization of dosing regimens will likely result in enhanced pharmacist and prescriber productivity, accuracy and workflow efficiencies.
- Ease of translation to other languages.

The adoption and incorporation of UMS into health care practice presents a significant opportunity for the industry to improve patient safety, promote better quality of care, and ensure more cost effective use of health care resources.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

APPENDIX A. MODEL STATE PHARMACY ACT AND MODEL RULES OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY AUGUST 2011

Section 3. Pharmacy Practice.

(a) Prescription Drug Order

A Prescription Drug Order shall contain the following information at a minimum:

(1) full name, date of birth, and street address of the patient;
(2) name, prescribing Practitioner's license designation, address, and, if required by law or rules of the Board, DEA registration number of the prescribing Practitioner;
(3) date of issuance;
(4) name, strength, dosage form, and quantity of Drug prescribed;
(5) directions for use;
(6) refills authorized, if any;
(7) if a written Prescription Drug Order, prescribing Practitioner's signature;
(8) if an electronically transmitted Prescription Drug Order, prescribing Practitioner's electronic or digital signature;
(9) if a hard copy Prescription Drug Order generated from electronic media, prescribing Practitioner's electronic or manual signature. For those with electronic signatures, such Prescription Drug Orders shall be applied to paper that utilizes security features that will ensure the Prescription Drug Order is not subject to any form of copying and/or alteration.

(e) Labeling

(1) All Drugs Dispensed for use by inpatients of a hospital or other health care facility, whereby the Drug is not in the possession of the ultimate user prior to Administration, shall meet the following requirements:
    (i) The label of a single-unit package of an individual-dose or unit-dose system of packaging of Drugs shall include:
        (A) the nonproprietary or proprietary name of the Drug;
        (B) the route of Administration, if other than oral;
        (C) the strength and volume, where appropriate, expressed in the metric system whenever possible;
        (D) the control number and expiration date;
        (E) identification of the repackager by name or by license number shall be clearly distinguishable from the rest of the label; and
        (F) special storage conditions, if required.
    (ii) When a multiple-dose Drug Distribution system is utilized, including Dispensing of single unit packages, the Drugs shall be Dispensed in a container to which is affixed a label containing the following information:
        (A) identification of the Dispensing Pharmacy;
        (B) the patient's name;
        (C) the date of Dispensing;
        (D) the nonproprietary and/or proprietary name of the Drug Dispensed; and

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

(E) the strength, expressed in the metric system whenever possible.

(2) All Drugs Dispensed to inpatients for self-administration shall be Labeled in accordance with Subparagraph 4 of this Section (e).

(3) Whenever any Drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:
- (i) name of solution, lot number, and volume of solution;
- (ii) patient's name;
- (iii) infusion rate;
- (iv) bottle sequence number or other system control number;
- (v) name and quantity of each additive;
- (vi) date of preparation;
- (vii) Beyond-Use Date and time of parenteral admixture; and
- (viii) ancillary precaution labels.

(4) All Drugs Dispensed to ambulatory or outpatients shall contain a label affixed to the container in which such Drug is Dispensed including:

(i) Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif typeface (such as "Arial"), minimum 12-point size, and in "sentence case." Field size and font size may be increased in the best interest of patient care. Critical information text should never be truncated and shall include:

(A) patient name
- *(-a-) legal name of the patient; or*
- *(-b-) if patient is an animal, include the last name of the owner, name of the animal, and animal species.*

(B) directions for use
- *(-a-) directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order; and*
- *(-b-) language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.*

(C) drug name
- *(-a-) if written for a brand name and a generic drug is dispensed, include phrase "Generic for [brand name];"and*
- *(-b-) include drug name suffixes, such as CD, SR, XL, XR, etc.*

(D) drug strength

(E) "use by" date
- *(-a-) date after which medication should be used; not expiration date of medication or expiration date of prescription; and*
- *(-b-) format as – "Use by: MM/DD/YY."*

(ii) Important information for patients – Must appear on the label but should not supersede critical information for patients and shall include:

(A) pharmacy name;

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

(B) pharmacy telephone number;
(C) prescriber name;
(-a-) format as – "Prescriber: [prescriber name]."
(D) "fill date;"
(-a-) format as – "Date filled: MM/DD/YY."
(E) prescription number;
(F) drug quantity;
(-a-) format as – "Qty: [number]."
(G) number of remaining refills;
(-a-) format as – "Refills: [number remaining]" or "No refills," using whole numbers only and managing partial fills through the pharmacy recordkeeping system;
(H) written or graphic product description;
(I) auxiliary information;
(J) any cautions and other provisions which may be required by federal or state law.

(iii) The following additional information for Patients – may appear on the label:
(A) bar codes;
(B) pharmacy address; and
(C) store number.

(5) No radiopharmaceutical may be Dispensed unless a label is affixed to the immediate container bearing the following information:
(i) the standard radiation symbol;
(ii) the words "Caution – Radioactive Material"; and
(iii) the prescription number.

(6) No radiopharmaceutical may be Dispensed unless a label is affixed to the outer or Delivery container bearing the following information:
(i) the standard radiation symbol;
(ii) the words "Caution – Radioactive Material";
(iii) the radionuclide and chemical form;
(iv) the activity and date and time of assay;
(v) the volume, if in liquid form;
(vi) the requested activity and the calibrated activity;
(vii) the prescription number;
(viii) patient name or space for patient name. Where the patient's name is not available at the time of Dispensing, a 72-hour exemption is allowed to obtain the name of the patient. No later than 72 hours after Dispensing the radiopharmaceutical, the patient's name shall become a part of the Prescription Drug Order to be retained for a period of three years;
(ix) the name and address of the nuclear Pharmacy;
(x) the name of the Practitioner; and
(xi) the lot number of the prescription.

(i) Patient Counseling

(1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate discussion of matters which will enhance or optimize Drug therapy with each patient or

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

caregiver of such patient. Such discussion shall be in Person, whenever practicable, or by telephone and shall include appropriate elements of Patient Counseling. Such elements may include the following:

(i) the name and description of the Drug;
(ii) the dosage form, dose, route of Administration, and duration of Drug therapy;
(iii) intended use of the Drug and expected action;
(iv) special directions and precautions for preparation, Administration, and use by the patient;
(v) 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;
(vi) techniques for self-monitoring Drug therapy;
(vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;
(viii) prescription refill information;
(ix) action to be taken in the event of a missed dose; and
(x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

(2) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(3) A Pharmacist providing telepharmacy services across state lines shall:
(i) identify himself or herself to patients as a "licensed Pharmacist"; and
(ii) notify patients of the State in which he or she is currently licensed to Practice Pharmacy and registered to Practice Telepharmacy across state lines.

(4) Patient Counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to Administer the Drug(s).
A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

Section 3(e)(4)(i)(B)(-a-). Comment.

Boards of pharmacy and licensees should recognize that "take as directed" may not provide sufficient information for the appropriate use of the medication. "Take as directed" is appropriate when specific directions are included on a unit-of-use package or dispensed package or in situations when directions are not able to be included on the label and the pharmacist presents directions to the patient and documents that such directions were given. "Take as directed" should not be used in lieu of patient counseling.

It is understood that prescription drug orders often do not include the indication for use.

Section 3(e)(4)(ii). Comment

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

Information traditionally included on the patient label must continue to be maintained and safeguarded by the record keeping system. Boards of pharmacy should require that record keeping systems prohibit any alteration or modification of these data unless an appropriate audit trail and justification exists. Record keeping systems should also prohibit any deletion of information except in accordance with state and federal requirements for data management and retention.

Section 3(e)(4)(ii)(A). Comment

Boards of pharmacy should recognize that some pharmacies "do business as" a name other than the corporate name.

Section 3(e)(4)(ii)(B). Comment

Phone number of the dispensing pharmacy recognizing that a central fill pharmacy may be involved in the filling process; boards of pharmacy should not require more than one telephone number on the label.

Section 3(e)(4)(ii)(D). Comment

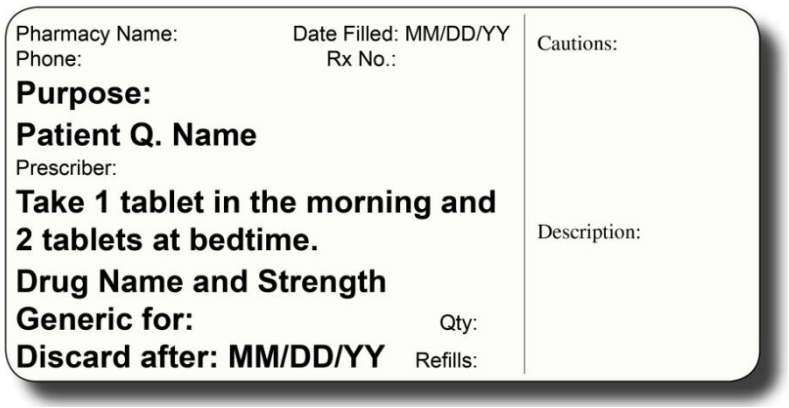
"Fill date" and "use by" date should be the only dates appearing on the prescription label. Other dates often found on labels, such as the original and expiration dates of the prescription drug order can be misunderstood by patients and clutter the label with unnecessary information.

Section 3(e)(4)(ii)(I). Comment

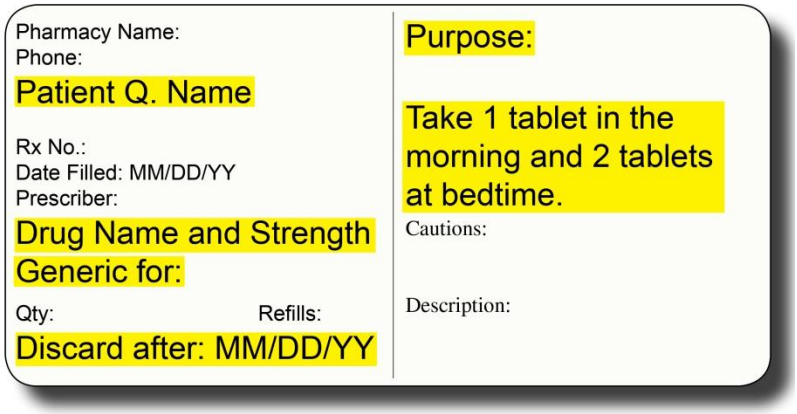
Auxiliary information, including auxiliary labels, should be evidence based, standardized, and demonstrated to complement the prescription label.

Section 3(e)(4)(i), (ii), and (iii). Comment

Boards of pharmacy may consider utilizing these suggested labeling formats provided below.



DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.



Section 3(i). Comment

The intent of this Section is to require that the Pharmacist personally initiate counseling for all new Prescriptions and to exercise his or her professional judgment for refills. Situations may arise, however, where the prescriber specifically indicates that a patient should not be counseled. In such circumstances, it is the responsibility of the Pharmacist to provide the best patient care through appropriate communication with the prescriber and to document the reason(s) for not providing counseling to the patient.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

APPENDIX B. CALIFORNIA STATUTE

4076.5. Standardized, Patient-Centered Prescription Labels; Requirements

(a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

(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.

(d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.

(e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:

(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
(B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
(C) The patient receives weekly or more frequent follow-up contacts by a nurse or pharmacist.
(D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.

(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

(f) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

(2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(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 10-point sans serif typeface or, if requested by the consumer, at least a 12-pooint 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 of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] 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 2011the 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) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. If interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.
(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.
(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

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

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

APPENDIX C. BEST PRACTICE RESEARCH

SUPPORTING EVIDENCE

MALLENBAKER.NET: http://www.mallenbaker.net/csr/post.php?id=429

- "In my view, Best Practice must surely be able to demonstrate a superior outcome achieved because of the way the thing has been done."

WIKIPEDIA: http://en.wikipedia.org/wiki/Best_practice

- In recent years, public agencies and NGOs have been exploring and adopting best practices when delivering health and human services. In these settings, the use of the terms "promising practices", "best practices", and "evidence-based practices" is common and often confusing as there is not a general consensus on what constitutes promising practices or best practices.
- **DHHS:** A general working definition used by the U.S. Department of Health and Human Services (HHS) in referring to a promising practice is defined as one with at least preliminary evidence of effectiveness in small-scale interventions or for which there is potential for generating data that will be useful for making decisions about taking the intervention to scale and generalizing the results to diverse populations and settings. (Reference: U.S. Department of Health and Human Services, Administration for Children and Families Program Announcement, 2003).
    - Since evidence of effectiveness, potential for taking the intervention to scale and generalizing the results to other populations and settings are key factors for best practices, the manner in which a method or intervention becomes a best practice can take some time and effort.
- **NREPP:** The National Registry of Evidence-Based Programs and Practices (NREPP) (External Link: http://nrepp.samhsa.gov) is a searchable online registry of interventions supporting substance abuse prevention and mental health treatment that have been reviewed and rated by independent reviewers
    - Minimum requirements include:
        - demonstration of one or more positive outcomes among individuals, communities, or populations
        - evidence of these outcomes has been demonstrated in at least one study using an experimental or quasi-experimental design
        - the results of these studies have been published in a peer-reviewed journal or other professional publication, or documented in a comprehensive evaluation report
        - implementation materials, training and support resources, and quality assurance procedures have been developed and are ready for use by the public.
- **CDRP:** There is existing controversy about the lack of culturally appropriate evidence-based best practices and the need to utilize a research-based approach to validate interventions. Some communities have deployed practices over a long period of time that have produced positive outcomes as well as a general community consensus to be successful. The California Reducing Disparities Project (CRDP) is working to identify such practices. (External Link:

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

http://www.dmh.ca.gov/Multicultural_Services/CRDP.asp) CRDP intends to improve access, quality of care, and increase positive outcomes for racial, ethnic and cultural communities.

FEDERAL REGISTER: http://www.gpo.gov/fdsys/pkg/FR-2003-07-09/pdf/03-17395.pdf

- Federal Register referenced above in Wikipedia article

THE HEALTH TELEVISION SYSTEM:
http://www.healthtvsystem.com/pressrm/docs/1167076048.PDF

- Comments from The Joint Commission and ISMP, two standards-setting organizations, represented:
  - Standards are just starting point
  - Standards don't go into sufficient detail to actually get the job done
  - Even if guidelines are prescriptive, they're on a patient by patient basis
  - When there's a variation, there's a rationale, and we all learn
- Interpretations: HEALTH OUTCOMES
  - The development of Best Practice Guidelines as relates to Patient Education will benefit from an understanding of and agreement on terminology and expectations.
  - The interpretations and definitions of health outcomes resulted in refining and honing criteria for Patient Education Best Practice Guidelines that will help in meeting patient specific educational needs and expectations.
  - Depending on patient population, outcomes can relate to:
    - Quality-of-life indicators
    - Functional indicators
    - Morbidity
    - These indicators incorporate subsets: e.g. medication compliance
    - Intent of education is to inform rather than persuade
    - Therapy/recovery strategy will be negotiated with patient
    - Patient's expectations of outcomes may be very different from those of the healthcare providers/educators
    - Outcome is based on patient's objectives, and the desired benefit that the patient wants to achieve
    - Focus must be on patient's perception of and satisfaction with the outcome (i.e. .the healthcare provider may think the patient is doing just fine)
    - The healthcare provider's outcome expectations and obligations often focus on: 'You must take'/ 'You must do' instead of patients' wants and needs

NATIONAL RESOURCE CENTER:
http://www.acf.hhs.gov/programs/ocs/ccf/about_ccf/gbk_pdf/pp_gbk.pdf

Research Validated	A program, activity or strategy that has the highest degree of proven effectiveness supported by objective and comprehensive research and

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

Best Practice	evaluation.
Field Tested Best Practice	A program, activity or strategy that has been shown to work effectively and produce successful outcomes and is supported to some degree by subjective and objective data sources.
Promising Practice	A program, activity or strategy that has worked within one organization and shows promise during its early stages for becoming a best practice with long term sustainable impact. A promising practice must have some objective basis for claiming effectiveness and must have the potential for replication among other organizations.

Criteria for Differentiating Types of Practices	
Research Validated Best Practice	■ Proven effectiveness in addressing a common problem. ■ Proven effectiveness in more than one organization and in more than one context. ■ Replicability on a broad scale. ■ Conclusive data from comparison to objective benchmarks with positive results. ■ Conclusive data from a comprehensive and objective evaluation by an external, qualified source (most often an academic institution or individual with the appropriate academic credentials).
Field Tested Best Practice	■ Effectiveness in addressing a common problem. ■ Effectiveness in more than one organization and in more than one context. ■ Replicability on a limited scale. ■ Supporting data from comparison to objective benchmarks with positive results. ■ Supporting data from an internal assessment or external evaluation.
Promising Practice	■ Suggested effectiveness in addressing a common problem. ■ Successful use in one organization and context. ■ Potential for replicability. ■ Limited supporting data from comparison to objective benchmarks with positive results. ■ Limited supporting data from internal assessment.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

JOURNAL OF YOUNG PHARMACISTS:
http://www.jyoungpharm.in/article.asp?issn=0975-1483;year=2010;volume=2;issue=1;spage=107;epage=111;aulast=Jeetu

- There is evidence available to detail "best practices" for improving dosage or usage instructions written by the prescribing physician and the format and content of prescription medication container labels designed by the dispensing pharmacy.
- A complete list of evidence-based, recommended standards for format, content, and instruction is as follows:
    - Use explicit text to describe dosage and interval in instructions.
    - Use a universal medication schedule (UMS) to convey and simplify dosage and use instructions.
    - Organize labels in a patient-centered manner.
    - According to need, include indication for use.
    - Simplify language, avoiding unfamiliar words or medical jargon.
    - Improve typography, use larger, sans serif font.
    - When applicable, use numeric versus alphabet characters.
    - Use typographic cues (bolding and highlighting) for patient content only.
    - Use horizontal text only.
    - Use a standard icon system for signaling and organizing auxiliary warnings and instructions.

US PHARMACOPEIA:
http://us.vocuspr.com/ViewAttachmentStrict.aspx?EID=bK0ke822q8svy24Psob15hb/gmKMwnuDvYOUnHhwyiw=
http://www.usp.org/usp-nf/notices/retired-compendial-notices/usp-seeks-comments-proposed-general-chapter-prescription-container-labeling

- The new standards, developed by the U.S. Pharmacopeial Convention (USP)—the nonprofit scientific organization that sets FDA-enforceable standards for the quality, purity and strength of medicines in the United States—are the result of a broad effort led by the Institute of Medicine (IOM) to improve health literacy in the United States by bringing together government, industry, associations and other groups to advance practical strategies that can be implemented to maximize patient comprehension of health information.
- Generally, the new standards propose that prescription container labels generated by pharmacies:
    - Are organized in a patient-centered manner—Organized in a way that best reflects how most patients understand medication instructions, featuring the most important information for safe and effective understanding and use.
    - Emphasize instructions and other important information to patients—Prominently display information that is critical to patient's safe and effective use of the medicine, such as, patient's name, drug name and strength, and clear directions for use. Less critical but important content (e.g., pharmacy name and number) should not supersede critical patient information.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

- Give explicit instructions—Instructions should clearly separate the dose itself from the timing of each dose and use numeric characters (e.g., “Take 2 tablets in the morning and 2 tablets in the evening” rather than “Take two tablets twice daily”).
- Include purpose for use—The medication’s purpose should be included on the label unless the patient prefers that it not appear. When included, use clear, simple terms (e.g., “for high blood pressure” rather than “for hypertension”).
- Improve readability—The label type should use high-contrast print (e.g. black print on white background); large font size (e.g., minimum 12-point Times New Roman or 11-point Arial); and horizontal text only.
- Limit auxiliary information—Labels, stickers, or other supplemental information should be expressed in simple and explicit language that is minimized to avoid distracting patients with nonessential information.

FDA/NCPDP: **http://www.fda.gov/downloads/Drugs/DrugSafety/UCM266631.pdf**

5	**Recommendation: Patient-Centered Pharmacy Warning Labels** • Employ general health literacy and plain language principles on the warning label to promote patient readability and understanding. • Patient-centered labels should reflect strategies (simple, clear language; font type and size) that promote optimal readability of critical information, consistent with recommendations by health literacy experts, plain language experts, and other organizations that have addressed patient-centered approaches to labeling in order to maximize readability and patient comprehension.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

APPENDIX D. TARGET CLEARRX IMPLEMENTATION

ClearRx: The Future of Pharmacy
*Target Introduces Innovation with Safety and Design for Gues*ts

Minneapolis, MN (May 1, 2005) — Target® introduced today ClearRx™, an innovative prescription distribution and communication system. ClearRx is a pharmacy concept that offers improvements in medication packaging and design, prescription and health information and patient communication.

"Improved consumer understanding and increased quality of care were driving forces behind this new system. Each year in the United States, as many as 3 billion prescriptions are administered which create significant opportunities for error," said Dr. Linda Rosenstock, dean of the University of California, Los Angeles School of Public Health. "An improved prescription distribution and communication system like ClearRx is a real step forward in helping patients better understand and more easily use the medications their physicians prescribe."

A recent survey commissioned by Target and conducted by Harris Interactive® revealed that nearly six out of 10 U.S. adults have taken prescription medication incorrectly. The same survey found the following reasons for why adults rarely or never read their prescription information sheets: the language is standard and does not vary from prescription to prescription, and information is too wordy, overwhelming, complex and incomprehensible.

"ClearRx makes it easier for people to understand how to take their medication," says Deborah Adler, ClearRx innovator and principal designer. "By rethinking the prescription bottle and label, we have created a new system that we think minimizes confusion for the consumer, such as misreading a dosage or taking another family member's medication. Ultimately, we hope that ClearRx will allow people to feel more confident and secure when it comes to filling their prescriptions and taking their medication."

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

FEATURES OF CLEARRX

In an effort to address the growing concern of medication errors, ClearRx was designed to offer the following benefits:

Re-designed Bottle — The new shape, which can easily be gripped and opened, places all the vital information right in the palm of the hand.

Easy-to-Read Label — Designed for readability and ease-of-use, this label sits flat across the front panel of the bottle so the bottle does not have to be turned to read the pertinent information. Type and easy-to-read fonts make information clearer to identify. In addition, prescription information is re-organized with the most important information—including drug name and prescribing instructions—at the top of the label accompanied by doctor name and prescription number.

Removable Information Card — Tucked securely on the back of the bottle in a permanent sleeve, this newly created information card summarizes the most common uses and side effects associated with the medication. This innovative card is ideal for quick reference and includes reader-friendly fonts and more comprehensive text.

Color-Coded Ring — For multi-member households, color-coded rings on the neck of the bottle help clearly identify each person's medication at-a-glance.

Re-Designed Warning Icons — Newly located on the flat back surface of the ClearRx bottle — these re-designed icons make important medical warnings clearer and easier to understand.

"This introduction allows us the opportunity to impact our guests in a meaningful and relevant way," remarked Mary Kelly, vice president, health & beauty and pharmacy, Target. "Great Design is so much a part of our DNA at Target. We brought this same belief of improving people's lives through great design to Target Pharmacy in a logical way with the introduction of ClearRx."

ClearRx will be available exclusively at Target Pharmacies nationwide starting this month.

Methodology

Harris Interactive® conducted the survey for Target by telephone between December 17 and 20, 2004 among a nationwide cross section of 1,033 U.S. adults aged 18 and older, of who 132 say they rarely or never read the prescription information card that comes with the prescription. Figures for age, sex, race, education, number of adults, number of voice/telephone lines in the household, region and size of place were weighted where necessary to align them with their actual proportions in the population.

In theory, with a probability sample of this size, one can say with 95 percent certainty that the results for the overall sample have a sampling error of plus or minus 3 percentage points. Sampling error for the adults who rarely or never read the prescription information card results is plus or minus 9 percentage points.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

APPENDIX E. NABP RESOLUTION

http://www.nabp.net/news/uniform-outpatient-pharmacy-prescription-container-labels-designed-for-patient-safety-resolution-108/

Uniform Outpatient Pharmacy Prescription Container Labels Designed for Patient Safety (Resolution 108-1-12)
May 25, 2012 01:14 PM

Topics: Resolutions

Resolution No. 108-1-12
Title: Uniform Outpatient Pharmacy Prescription Container Labels Designed for Patient Safety
Action: Pass

Whereas, medication misuse has resulted in more than one million adverse drug events per year in the United States; and

Whereas, patients' best source (and often only source) of information regarding the medications they have been prescribed is on the prescription container label; and

Whereas, other written information and oral counseling should be available, the prescription container label must fulfill the professional obligations of the prescriber and pharmacist; and

Whereas, these obligations include giving the patient the most essential information needed to understand how to safely and appropriately use the medication and to adhere to the prescribed medication regimen; and

Whereas, the purpose of the prescription label is for the patient, not the regulator or auditor; as such, the only information needed on the label is information the patient needs to take the medication correctly; and

Whereas, the National Association of Boards of Pharmacy (NABP), US Pharmacopeial Convention and the Institute for Safe Medication Practices have researched, identified, and agreed upon elements that do need to be on the patient prescription container label to ensure patient safety; and

Whereas, the elimination of data elements not required for patient safety will increase readability and understanding by allocating more white space, increasing the ability to use larger font size, providing more space so as not to truncate medication names or directions, and affording space for a description of the medication on the patient's medication container label; and

Whereas, these various labeling standards could potentially create a risk for patient confusion due to various jurisdictions requiring differing label formats, thus defeating the goal of a uniform, patient centered label;

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

THEREFORE BE IT RESOLVED that NABP support the state boards of pharmacy in their efforts to require a standardized prescription container label recommended by the 2008-2009 NABP Task Force on Uniform Prescription Labeling Requirements, the elements of which are found in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*.

(Resolution passed at the NABP 108th Annual Meeting, Philadelphia, PA)

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

APPENDIX F. IMAGERY EXAMPLES

From FIP website (http://www.fip.org/pictograms)

Pictograms give health professionals a means of communicating medication instructions to people with no common language and / or who may be illiterate. Pictograms may also be used for those who have slight cognitive impairment or difficulties seeing such as the elderly. To help improve communication, various formats of the medication instructions can be printed (see below):

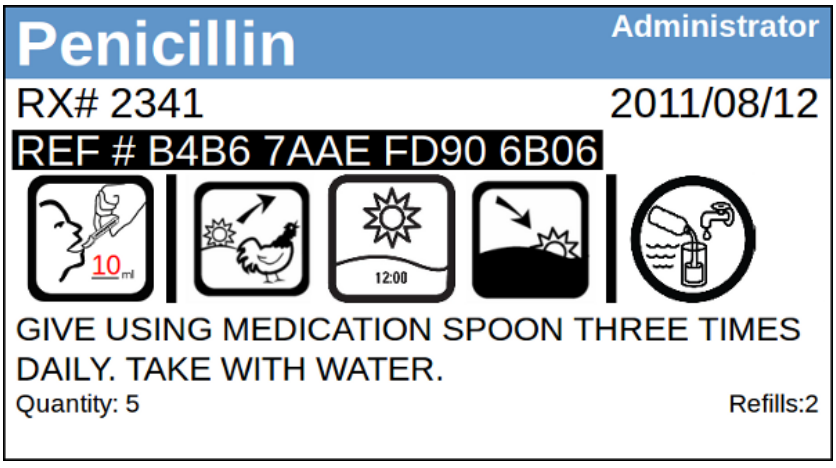
- A label with customizable size
- A medication information sheet for one medication
- A prescription calendar that combines all medicines
- A storyboard of a medication

Medication instructions included:

- Medication name
- Route and quantity of medicines per dose
- Frequency

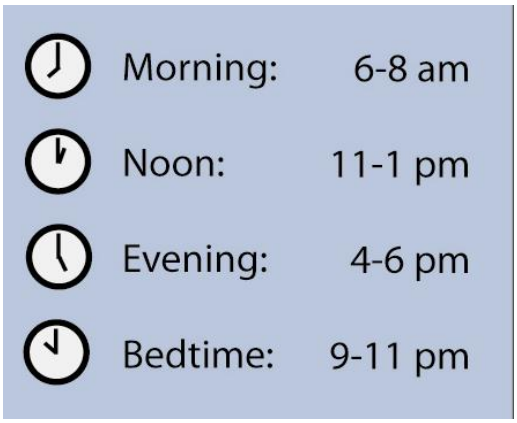
Optional instructions to include on information sheets:

- The picture of the medication
- Reason(s) for use
- Precautions
- Side effects (up to 2)

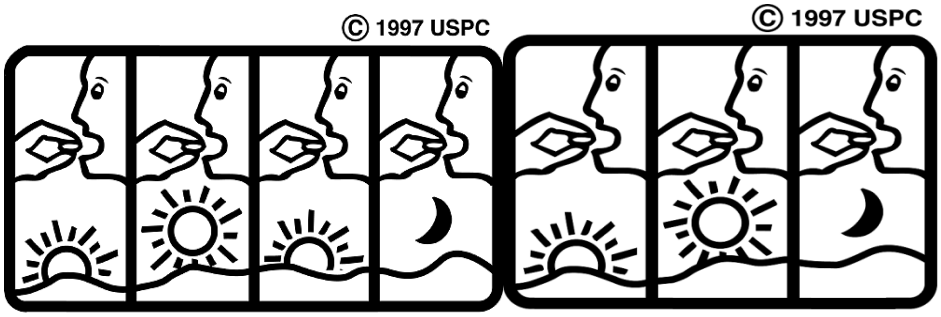


The same type of simple imagery could be added to prescription labels:

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.



The US Pharmacopeial provided the following sample pictograms:



Take 4 times a day

Take 3 times a day

Take at bedtime

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

Take in the morning

Breakfast	Lunch	Dinner	Bedtime
1		1	

Copyright © Polyglot Systems, Inc.

once daily	X			
twice a day	X		X	
three times a day	X	X	X	
four times a day	X	X	X	X
evening			X	
bedtime				X

©National Council for Prescription Drug Programs, Inc.

APPENDIX G. CONTRIBUTORS

Stacy Cooper Bailey, PhD MPH
School of Pharmacy
University of North Carolina at Chapel Hill

Terri Bernacchi, PharmD, MBA
CHAPS, LLC

Donna Bohannon, RPh, CPPS
U.S. Pharmacopeial Convention (USP)

Mark Brueckl, RPh, MBA
Academy of Managed Care Pharmacy

John Dorsey
Target Corporation

Sandra Eyerly
MWV Healthcare

David Fong, PharmD
PDX-NHIN

Robert Franz, RPh
Express Scripts, Inc.

Virginia Herold
California State Board of Pharmacy

Peter Kaufman, MD
DrFirst

Charles Lee, MD
Polyglot Systems, Inc.

Eileen Lewalski, PharmD, JD
National Association of Boards of Pharmacy

Melissa Madigan, PharmD, JD
National Association of Boards of Pharmacy

Terri Meredith, RPh, MSCIS
Cerner Corporation

R.J. Sims Preston, JD
Polyglot Systems, Inc.

Marge Simos
JenKare, LLC

Sue Thompson
NCPDP

Thomas Stanze
Express Scripts, Inc.

Thomas Sullivan, MD
DrFirst

Laura Topor
Granada Health

Michael Wolf, PhD, MPH
Feinberg School of Medicine
Northwestern University

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

14 ENDNOTES

[i] http://eclkc.ohs.acf.hhs.gov/hslc/tta-system/operations/Fiscal/After%20the%20Grant%20Award/Closeout_Procedures/tAreBestPracti.htm

[ii] National Registry of Evidence-Based Programs and Practices. Federal Register/Vol. 76, No. 180/Friday, September 16, 2011/Notices page 57743.

[iii] http://www.dmh.ca.gov/Multicultural_Services/docs/CRDP_FactSheet_Final_February2010.pdf

[iv] http://www.acf.hhs.gov/sites/default/files/ocs/id_bestpractices.pdf

[v] Jeetu G, Girish T. Prescription Drug Labeling Medication Errors: A Big Deal for Pharmacists. J Young Pharmacists [serial online] 2010 [cited 2013 Jan 30];2:107-11. Available from: http://www.jyoungpharm.in/text.asp?2010/2/1/107/62218

37 Shrank WH, Avorn J, Rolón C, Shekelle P. The effect of the content and format of prescription drug labels on readability, understanding and medication use: A systematic review. Ann Pharmacother 2007;41:783-801.

30 Davis TC, Wolf MS, Bass PF, Tilson H, Neuberger M, Parker RM. Literacy and misunderstanding of prescription drug labels. Ann Intern Med 2006; 145:887-94

[vi] http://www.health.gov/communication/hlactionplan/

[vii] http://www.nabp.net/publications/model-act/

[viii] http://www.jointcommission.org/assets/1/18/R3%20Report%20Issue%201%2020111.PDF

[ix] http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf

[x] http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html

[xi] http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=18

[xii] http://www.healthypeople.gov/2020/topicsobjectives2020/pdfs/HP2020objectives.pdf

[xiii] http://www.npsf.org/for-healthcare-professionals/programs/ask-me-3/

[xiv] Implementation of a VA patient-centered prescription label. Keith W. Trettin, Erin Narus VA National Center for Patient Safety

[xv] Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low health literacy and health outcomes: an updated systematic review. Ann Intern Med. 011; 155(2):97–107.

[xvi] Northwestern University's Feinberg School of Medicine (PI: Michael Wolf, PhD MPH Research Grant

1. Institute of Medicine. *Preventing medication errors*. Washington DC: National Academy Press; 2006.
2. Institute of Medicine. *The safe use initiative and health literacy [workshop summary]*. Washington, DC: National Academy Press; 2010.
3. Haynes RB, Yao X, Degani A, Kripalani S, Garg A, McDonald HP. Interventions for enhancing medication adherence (Review). *Cochrane Database of Systematic Reviews.* 2005;4.
4. Wolf MS, Curtis LM, Waite K, et al. Helping patients simplify and safely use complex prescription regimens. *Arch. Intern. Med.* Feb 28 2011;171(4):300-305.
5. Davis TC, Wolf MS, Bass PF, 3rd, et al. Literacy and misunderstanding prescription drug labels. *Ann. Intern. Med.* Dec 19 2006;145(12):887-894.
6. Wolf MS, Davis TC, Tilson HH, Bass PF, 3rd, Parker RM. Misunderstanding of prescription drug warning labels among patients with low literacy. *Am. J. Health. Syst. Pharm.* Jun 1 2006;63(11):1048-1055.
7. Farber HJ, Capra AM, Finkelstein JA, et al. Misunderstanding of asthma controller medications: association with nonadherence. *J. Asthma.* Feb 2003;40(1):17-25.
8. Gu Q, Dillon CF, Burt VL. Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007-2008. In: Statistics NCfH, ed2010.
9. Fischer MA, Stedman MR, Lii J, et al. Primary medication non-adherence: analysis of 195,930 electronic prescriptions. *J. Gen. Intern. Med.* Apr 2010;25(4):284-290.
10. Osterberg L, Blaschke T. Adherence to medication. *The New England journal of medicine.* Aug 4 2005;353(5):487-497.
11. Choudhry NK, Shrank WH, Levin RL, et al. Measuring concurrent adherence to multiple related medications. *Am. J. Manag. Care.* Jul 2009;15(7):457-464.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

12. Benner JS, Glynn RJ, Mogun H, Neumann PJ, Weinstein MC, Avorn J. Long-term persistence in use of statin therapy in elderly patients. *JAMA.* Jul 24-31 2002;288(4):455-461.
13. Siegel D, Lopez J, Meier J. Antihypertensive medication adherence in the Department of Veterans Affairs. *Am. J. Med.* Jan 2007;120(1):26-32.
14. van Wijk BL, Avorn J, Solomon DH, et al. Rates and determinants of reinitiating antihypertensive therapy after prolonged stoppage: a population-based study. *J. Hypertens.* Mar 2007;25(3):689-697.
15. Sarkar U, Handley MA, Gupta R, et al. What happens between visits? Adverse and potential adverse events among a low-income, urban, ambulatory population with diabetes. *Qual Saf Health Care.* 2010.
16. Gandhi TK, Weingart SN, Borus J, et al. Adverse drug events in ambulatory care. *N. Engl. J. Med.* Apr 17 2003;348(16):1556-1564.
17. Elder NC, Dovey SM. Classification of medical errors and preventable adverse events in primary care: a synthesis of the literature. *J. Fam. Pract.* Nov 2002;51(11):927-932.
18. Field TS, Gurwitz JH, Harrold LR, et al. Risk factors for adverse drug events among older adults in the ambulatory setting. *J. Am. Geriatr. Soc.* Aug 2004;52(8):1349-1354.
19. Field TS, Mazor KM, Briesacher B, Debellis KR, Gurwitz JH. Adverse drug events resulting from patient errors in older adults. *J. Am. Geriatr. Soc.* Feb 2007;55(2):271-276.
20. Gurwitz JH, Field TS, Harrold LR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *JAMA.* March 5, 2003 2003;289(9):1107-1116.
21. Sahm LJ, MacCurtain A, Hayden J, Roche C, Richards HL. Electronic reminders to improve medication adherence--are they acceptable to the patient? Pharm. World Sci. Dec 2009;31(6):627-629.
22. Institute of Medicine. Preventing medication errors. Washington DC: National Academy Press; 2006.
23. Institute of Medicine. The safe use initiative and health literacy [workshop summary]. Washington, DC: National Academy Press; 2010.
24. Haynes RB, Yao X, Degani A, Kripalani S, Garg A, McDonald HP. Interventions for enhancing medication adherence (Review). Cochrane Database of Systematic Reviews. 2005;4.
25. Farber HJ, Capra AM, Finkelstein JA, et al. Misunderstanding of asthma controller medications: association with nonadherence. J. Asthma. Feb 2003;40(1):17-25.
26. Gu Q, Dillon CF, Burt VL. Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007-2008. National Center for Health Statistics, 2010.
27. Fischer MA, Stedman MR, Lii J, et al. Primary medication non-adherence: analysis of 195,930 electronic prescriptions. J. Gen. Intern. Med. Apr 2010;25(4):284-290.
28. Osterberg L, Blaschke T. Adherence to medication. N. Engl. J. Med. Aug 4 2005;353(5):487-497.
29. Choudhry NK, Shrank WH, Levin RL, et al. Measuring concurrent adherence to multiple related medications. Am. J. Manag. Care. Jul 2009;15(7):457-464.
30. Benner JS, Glynn RJ, Mogun H, Neumann PJ, Weinstein MC, Avorn J. Long-term persistence in use of statin therapy in elderly patients. JAMA. Jul 24-31 2002;288(4):455-461.
31. Siegel D, Lopez J, Meier J. Antihypertensive medication adherence in the Department of Veterans Affairs. Am. J. Med. Jan 2007;120(1):26-32.
32. van Wijk BL, Avorn J, Solomon DH, et al. Rates and determinants of reinitiating antihypertensive therapy after prolonged stoppage: a population-based study. J. Hypertens. Mar 2007;25(3):689-697.
33. Gandhi TK, Weingart SN, Borus J, et al. Adverse drug events in ambulatory care. N. Engl. J. Med. Apr 17 2003;348(16):1556-1564.
34. Elder NC, Dovey SM. Classification of medical errors and preventable adverse events in primary care: a synthesis of the literature. J. Fam. Pract. Nov 2002;51(11):927-932.
35. Field TS, Gurwitz JH, Harrold LR, et al. Risk factors for adverse drug events among older adults in the ambulatory setting. J. Am. Geriatr. Soc. Aug 2004;52(8):1349-1354.
36. Field TS, Mazor KM, Briesacher B, Debellis KR, Gurwitz JH. Adverse drug events resulting from patient errors in older adults. J. Am. Geriatr. Soc. Feb 2007;55(2):271-276.
37. Gurwitz JH, Field TS, Harrold LR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. JAMA. March 5, 2003 2003;289(9):1107-1116.

©National Council for Prescription Drug Programs, Inc.

38. Sarkar U, Handley MA, Gupta R, et al. What happens between visits? Adverse and potential adverse events among a low-income, urban, ambulatory population with diabetes. Qual Saf Health Care. 2010.
39. Persell SD, Osborn CY, Richard R, Skripkauskas S, Wolf MS. Limited health literacy is a barrier to medication reconciliation in ambulatory care. J. Gen. Intern. Med. Nov 2007;22(11):1523-1526.
40. Wolf MS, Davis TC, Arozullah A, et al. Relation between literacy and HIV treatment knowledge among patients on HAART regimens. AIDS Care. Oct 2005;17(7):863-873.
41. Bailey SC, Pandit A, Yin HS, Wolf MS. Predictors of misunderstanding pediatric liquid medication instructions. Fam. Med. 2009;41(10):715-721.
42. Wolf MS, Davis TC, Cross JT, Marin E, Green K, Bennett CL. Health literacy and patient knowledge in a Southern US HIV clinic. Int. J. STD AIDS. Nov 2004;15(11):747-752.
43. Davis TC, Fredrickson DD, Potter L, et al. Patient understanding and use of oral contraceptive pills in a southern public health family planning clinic. South. Med. J. Jul 2006;99(7):713-718.
44. Paasche-Orlow MK, Cheng DM, Palepu A, Meli S, Faber V, Samet JH. Health literacy, antiretroviral adherence, and HIV-RNA suppression: a longitudinal perspective. J. Gen. Intern. Med. 2006;21(8):835-840.
45. Gazmararian JA, Kripalani S, Miller MJ, Echt KV, Ren JL, Rask K. Factors associated with medication refill adherence in cardiovascular-related diseases: A focus on health literacy. J Gen. Intern. Med. 2006;21(12):1215-1221.
46. Golin CE, Liu HH, Hays RD, et al. A prospective study of predictors of adherence to combination antiretroviral medication. J Gen. Intern. Med. 2002;17(10):756-765.
47. Kalichman SC, Pope H, White D, et al. Association between health literacy and HIV treatment adherence: further evidence from objectively measured medication adherence. J Int Assoc Physicians AIDS Care (Chic Ill). 2008;7(6):317-323.
48. Stone VE, Hogan JW, Schuman P, et al. Antiretroviral regimen complexity, self-reported adherence, and HIV patients' understanding of their regimens: survey of women in the her study. J. Acquir. Immune Defic. Syndr. Oct 1 2001;28(2):124-131.
49. Shin HB, Kominski RA. Language Use in the United States: 2007. American Community Surveys, 2010.
50. Jacobs E, Chen AH, Karliner LS, Agger-Gupta N, Mutha S. The need for more research on language barriers in health care: a proposed research agenda. Milbank Q. 2006;84(1):111-133.
51. Institute of Medicine. Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care. Washington DC: National Academy Press; 2002.
52. Weiss L, Gany F, Rosenfeld P, et al. Access to multilingual medication instructions at New York City pharmacies. J. Urban Health. 2007;84(6):742-754.
53. Sharif I, Lo S, Ozuah PO. Availability of Spanish prescription labels. J. Health Care Poor Underserved. Feb 2006;17(1):65-69.
54. Flores G, Tomany-Korman SC. Racial and ethnic disparities in medical and dental health, access to care, and use of services in US children. Pediatrics. 2008;121(2):e286.
55. Bradshaw M, Tomany-Korman S, Flores G. Language barriers to prescriptions for patients with limited English proficiency: a survey of pharmacies. Pediatrics. Aug 2007;120(2):e225-235.
56. Bailey SC, Pandit AU, Curtis LM, Wolf MS. Availability of Spanish prescription labels: a multi-state pharmacy survey. Med. Care. Jun 2009;47(6):707-710.
57. Sharif I, Tse J. Accuracy of Computer-Generated, Spanish-Language Medicine Labels. Pediatrics. 2010.
58. Muzyk AJ, Muzyk TL, Barnett CW. Counseling Spanish-speaking patients: Atlanta pharmacists' cultural sensitivity, use of language-assistance services, and attitudes. J Am Pharm Assoc. 2004;44(3):366-374.
59. Westberg SM, Sorensen TD. Pharmacy-related health disparities experienced by non-English-speaking patients: impact of pharmaceutical care. J Am Pharm Assoc. 2005;45(1):48-54.
60. Sleath B, Blalock SJ, Bender DE, Murray M, Cerna A, Cohen MG. Latino patients' preferences for medication information and pharmacy services. J Am Pharm Assoc (2003). Sep-Oct 2009;49(5):632-636.
61. Institute of Medicine. Health literacy: A prescription to end confusion. Washington DC: National Academy Press; 2004.

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

62. Stevenson FA, Cox K, Britten N, Dundar Y. A systematic review of the research on communication between patients and health care professionals about medicines: the consequences for concordance. Health Expect. Sep 2004;7(3):235-245.
63. Tarn DM, Heritage J, Paterniti DA, Hays RD, Kravitz RL, Wenger NS. Physician communication when prescribing new medications. Arch. Intern. Med. Sep 25 2006;166(17):1855-1862.
64. Morris LA, Tabak ER, Gondek K. Counseling patients about prescribed medication: 12-year trends. Med. Care. Oct 1997;35(10):996-1007.
65. Metlay JP, Cohen A, Polsky D, Kimmel SE, Koppel R, Hennessy S. Medication safety in older adults: home-based practice patterns. J. Am. Geriatr. Soc. Jun 2005;53(6):976-982.
66. Sleath B, Roter D, Chewning B, Svarstad B. Asking questions about medication: analysis of physician-patient interactions and physician perceptions. Med. Care. Nov 1999;37(11):1169-1173.
67. Wolf MS, Davis TC, Shrank WH, Neuberger M, Parker RM. A critical review of FDA-approved Medication Guides. Patient Educ. Couns. Sep 2006;62(3):316-322.
68. Webb J, Davis TC, Bernadella P, Wolf MS. Patient-centered approach for improving prescription drug warning labels. Patient Educ. Couns. Sep 2008;72(3):443-449.
69. Wallace LS, Keenum AJ, DeVoe JE. Evaluation of consumer medical information and oral liquid measuring devices accompanying pediatric prescriptions. Acad. Pediatr. 2010;10(4):224-227.
70. Wallace LS, Roskos S, Weiss BD. Readability characteristics of consumer medication information for asthma inhalation devices. J. Asthma. 2006;43(5):375-378.
71. Shrank WH, Agnew-Blais J, Choudhry NK, et al. The variability and quality of medication container labels. Arch. Intern. Med. Sep 10 2007;167(16):1760-1765.
72. Sahm LJ, Wolf MS, Curtis LM, Behan R, Brennan M, Gallwey H, McCarthy S. What's in a label? An Exploratory Study of Patient-Centered Drug Instructions. Journal of General Internal Medicine. Under review.
73. Hanchak NA, Patel MB, Berlin JA, Strom BL. Patient misunderstanding of dosing instructions. J. Gen. Intern. Med. 1996;11(6):325-328.
74. Health Information Technology for Economic and Clinical Health (HITECH) Act. Prepared by the Majority Staff of the Committees on Energy and Commerce, Ways and Means, and Science and Technology, January 2009.

xvii http://www.gpo.gov/fdsys/pkg/CFR-2003-title21-vol4/pdf/CFR-2003-title21-vol4-sec290-2.pdf.
xviii http://www.usp.org/sites/default/files/usp_pdf/EN/hottopics/c17.pdf
xix http://www.usp.org/usp-nf/hot-topics/usp-nf-general-chapter-prescription-container-labeling
xx http://scriptyourfuture.org/
xxi http://archpedi.jamanetwork.com/article.aspx?articleid=380096
xxii Wolf MS, et al. Improving prescription drug warnings to promote patient comprehension. *Arch Intern Med. 2010;170(1):50-56*
xxiii http://www.migrationinformation.org/integration/LEPdatabrief.pdf
xxiv http://www.pharmacy.ca.gov/publications/labels_info.shtml
xxv http://www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit/ToolkitPart11.html
xxvi http://assembly.state.ny.us/2012budget/?sec=bill&bill=A.9057
xxvii http://www.ncsl.org/issues-research/health/state-initiatives-to-reduce-medication-errors-ncsl.aspx

DRAFT RELEASE
©National Council for Prescription Drug Programs, Inc.

NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications

Version 1.0

March 2014

This paper provides the healthcare industry, in particular the pharmacy sector, with historical and background information on the patient risks associated with the dosing of liquid medications and recommendations to mitigate those risks through best practices in prescription orders, prescription labeling and the provision of dosing devices.

NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications

Version 1.Ø

NCPDP recognizes the confidentiality of certain information exchanged electronically through the use of its standards. Users should be familiar with the federal, state, and local laws, regulations and codes requiring confidentiality of this information and should utilize the standards accordingly.

NOTICE: In addition, this NCPDP Standard contains certain data fields and elements that may be completed by users with the proprietary information of third parties. The use and distribution of third parties' proprietary information without such third parties' consent, or the execution of a license or other agreement with such third party, could subject the user to numerous legal claims. **All users are encouraged to contact such third parties to determine whether such information is proprietary and if necessary, to consult with legal counsel to make arrangements for the use and distribution of such proprietary information**.

Published by:
National Council for Prescription Drug Programs

Publication History:
Version 1.Ø
Copyright © 2Ø14

All rights reserved.
Permission is hereby granted to any organization to copy and distribute this material as long as the copies are not sold.
National Council for Prescription Drug Programs
924Ø E. Raintree Drive
Scottsdale, AZ 8526Ø
(48Ø) 477-1ØØØ
ncpdp@ncpdp.org

Acknowledgements

The National Council for Prescription Drug Programs Work Group (WG10) Professional Pharmacy Services and its mL White Paper Task Group would like to acknowledge and thank the Task Group members and other stakeholders that participated in the creation and review of this white paper, including representatives from all facets of the pharmacy industry and regulatory bodies. For a listing of contributors, please see "*Appendix D. Contributors to this White Paper.*"

Table of Contents

ACKNOWLEDGEMENTS **2**

TABLE OF CONTENTS **3**

DISCLAIMER **5**

EXECUTIVE SUMMARY **6**

1. AUDIENCE **9**

2. PURPOSE, GOALS, AND KEY RECOMMENDATIONS **9**

3. BACKGROUND **11**

3.1 Why an NCPDP White Paper? 11

3.2 How Does Standardizing Dosing Designations on Prescription Container Labels of Oral Liquid Medications Dispensed from Community Pharmacies Relate to Efforts in Other Settings? 11

4. RATIONALE FOR KEY RECOMMENDATIONS **13**

4.1 Recommendation 1: Milliliter (mL) Should be the Standard Unit of Measure Used on Prescription Container Labels of Oral Liquid Medications 13

4.1.1 The Need to Measure Oral liquid Medication Volumes Makes Accurate Use More Challenging than for Solid Medications *13*

4.1.2 The Use of Multiple Volumetric Measures Contributes to Oral Liquid Medication Dosing Errors *14*

4.1.3 Parents Measure Liquids More Accurately Using mL *16*

4.1.4 Milliliter Has Been Endorsed as the Standard Unit of Measure for Oral Liquid Medications by Many Professional and Patient Safety Organizations *16*

4.2 Recommendation 2: Dose Amounts Should Always Use Leading Zeros Before a Decimal Point and Should Not Use Trailing Zeros After a Decimal Point on Prescription Container Labels of Oral Liquid Medication 17

4.2.1 How Amounts are Expressed Can Cause Significant Overdoses *17*

4.2.2 Existing Healthcare Standards Suggest Dose Designations Always Use Leading Zeros and Never Use Trailing Zeros *18*

In addition, the ISMP, FDA, ASHP, NCC-MERP, and others (Appendix B) have issued statements or endorsed recommendations to use leading zeros and avoid trailing zeros in dose designations in all settings." 18

4.3 Recommendation 3: Dosing Devices With Numeric Graduations and Units That Correspond to the Container Labeling Should be Made Easily and Universally Available Such as Including a Device Each Time Oral Liquid Prescription Medications are Dispensed 18

4.3.1 How Dosing Designations Are Represented on Dosing Devices Contributes to Medication Administration Errors *18*

4.3.2 Use of Household Spoons or Other Utensils Can Cause Administration Errors *19*

4.3.3 Guidelines for Over-the-Counter Medications Already Recommend that Milliliter (mL) Should be the Standard Unit of Measure Used for Oral Liquid Medication Dosing Devices *19*

5. REGULATION OVERVIEW **20**

6. STAKEHOLDER CHALLENGES AND OPPORTUNITIES **21**

6.1. Pharmacy System Software Companies 21

6.1.1 Assessment of Input and Output of Standard Dosing Designations *21*
6.1.2 Enhancing Systems for Standardizing Dosing Designations *22*
6.2 Electronic Drug Database Publishers 23
6.3 Prescribing Software Companies (including electronic health record (EHR) with prescribing applications) 24
6.4 Pharmacy Leadership 25
6.4.1 Pharmacy System Software *25*
6.4.2 Workflow *25*
6.4.3 Support of Pharmacy Staff and Patient Education *25*
6.4.4 Consistency Across Care Settings and Products *26*
7. STAKEHOLDER CALL TO ACTION: ADOPT, IMPLEMENT, ADHERE, COMMUNICATE, AND EDUCATE 26
7.1 Stakeholder Map: Call to Action, Challenges, and Opportunities 28
8. CONCLUSIONS 38
9. REFERENCES 39
10. APPENDICES 45
10.1 Appendix A: Documents and Resources Consistent with the White Paper Recommendation on the Use of Milliliter (mL) 46
HTTP://WWW.AAFP.ORG/ABOUT/POLICIES/ALL/PREFERRED-UNIT.HTML 46
10.2 Appendix B: Documents and Resources Consistent with the White Paper Recommendation on the Use of Leading Zeros and Avoidance of Trailing Zeros 51
10.3 Appendix C: Documents and Resources Consistent with the White Paper Recommendation on the Use of Dosing Devices for Oral Liquid Medicines 56
10.4 Appendix D: Contributors to this White Paper 58

Disclaimer

This document is Copyright © 2014 by the National Council for Prescription Drug Programs (NCPDP). It may be freely redistributed in its entirety provided that this copyright notice is not removed. It may not be sold for profit or used in commercial documents without the written permission of the copyright holders. This document is provided “as is” without any express or implied warranty.

While all information in this document is believed to be correct at the time of writing; the writers of this paper may review and possibly update their recommendations should any significant changes occur. This document is for educational and awareness purposes only and does not purport to provide legal advice. If you require legal advice, you should consult with an attorney. The information provided here is for reference use only and does not constitute the rendering of legal, financial, or other professional advice or recommendations by NCPDP. The listing of an organization does not imply any sort of endorsement and the NCPDP takes no responsibility for the products or tools.

The existence of a link or organizational reference in any of the following materials should not be assumed as an endorsement by the NCPDP.

Executive Summary

The purpose of this white paper is to provide recommendations and guidance for standardizing the dosing designation (the amount and volumetric units) used on prescription container labels of oral liquid medications dispensed from community pharmacies. The goal is to improve patient safety and outcomes by decreasing the potential for error when patients and caregivers take and administer these medications. To accomplish this, the white paper advocates harmonizing prescribing, transcribing, labeling, dispensing, and administering these medications in the community setting with standards used in hospital and other healthcare settings, recommendations for over-the-counter (OTC) medications, and international standards of expressing volumetric measurement.

The audience for this white paper are all stakeholders who: dispense oral liquid prescription medication; review, revise, or generate prescription container labels; develop, produce, deploy, or use pharmacy system software, prescribing software, or drug information content; design or manufacture drug dosing devices; or educate healthcare professionals, patients, and caregivers on the appropriate use of these medications.

In September 2012, NCPDP hosted a stakeholder meeting involving 27 participants representing a wide range of perspectives to discuss the possibility of improving the standardization and consistency of dosing designations used on prescription container labels of oral liquid medications. This stakeholder meeting was catalyzed by the PROTECT Initiative, a public-private partnership, which has as one of its objectives to reduce the likelihood of patient and caregiver errors by standardizing dose designations of oral liquid medications. Based on the success of NCPDP's previous efforts to promote patient safety through improving prescription container labels, this effort was assigned to a task group of the NCPDP Professional Pharmacy Services Work Group (WG10).

Dosing errors involving oral liquid medications administered by patients and caregivers in home settings have been a source of concern for many years. Of particular concern are medication errors involving young children, as they may be more susceptible to harm from measurement errors and overdoses. To administer most oral liquid medications, a patient or caregiver must rely on the container label dosing designation to guide him/her in measuring out the proper dose with a dosing device. This additional step introduces numerous opportunities for error with each administration of an oral liquid medication.

Error-prone dosing designations contribute to medication errors and patient harm. The use of both multiple volumetric units (e.g., teaspoons, tablespoons, droppersful) and multiple abbreviations for the same volumetric units (e.g., mL, cc, mls; tsp, TSP, t) increase the likelihood of dosing errors by healthcare professionals, patients, and caregivers. One of the most common dosing errors is a patient or caregiver confusing teaspoons and tablespoons, resulting in three-fold dosing errors. In addition, the use of teaspoons and tablespoons as units of measure on labels may encourage the public to believe they can use non-calibrated household spoons for dosing medications. The omission of leading zeros for decimal amounts less than one and the use of unnecessary trailing zeros after whole number or decimal amounts can lead to potentially more serious ten-fold dosing errors by patients or caregivers. Further,

Copyrighted Materials – See Copyright Statement for Allowed Use

assuming a patient or caregiver does use a calibrated dosing device, there is another opportunity for administration error if the numeric graduations and units of measure on the device do not correspond to the amounts and units of the container label dosing designation. Finally, the combination of multiple volumetric units and automation in some retail pharmacy computer systems may facilitate dosing designation misinterpretations by healthcare professionals when translating a prescription to a dosing designation on a container label.

This white paper outlines a concise set of recommendations and guidance that can be applied to the practices, systems and procedures for processing electronic prescriptions, printing prescription container labels, encouraging the use of appropriate dosing devices for oral liquid medications, and educating healthcare professionals, patients, and caregivers.

NCPDP Recommendations for Standardizing the Dosing Designation on Prescription Container Labels for Oral Liquid Medications	
1	Milliliter (mL) should be the standard unit of measure used on prescription container labels for oral liquid medications.
2	Dose amounts should always use leading zeros before the decimal point for amounts less than one and should not use trailing zeros after a decimal point on prescription container labels for oral liquid medications.
3	Dosing devices with numeric graduations and units that correspond to the container labeling should be made easily and universally available such as including a device each time oral liquid prescription medications are dispensed.

The NCPDP Task Group Call to Action maps out roles for many stakeholders, but particularly relies on local and corporate pharmacy leadership to:

- Adopt the recommendations in this white paper
- Communicate these recommendations as preferences or policies to all pharmacy staff
- Measure the performance of your organization in achieving these recommendations and stress accountability across your organization for adhering to them Explore innovative patient-centered communication and education initiatives that encourage pharmacist-to-patient education at point of dispensing
- Facilitate communication by stakeholders outside the community pharmacy system, including prescribers, with a role in patient and healthcare professional education on using standardized dosing designations for prescribed oral liquid medications.

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

A stakeholder map identifies all the relevant stakeholders who need to play a role in adopting, communicating, adhering, and educating. The map outlines a call to action and identifies some of the challenges and opportunities for each stakeholder group.

Adoption of this white paper's recommendations will standardize dosing designations for prescription container labels of oral liquid medications in the community setting with standards used in hospital and other healthcare facilities, recommendations for OTC medications, and international standards of volumetric measurement.

NCPDP calls on all the relevant stakeholders to support efforts to adopt, implement, and adhere to the recommendations in this white paper, and to educate healthcare professionals, patients, and caregivers on how to accurately measure and administer oral liquid medications.

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

1. Audience

The audience for this white paper includes all stakeholders who:

- Dispense oral liquid prescription medication
- Review, revise, or generate prescription container labels
- Develop, produce, deploy, or use pharmacy system software
- Develop, produce, deploy, or use prescribing software
- Develop, produce, deploy, or use drug information content
- Design or manufacture drug dosing devices
- Educate healthcare professionals, patients, and other caregivers on the appropriate administration of prescribed oral liquid medications

2. Purpose, Goals, and Key Recommendations

The purpose of this white paper is to provide recommendations and guidance for standardizing dosing designation (the amount and volumetric units) used on prescription container labels of oral liquid medications dispensed from community pharmacies.

The immediate goals of the recommendations are to:

(1) Reduce variability in dosing designations on prescription container labels of oral liquid medications dispensed from community pharmacies by harmonizing the dosing designations with standards used in hospital and other healthcare facilities, recommendations for over-the-counter (OTC) medications, and international standards of volumetric measurement.

(2) Facilitate proper administration by patients and caregivers of oral liquid medications dispensed from community pharmacies.

The ultimate goal of the recommendations is to improve patient safety and patient outcomes by decreasing the potential for overdoses, underdoses, and other errors when patients and caregivers measure and administer oral liquid prescription medications dispensed from community pharmacies.

To meet these goals, NCPDP outlines below a set of recommendations and guidance that can be applied to the practices, systems, and procedures for processing prescriptions, printing prescription container labels, encouraging the use of appropriate dosing devices for oral liquid medications, and educating healthcare professionals, patients, and caregivers.

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

RECOMMENDATIONS	
1	**Milliliter (mL) should be the standard unit of measure used on prescription container labels of oral liquid medications.** • Metric units should be used whenever possible. Non-metric and non-volumetric units of measure should be avoided. • When the prescription Sig contains dosing designations in mL, mL dosing instructions should be used on the prescription container label. • When the prescription Sig contains dosing instructions in non-volumetric units (e.g., mg) or non-standard volumetric units (e.g., dropperful), convert the dosing instructions to mL, and use mL dosing instructions on the prescription container label. • The standard abbreviation "mL" should be used on the prescription container label. Other abbreviations for milliliter (e.g., cc, mls) should be avoided. If use of mixed case is not possible (e.g., because of legacy software limitations), lowercase ("ml") or uppercase ("ML") may be used while changes to the preferred "mL" can be implemented. • Mnemonics, Sig codes, or any defaults used in computer systems to print prescription labels should produce dosing designations using mL.
2	**Dose amounts should always use leading zeros before a decimal point for amounts less than one and should not use trailing zeros after a decimal point on prescription container labels of oral liquid medications.** • The dose designation on a prescription container label should be "0.5" mL, NOT ".5" mL. • The dose designation on a prescription container label should be "5" mL, NOT "5.0" mL. Do not use trailing zeros in the hundredths, or thousandths position (e.g., "2.5" mL NOT "2.50" mL or "2.500" mL) either. • Place adequate space between the dose and unit of measure (e.g., "5 mL" NOT "5mL").
3	**Dosing devices with numeric graduations and units that correspond to the container labeling should be made easily and universally available such as including a device each time oral liquid prescription medications are dispensed.** • The standard abbreviation "mL" should be used on the dosing device to correspond to the prescription container label. • Leading zeros before a decimal point should always be used on dosing devices and trailing zeros after a decimal point should never be used on dosing devices to correspond to the prescription container label.

Copyrighted Materials – See Copyright Statement for Allowed Use

3. Background

3.1 Why an NCPDP White Paper?

In September 2012, NCPDP hosted a stakeholder meeting involving 27 participants representing a wide range of perspectives[1] to discuss the possibility of improving the standardization and consistency of dosing designations (i.e., the amount to be given and the unit of measure to use) on prescription container labels of oral liquid medications. This stakeholder meeting was catalyzed by the PROTECT Initiative,[2] a public-private partnership, which has as one of its objectives to reduce the likelihood of healthcare professional, patient, and caregiver errors by standardizing dosing designations used for oral liquid medications.

NCPDP has previously played a key role in efforts to clarify information on the labels of prescription drugs. An NCPDP white paper on improving prescription container labels for medications containing acetaminophen[3] has, along with subsequent implementation efforts by partner organizations, helped lead to the use of "acetaminophen" instead of the more confusing acronym "APAP" on the labels of hundreds of prescription products. NCPDP also has led the way in promoting a universal medication schedule (UMS) for use on prescription medication labels, with a white paper recommending the removal of arcane notations, such as BID, or confusing instructions, such as "twice daily," and substituting plain language instructions, such as "take 1 tablet in the morning."[4]

Based on the success of these previous NCPDP efforts to promote patient safety through improving prescription container labels, NCPDP determined that best practices also could be developed to decrease the variability of dosing designations used for oral liquid medications. This effort was assigned to a task group of the NCPDP Professional Pharmacy Services Work Group (WG10).

3.2 How Does Standardizing Dosing Designations on Prescription Container Labels of Oral Liquid Medications Dispensed from Community Pharmacies Relate to Efforts in Other Settings?

While healthcare professionals measure and administer medications within healthcare facilities, it is up to patients or caregivers to accurately measure and administer liquid medications outside of healthcare facilities. When patients or caregivers administer liquid medications, the dosing

[1] Participants included electronic drug database publishers, chain pharmacies, mail order pharmacies, drug distributors, community pharmacy system software vendors, drug manufacturers (McNeil Healthcare), government (Food and Drug Administration [FDA] and Centers for Disease Control and Prevention [CDC]), and non-governmental organizations (Institute for Safe Medication Practices [ISMP], National Association of Boards of Pharmacy [NABP], National Association of Chain Drug Stores [NACDS], and United States Pharmacopeial Convention [USP])

[2] Centers for Disease Control and Prevention. The PROTECT Initiative: Advancing Children's Medication Safety. http://www.cdc.gov/medicationsafety/protect/protect_Initiative.html (accessed November 29, 2013).

[3] National Council for Prescription Drug Programs, Inc. NCPDP Recommendations for Improved Prescription Container Labels for Medicines Containing Acetaminophen Version 1.1. http://www.ncpdp.org/Whitepaper.aspx (accessed November 29, 2013).

[4] National Council for Prescription Drug Programs, Inc. Universal Medication Schedule White Paper. http://www.ncpdp.org/Whitepaper.aspx (accessed October 24, 2013).

Copyrighted Materials – See Copyright Statement for Allowed Use

designations on the medication container labels and consistency with accompanying dosing devices are particularly important because container labels often provide the only instructions they use when administering medications.

For many decades, the American Society of Health-System Pharmacists (ASHP) and other practice organizations (e.g., American Health Care Association (AHCA), American Pharmacists Association (APhA)) have recommended the use of metric units and metrically marked dosing devices for the measurement and administration of oral liquid medications.[5,6,7,8,9] Confusion and resultant medication errors (e.g., unit conversions) from multiple systems of measure was the principal rationale for the recommended use of metric units in these settings. In fact, in some studies, the majority of dosing errors were associated with administration of wrong doses of liquid medications.

The Joint Commission also has required the facilities it accredits (e.g., hospitals, nursing and rehabilitation centers) to standardize dosing designations in order to reduce medication administration errors in inpatient healthcare facilities.[10] Other organizations, including the Institute for Safe Medication Practices (ISMP)[11] and the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP), have supported using the same or similar recommendations in all healthcare settings.

Since 2011, to reduce medication administration errors when using over-the-counter (OTC) oral liquid medication outside of healthcare facilities, a Consumer Healthcare Products Association (CHPA) guideline[12] and the Food and Drug Administration (FDA) Voluntary Guidance for Industry[13] have provided details for standardization and consistency in medication dosing designations for OTC product labels and dosing devices.

A recent study of the most commonly used pediatric OTC liquid medications demonstrated that just two years after these voluntary standards were finalized, 91% of dosing directions and 62%

[5] American Society of Hospital Pharmacists. Guidelines for single unit packages of drugs. Approved by the ASHP Board of Directors December 2, 1966. *Am J Hosp Pharm.* 1971; 28:110-2.

[6] American Health Care Association, American Pharmaceutical Association, and American Society of Hospital Pharmacists. Pharmaceutical services in the long-term care facility. 7th edition, second printing. Washington, DC: 1975.

[7] Barker KN, Heller WM. The development of a centralized unit-dose dispensing system for UMAC. Part III: An editing center for physicians' medication orders. Am J Hosp Pharm. 1964; 21;66-7.

[8] Hynniman CE, Conrad WF, Urch WA, Parker PF. A comparison of errors under the University of Kentucky unit dose system and traditional drug distribution systems in four hospitals. Am J Hosp Pharm. 1970; 27:802-14.

[9] American Society of Health-System Pharmacists. Recommendations from the National Coordinating Council for Medication Error Reporting and Prevention. www.ashp.org/s_ashp/docs/files/BP07/MedMis_End_NCCMERP.pdf. (accessed October 24, 2013).

[10] The Joint Commission. Facts about the Official "Do Not Use" List. http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf. (accessed October 24, 2013).

[11] Institute for Safe Medication Practices. ISMP's list of error-prone abbreviations, symbols, and dose designations. http://www.ismp.org/Tools/errorproneabbreviations.pdf. (accessed November 06, 2013).

[12] Consumer Healthcare Products Association. Guideline Volumetric Measures for Dosing of Over-the-Counter Liquid Oral Drug Products for Children ≤12 Years of Age. http://www.chpa.org/voluntarycodes_volumetricmeasurepediatricliquids.aspx (accessed October 24, 2013).

[13] U.S. Food and Drug Administration. Guidance for Industry: Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm188992.pdf (accessed November 29, 2013).

Copyrighted Materials – See Copyright Statement for Allowed Use

of dosing devices adhered to all top-tier recommendations, suggesting that voluntary initiatives can promote adherence to safety recommendations.[14] Similar or higher adoption rates are the goal for prescription oral liquid medications.

In 2013, FDA released draft guidance for industry on safety considerations for commercial container labels and carton labeling design to minimize medication errors. This guidance includes details for standardization and consistency of dosing designations for commercial container and carton labeling of prescription drug and biological products but does not specifically address containers or cartons dispensed from the community pharmacies.[15] While some medications are dispensed from community pharmacies in the original carton or container, many, if not most, are dispensed from community pharmacies in other containers filled by the pharmacy with only the prescribed amount. In addition, even when medications are dispensed in the original container or carton, labels created in the community pharmacy with dosing directions that are ordered for the specific patient are added and may differ in units of measure and other dosing instructions.

Because more and more community prescriptions are ordered by electronic transmission of prescriptions from the prescriber to the community pharmacy (e-prescribing), in 2013, the American Academy of Pediatrics (AAP) issued a policy statement outlining safe practices for e-prescribing which also includes details for standardization and consistency in medication dosing designations transmitted to community pharmacies.[16]

This white paper draws on these existing standards and medication safety research to provide recommendations for portraying dosing designations on the prescription container label of oral liquid medications dispensed from community pharmacies that align with recommendations for inpatient settings and other healthcare facilities, for OTC medications, for the original container and carton labeling, and for e-prescribing.

4. Rationale for Key Recommendations

4.1 Recommendation 1: Milliliter (mL) Should be the Standard Unit of Measure Used on Prescription Container Labels of Oral Liquid Medications

4.1.1 The Need to Measure Oral liquid Medication Volumes Makes Accurate Use More Challenging than for Solid Medications

[14] Budnitz DS, Lovegrove MC, Rose KO. Adherence to Label and Device Recommendations for Over-the-Counter Pediatric Liquid Medications. Pediatrics, online early release, January 6, 2014 http://pediatrics.aappublications.org/content/early/2014/01/01/peds.2013-2362 (accessed January 15, 2014)

[15] DRAFT FDA Guidance for Industry – Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors, Draft Guidance issued by US HHS FDA Center for Drug Evaluation and Research (CDER) (April 2013). Page 12 – Leading and Terminal Zeros, Decimals, and Commas. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf (accessed January 15, 2014).

[16] AAP Policy Statement - Electronic Prescribing in Pediatrics: Toward Safer and More Effective Medication Management, Pediatrics 2013;131:824–826, April 1, 2013. http://pediatrics.aappublications.org/content/131/4/824.full.pdf (accessed January 15, 2014).

Copyrighted Materials – See Copyright Statement for Allowed Use

Using oral liquid prescription medications is more complicated than using solid medication dosage forms. Unlike oral solid dosage forms, most liquid medications are not "pre-packaged" in unit-of-use containers or dosing units. Oral liquid medications typically must be measured by a patient or caregiver at every administration. This additional step requires further manipulation of the product and introduces opportunities for error.

Healthcare professionals often rely on liquid formulations when prescribing medications for young children. Because of their small body mass, young children may be more susceptible to harm from measurement errors and overdoses. In any given week in the United States, 20% of children younger than 12 years of age are taking at least one prescription medication.[17] This high rate of medication use in children indicates the importance of addressing the problem of caregiver medication administration errors.

4.1.2 The Use of Multiple Volumetric Measures Contributes to Oral Liquid Medication Dosing Errors

While essentially all solid dosage form medications have been measured in metric units (e.g., mg for milligrams) for decades, dosing designations for oral liquid medications still use, and patients and caregivers are still instructed to administer medications using,[18] a variety of U.S. customary or household units (teaspoons, tablespoons), non-standard units (droppersful), apothecary units (drams), and metric units (milliliters, mL). The use of non-standard metric abbreviations or terminology unfamiliar to parents and other caregivers, such as cubic centimeters (cc), creates an additional potential source of confusion. The cc abbreviation also is associated with other errors of misinterpretation.

The use of multiple volumetric measures increases the likelihood of multi-fold dosing errors by patients, caregivers, and healthcare professionals. For example, a hurried prescriber or pharmacist who switches mL and teaspoon may mistakenly prescribe or dispense a 5-fold overdose or underdose. A caregiver who confuses teaspoon and tablespoon can accidentally administer a 3-fold overdose or underdose.

During pharmacy dispensing, numerous cases have been reported of errors involving multiple volumetric measures, most frequently due to a physician's prescription being changed from an mL dose to a teaspoon dose.[19] The design of some community pharmacy computer systems may facilitate confusion involving multiple volumetric measures. For efficiency, some systems may default to a dose expressed in teaspoon amounts in the directions when oral liquids are selected. (Some prescribing systems may default to teaspoons as well.) If this happens when an mL dose is intended, pharmacists and pharmacy technicians may not remember to change the instructions for the container label back to mL when teaspoons automatically appear.

[17] Vernacchio L, Kelly JP, Kaufman DW, Mitchell AA. Medication use among children <12 years of age in the United States: results from the Slone Survey. Pediatrics. 2009 Aug;124(2):446-54.
[18] Sobhani S, Christopherson J, Ambrose PJ, Corelli RL. Accuracy of oral liquid measuring devices: comparison of dosing cup and oral dosing syringe. Ann Pharmacother. 2008;42:46-52.
[19] Seifert SA, Jacobitz K. Pharmacy prescription dispensing errors reported to a regional poison control center. J Toxicol Clin Toxicol. 2002;40(7):919-23.

Copyrighted Materials – See Copyright Statement for Allowed Use

Distractions and confirmation bias will inevitably contribute to pharmacy personnel and prescribers forgetting to change the dosing designations from these error-prone default settings.

The ISMP reports over 50 serious cases in which confusion with units of measure has led to errors, primarily attributed to transcription/dispensing errors.

> Example: A pharmacist accidentally put on a child's prescription container label that the child should be given 3.5 teaspoons of an antibiotic instead of the 3.5 mL that the doctor had ordered, resulting in administration of a 5-fold overdose for 3 days.[20]
>
> Example: A pharmacist typed out instructions on the prescription container label as "take 4 cc (4/5 teaspoon) three times a day." The parents of the child did not understand the term "cc" and mistook the slash mark to mean 4.5 teaspoons. The child was given 4.5 teaspoons three times daily, almost five times more than intended.[21]

When oral liquid medications are administered in home settings, volumetric measure confusion by parents and other caregivers has been a source of concern for the ISMP and the FDA for many years.[22,23] Over 10,000 calls made to U.S. poison control centers annually are attributed to confusion around units of measurement, with approximately three quarters involving children 12 years of age or younger.[24,25,26,27,28,29]

[20] Institute for Safe Medication Practices. Another TEAspoon—mL mix-up. *ISMP Med Saf Alert Acute Care*. 2011;16(19):3.
[21] Institute for Safe Medication Practices. Misunderstood abbreviations. *ISMP Med Saf Alert Com/Amb Care*. 2005 Aug;4(8):2.
[22] Institute for Safe Medication Practices. Another TEAspoon—mL mix-up. *ISMP Med Saf Alert Acute Care*. 2011;16(19):3.
[23] Food and Drug Administration. Information for Healthcare Professionals: Long-Acting Hydrocodone-Containing Cough Product. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126196.htm (accessed October 24, 2013).
[24] Bronstein AC, Spyker DA, Cantilena LR Jr, Green J, Rumack BH, Heard SE. 2006 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS). Clin Toxicol (Phila). 2007 Dec;45(8):815-917.
[25] Bronstein AC, Spyker DA, Cantilena LR Jr, Green JL, Rumack BH, Heard SE; American Association of Poison Control Centers. 2007 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 25th Annual Report. Clin Toxicol (Phila). 2008 Dec;46(10):927-1057.
[26] Bronstein AC, Spyker DA, Cantilena LR Jr, Green JL, Rumack BH, Giffin SL. 2008 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 26th Annual Report. Clin Toxicol (Phila). 2009 Dec;47(10):911-1084.
[27] Bronstein AC, Spyker DA, Cantilena LR Jr, Green JL, Rumack BH, Giffin SL. 2009 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 27th Annual Report. Clin Toxicol (Phila). 2010 Dec;48(10):979-1178.
[28] Bronstein AC, Spyker DA, Cantilena LR Jr, Green J, Rumack BH, Dart RC. 2010 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 28th Annual Report. Clin Toxicol (Phila). 2011 Dec;49(10):910-941.
[29] Bronstein AC, Spyker DA, Cantilena LR Jr, Green J, Rumack BH, Dart RC. 2011 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 29th Annual Report. Clin Toxicol (Phila). 2012 Dec;50(10):911-1164.

Copyrighted Materials – See Copyright Statement for Allowed Use

Errors attributed to confusion around units of measure have been associated with sometimes severe adverse events in young children.[30]

4.1.3 Parents Measure Liquids More Accurately Using mL

Although prescribers and pharmacists may assume that parents and other caregivers cannot administer liquid medications accurately using mL, a recent study indicates this is a false assumption. The study showed that parents who reported their dose in mL were not only more likely to use a standardized dosing device, but also were half as likely to make a dosing error.[31]

4.1.4 Milliliter Has Been Endorsed as the Standard Unit of Measure for Oral Liquid Medications by Many Professional and Patient Safety Organizations

The Joint Commission requires the facilities it accredits (e.g., hospitals and nursing and rehabilitation centers) to standardize dosing designations in order to reduce medication administration errors within inpatient healthcare facilities and has suggested that organizations avoid apothecary units (e.g., dram) and non-standard abbreviations (e.g., do not use cc; mL is preferred).[32] Based on reports of errors and patient harm, ISMP,[33] NCC-MERP, ASHP,[34,35,36] and others also have issued or endorsed recommendations to only use metric units (mL) in all settings (Appendix A).

The United States Pharmacopeial Convention (USP) adopted the use of metric units as a standard over thirty years ago. More recently, USP has published standards stating that prescriptions for medications should be written to state the quantity and/or strength of the medication in metric units unless otherwise indicated in an individual monograph. The USP also states that if an amount of a medication is prescribed by any other system of measure, only the

[30] Tzimenatos L, Bond GR; Pediatric Therapeutic Error Study Group. Severe injury or death in young children from therapeutic errors: a summary of 238 cases from the American Association of Poison Control Centers. Clin Toxicol (Phila). 2009 Apr;47(4):348-54.

[31] Yin HS et al. Association between Unit of Measurement Used and Parent Medication Dosing Errors. Under review.

[32] The Joint Commission. The Joint Commission Official "Do Not Use" List, 2009. http://www.jointcommission.org/assets/1/18/dnu_list.pdf (accessed January 21, 2014).

[33] Institute for Safe Medication Practices. ISMP Statement on Use of Metric Measurements to Prevent Errors with Oral Liquids. http://www.ismp.org/pressroom/PR20110808.pdf (accessed October 24, 2013).

[34] American Society of Health-System Pharmacists. Recommendations from the National Coordinating Council for Medication Error Reporting and Prevention. www.ashp.org/s_ashp/docs/files/BP07/MedMis_End_NCCMERP.pdf *(accessed October 24, 2013).*

[35] American Society of Hospital Pharmacists. Guidelines for single unit packages of drugs. Approved by the ASHP Board of Directors December 2, 1966. Am J Hosp Pharm. 1971; 28:110-2.

[36] American Health Care Association, American Pharmaceutical Association, and American Society of Hospital Pharmacists. Pharmaceutical services in the long-term care facility. 7th edition, second printing. Washington, DC: 1975.

Copyrighted Materials – See Copyright Statement for Allowed Use

metric equivalent amount should be dispensed and labeled accordingly.[37]

Unfortunately, changes made in the volumetric units during community pharmacy dispensing may decrease the use of mL on container labeling. In a study of liquid medications dispensed to children 12 years of age or younger from 4 community pharmacies, 68% of prescription instructions were written using milliliters; 24% used teaspoons; and 7% used other units. When the corresponding container labels were examined, 62% used milliliters and 29% used teaspoons, suggesting that at least 5% of prescriptions were switched from milliliters to teaspoons.[38]

4.2 Recommendation 2: Dose Amounts Should Always Use Leading Zeros Before a Decimal Point and Should Not Use Trailing Zeros After a Decimal Point on Prescription Container Labels of Oral Liquid Medication

4.2.1 How Amounts are Expressed Can Cause Significant Overdoses

Error-prone methods of expressing doses have contributed to medication errors and patient harm.[39,40,41,42,43] The inclusion of a decimal point and trailing zero for whole number doses (e.g., 5.0 instead of 5) and the failure to include a zero before the decimal point for doses less than a whole unit (e.g., .5 instead of 0.5) have resulted in 10-fold dosing errors. Such errors can be fatal.[44]

> Example: A 9-month-old girl tragically died following a 10-fold overdose of morphine. The baby's physician wrote an order, without the use of a leading zero, for morphine ".5

[37] The USP-NF adopted the use of metric units as a standard as expressed in the International System of Units (SI) as established and revised by the *Conference generale des poid et measures* over 30 years ago. The convention includes milliliter (mL) as a standard metric unit. The convention has been incorporated into standards for prescribing and dispensing that state that compendial articles (drug/drug product) must be written to state the quantity and/or strength desired in metric units. Additionally, "teaspoon," a definition for a measuring device that is currently published in the USP-NF has been expressed in metric units as a standard since 1995 and United States Pharmacopeial Convention. General Notices and Requirements, Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia 9 – Prescribing and Dispensing, USP 36 – NF 31 edition May 1, 2013.

[38] Shah, Rita; Blustein, Leona; Kuffner, Edward; Davis, Lisa. Communicating Doses of Pediatric Liquid Medicines to Parents/Caregivers: A Comparison of Written Dosing Directions on Prescriptions with Labels Applied by Dispensed Pharmacy.*JPeds*, 2013. http://www.jpeds.com/article/S0022-3476(13)01393-0/abstract (accessed December 23, 2013).

[39] The Joint Commission. Facts about the Official "Do Not Use" List. http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf. (accessed October 24, 2013.

[40] Institute for Safe Medication Practices. ISMP's list of error-prone abbreviations, symbols, and dose designations. http://www.ismp.org/Tools/errorproneabbreviations.pdf. (accessed November 06, 2013).

[41] U.S. Food and Drug Administration. Medication Errors. http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/default.htm (accessed November 12, 2013).

[42] Barker KN, Heller WM. The development of a centralized unit-dose dispensing system for UMAC. Part III: An editing center for physicians' medication orders. *Am J Hosp Pharm.* 1964; 21;66-7.

[43] Hynniman CE, Conrad WF, Urch WA, Parker PF. A comparison of errors under the University of Kentucky unit dose system and traditional drug distribution systems in four hospitals. *Am J Hosp Pharm*. 1970; 27:802-14.

[44] Gaunt MJ, Cohen MR. Error-prone abbreviations and dose expressions. In: Cohen MR, ed. Medication errors. 2nd ed. Washington (DC): American Pharmacists Association; 2007:165.

Copyrighted Materials – See Copyright Statement for Allowed Use

mg." However, the decimal point was missed and the order misinterpreted. Two 5 mg doses were administered to the baby.[45]

4.2.2 Existing Healthcare Standards Suggest Dose Designations Always Use Leading Zeros and Never Use Trailing Zeros

The Joint Commission's Information Management Standard IM.02.02.01 requires accredited organizations to adhere to the Joint Commission's official "Do Not Use" list. This list dictates that when the amount of medication is a whole number, the amount should never be designated with a trailing zero (e.g., express as 5 not 5.0). If the amount of medication is less than 1, the amount should always include a leading zero (e.g., express as 0.5 not .5).[46] The USP has published similar standards when expressing the active ingredients of drug products.[47]

In addition, the ISMP, FDA, ASHP, NCC-MERP, and others (Appendix B) have issued statements or endorsed recommendations to use leading zeros and avoid trailing zeros in dose designations in all settings.[48,49,50]

4.3 Recommendation 3: Dosing Devices With Numeric Graduations and Units That Correspond to the Container Labeling Should be Made Easily and Universally Available Such as Including a Device Each Time Oral Liquid Prescription Medications are Dispensed

4.3.1 How Dosing Designations Are Represented on Dosing Devices Contributes to Medication Administration Errors

Non-metric units of measure presented, alone or in combination, on dosing devices also have contributed to errors. Inclusion of units such as drams, minims, fluid ounces, cc, TSP (teaspoon), TBSP (tablespoon), and DSSP (dessertspoon) have caused mistakes when healthcare professionals, patients, and caregivers confuse the unit of measure on a measuring device with the unit of measure specified on a prescription container label or other set of instructions.

---

[45] Institute for Safe Medication Practices. Please don't sleep through this wake-up call. *ISMP Med Saf Alert Acute Care*. 2001;6(9):1. Available from Internet: http://www.ismp.org/Newsletters/acutecare/articles/20010502.asp (accessed November 06, 2013).

[46] The Joint Commission. Facts about the Official "Do Not Use" List. http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf (accessed October 24, 2013).

[47] United States Pharmacopeial Convention General Notices and Requirements, Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia 10 - Preservation, Packaging, Storage, and Nomenclature, from USP 36 – NF 31 edition May 1, 2013.

[48] Institute for Safe Medication Practices. ISMP's list of error-prone abbreviations, symbols, and dose designations. http://www.ismp.org/Tools/errorproneabbreviations.pdf. (accessed November 06, 2013).

[49] Institute for Safe Medication Practices. ISMP and FDA campaign to eliminate the use of error-prone abbreviations. 2006. http://www.ismp.org/tools/abbreviations/. (accessed November 06, 2013).

[50] American Society of Health-System Pharmacists. Recommendations from the National Coordinating Council for Medication Error Reporting and Prevention. www.ashp.org/s_ashp/docs/files/BP07/MedMis_End_NCCMERP.pdf (accessed October 24, 2013).

Copyrighted Materials – See Copyright Statement for Allowed Use

Example: A nurse administered five drams of acetaminophen concentrate liquid (100 mg/mL) instead of 5 mL. As a result, the patient received 18.45 mL or 1.845 g of acetaminophen, almost four times the intended amount (Figure 1).[51]

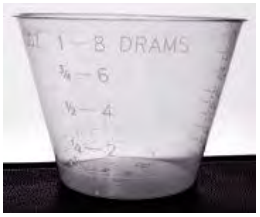


Figure 1. Dose cup used to measure liquid acetaminophen (Image courtesy of the ISMP)

4.3.2 Use of Household Spoons or Other Utensils Can Cause Administration Errors

Household teaspoons and tablespoons have proven to be inaccurate and error-prone when used by patients and caregivers as medication measuring tools since volumes in these household devices are not standardized. Although some kitchen measuring sets include a volumetric measure along with the household measure, these too cannot be relied on to provide accurate dosing.

In addition, the use of teaspoons or tablespoons in dosing designations on prescription container labels may encourage patients and caregivers to believe that using household spoons or other kitchen utensils is advisable if a pharmacy-provided dosing device is not available.[52] Dispensing dosing devices with numeric graduations and units (mL) that correspond with the container labeling can reinforce use of a calibrated dosing device rather than household spoons or kitchen utensils.

4.3.3 Guidelines for Over-the-Counter Medications Already Recommend that Milliliter (mL) Should be the Standard Unit of Measure Used for Oral Liquid Medication Dosing Devices

Voluntary guidelines from CHPA and FDA suggest that dosing devices should always accompany OTC oral liquid medications, and these devices should include the units and numeric doses as described in the dosing directions.[53,54] CHPA further recommends that mL be the preferred unit of measure in dosing directions.[55] Other organizations, such as the American

[51] Institute for Safe Medication Practices. Archaic liquid measure a factor in medication errors. *ISMP Med Saf Alert Com/Amb*. 2012;11(7):1-2.
[52] Dewalt DA. Ensuring Safe and Effective Use of Medication and Health Care: Perfecting the Dismount. JAMA. 2010; 304(23):2641-2642.
[53] Consumer Healthcare Products Association. Guideline Volumetric Measures for Dosing of Over-the-Counter Liquid Oral Drug Products for Children ≤12 Years of Age. http://www.chpa.org/voluntarycodes_volumetricmeasurepediatricliquids.aspx. Accessed October 24, 2013.
[54] Food and Drug Administration. Nonprescription Cough and Cold Medicine Use in Children – Full Version. http://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/ucm078927.htm. Accessed October 24, 2013.
[55] Consumer Healthcare Products Association. Guideline Volumetric Measures for Dosing of Over-the-Counter Liquid Oral Drug Products for Children ≤12 Years of Age.

Copyrighted Materials – See Copyright Statement for Allowed Use

Pharmacists Association (APhA), also recommend that standardized dosing devices be included with all liquid medications, while ISMP specifies that dosing devices should allow parents and other caregivers to measure liquid medications in mL (Appendix C).

5. Regulation Overview

The content of prescription container labels is subject to both federal and state authorities.

- Examples of federal statutes and regulations concerning prescription labels include:
  - 0 Food, Drug and Cosmetic (FD&C) Act[56] – "Exemptions and consideration for certain drugs, devices, and biological products"
  - 0 Controlled Substances Act – Labeling and Packaging[57] which includes "Statement of required warning"[58] and "Labeling of substances and filling of prescriptions"[59]
- Additional provisions are mandated by the individual state governments.

The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (NABP Model Act)[60] identify critical and important information for patients that must appear, as well as additional information that may appear, on all prescription labels.

As previously mentioned, oral liquid medications may be prescribed in a variety of units of measure. Although federal and state laws mandate the required elements of prescription container labels, including directions for use, it is allowable for pharmacists to use their professional judgment to determine the appropriate units of measure, such as mL, to include on the prescription container label to ensure that oral liquid medications are dosed accurately.

A review of state labeling requirements indicates that there are no existing laws or regulations that expressly prohibit a pharmacist from changing the unit of measure or notation of decimal amounts to be used on a prescription label.[61]

Most states provide for labels to contain "directions for use," and therefore by interpretation, would allow pharmacists to use mL as the unit of measure. Certainly, in instances where the prescriber has indicated the dosage in mL, pharmacists should be encouraged to prepare the prescription label according to the prescription, and should not arbitrarily change it to teaspoons or any other measure. NABP endorses the use of mL and supports pharmacists in exercising professional judgment to select mL as the preferred unit of measure.

http://www.chpa.org/voluntarycodes_volumetricmeasurepediatricliquids.aspx. Accessed October 24, 2013.

[56] 21 United States Code (USC) §353 (b) (2)

[57] 21 USC §825 (c)

[58] 21 CFR §290.5

[59] 21 CFR §1306.24

[60] NABP. Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy *(NABP Model Act)*, August 2012. http://www.nabp.net/publications/model-act/ (accessed December 11, 2013).

[61] **NABP***LAW*® Search results of state labeling requirements conducted 4/17/13

Copyrighted Materials – See Copyright Statement for Allowed Use

6. Stakeholder Challenges and Opportunities

Variations in how a liquid medication is ordered, transcribed and transmitted, and then interpreted, entered and printed provide opportunities for errors in what appears on the prescription container labels of oral liquid prescription medications. Mitigation of these errors requires consistent use of mL as the standard unit of measure and the use of leading zeros and avoidance of trailing zeros in dose designations by all the stakeholders who play a role in prescribing or providing patient instructions on the prescription container label. This consistency needs to extend to any oral instructions given to the patient at the time of prescribing and dispensing.

Even when the prescription container label utilizes mL as the standard unit of measure and standard notation of decimal amounts in dosing designations, a dosing device with numeric graduations and units that correspond to the container labeling should be made available and its use explained to the patient or caregiver so that the dose can be correctly interpreted and measured. Otherwise, if the patient or caregiver does not understand how to use the measuring device, he or she may resort to the use of the familiar and available household teaspoon or tablespoon. Because the volumes of these household utensils are not standardized, they have proven to be inaccurate and error-prone when used as medication measuring tools. Even sets of kitchen measuring spoons are not designed to accurately deliver oral doses of medications.

6.1. Pharmacy System Software Companies

Pharmacy system software can automate and speed outpatient medication dispensing. Pharmacy system software also can help standardize dosing units of measure and notation of amounts that display and print on container labels, but current software systems may have limitations.

6.1.1 Assessment of Input and Output of Standard Dosing Designations

Pharmacy systems may need to make modifications to Sig or directions components to be able to use mL as the standard unit of measure for oral liquid prescription medications, instead of teaspoon, tablespoon, cc, dram, and others, and to express dose amounts, per the white paper recommendations. For a pharmacy system to output the recommended standardized dosing designations, consideration must be given to the inputs into the pharmacy system. A key first step is to confirm the pharmacy system can accept, and is in fact receiving, dose designation information input as recommended from: drug databases, prescribing system software (particularly in the case of true e-prescribing), directly input data from the user, and other data input sources (e.g. payer claim responses, other interfaces such as eMAR/HL7 data sources.)

Because pharmacy systems also may output data to other systems, the impact of changing pharmacy systems to output recommended standardized dosing designations also should be assessed. For example, some pharmacy software systems may be unable to fully support mixed case character sets in text strings, including drug descriptions and units of measure. These legacy limitations may require all UPPER CASE drug descriptions when displaying information on a computer monitor, printing on prescription labels and in patient education

Copyrighted Materials – See Copyright Statement for Allowed Use

materials, and other situations. Furthermore, systems may not be able to programmatically convert internal use of UPPER CASE characters to lower case or mixed case immediately prior to transmitting data to a third party via NCPDP SCRIPT[62] transactions, continuity of care documentation, or electronic medical records and health information exchange. Typically, systems that have this type of limitation may be able to receive lower case or mixed case text, but once received, these are converted automatically to upper case so that the internal applications can properly process the data, and the data may not be able to be converted back

While lower case "ml" is not optimal or recommended due to the potential confusion between the lower case letter "l" and the number one ("1") in some printer and display fonts, "ml" still is preferable to the use of teaspoon, tablespoon, cc, dram, liquid ounce, oz, pint, etc. Therefore, although ISMP, USP, this white paper, and others recommend that milliliter be represented in mixed case (i.e., "mL"), some systems currently have no option other than to represent milliliter in upper case, or "ML", and some may only be able to represent milliliter in all lower case, or "ml". These limiting situations currently may affect systems' programmatic testing, error testing, and compliance reporting. However, NCPDP recommends that the pharmacy system industry respond to these challenges by working to resolve these limitations to enable universal use of mL as the standard unit of measure and dosing and move as expeditiously as possible toward explicitly mandating mixed case support in future interface standards.

6.1.2 Enhancing Systems for Standardizing Dosing Designations

After it is confirmed that pharmacy systems can receive standardized dosing designation inputs, it still is likely that not all dosing information will be input as recommended. Appropriate decimal notation for amounts and mL as the unit of measure can be input manually by users by utilizing a "free form Sig" in combination with standard system Sig codes. However, manual data input by pharmacy system users takes more time and requires workflow changes, and asks for 100% compliance by users.

Pharmacy systems can facilitate standardized dosing designations by removing non-standard designations from the "Sig File" and setting default values to standardized dose designations.

Use of the NCPDP Structured and Codified Sig [63] within SCRIPT in conjunction with the recommendations in this white paper for standardizing dosing designations for oral liquid medication could further reduce ambiguity of the instructions.

Until widespread adoption of Structured and Codified Sig is achieved, implementation of enhanced pharmacy system logic can help standardize ("edit" or "scrub") inputs by users.

[62] The SCRIPT is an NDPDP standard developed for transmitting prescription information electronically between prescribers, pharmacies, payers, and other entities for new prescriptions, changes of prescriptions, prescription refill requests, prescription fill status notifications, cancellation notifications, relaying of medication history, transactions for long-term care, electronic prior authorization and other transactions.

[63] The Structured and Codified Sig Format is intended to facilitate communication between prescribers and pharmacists, improve the efficiency of the prescribing and dispensing activities, and help reduce the opportunity for errors. It provides standardization of the portion of an electronic prescription containing the directions for use, using existing, accepted electronic transmission standards. The structured and codified is available in NCPDP SCRIPT Standard 10.4 and above.

Copyrighted Materials – See Copyright Statement for Allowed Use

Enhanced system logic may be designed to automatically express the Sig in desired "mL" units when oral liquids are selected. When a user inputs ".5," enhanced system logic can 'auto-correct' and store/output the data as "0.5". When a user inputs "ML", enhanced system logic can 'auto-correct' and store/output the data as "mL".

6.2 Electronic Drug Database Publishers

Pharmacy system software must reference accurate and timely drug databases to safely dispense medications as well as efficiently process medication claims. For claims processing, the NCPDP Billing Unit Standard contains mL as one of three billing units. Use of "mL" is indicated when a product is measured by its liquid volume, including liquid non-injectable products of 1 mL or greater.[64] For safe and accurate medication dispensing, drug database publishers often offer dosing-related modules, such as structured Sig strings, Sig building tools, and dose screening databases. These dosing-related modules also can be used by payers and pharmacy benefit managers (PBMs) to process drug claims, but when embedded into workflow applications for use by prescribers, pharmacists, nurses, and other healthcare professionals, they can help ensure medications are dispensed in appropriate doses and labeled with appropriate dosing designations.

Drug database modules and tools such as structured Sig strings, Sig builders, and dose screening, should consistently represent liquid volumes in metric units and use the metric designation "mL" as a unit of measure for liquids where appropriate. In 2009, ISMP issued a call to action for healthcare professionals, prescribing software companies, and pharmacy system software companies in an effort to eliminate the use of non-metric measurements, such as "teaspoon" and "tablespoon," or associated variations like "tsp," to prevent medication errors in prescription instructions.[65,66] As supported by ISMP case reports, the disparity between the actual volume measured by using a household teaspoon or tablespoon as well as the possible confusion between the two easily can lead to incorrect dosing, with potentially serious consequences, especially in the pediatric population. In support of the ISMP initiative, drug database publishers reviewed their clinical database offerings to make sure that no non-metric measurements were included and metric units were used in dose screening databases and Sig databases.

Pharmacy system software companies that use drug database publishers' flat file data in their software are encouraged to adopt "mL" for use in structured Sig strings, just as "mL" is used in Application Programming Interfaces (APIs) units for alert messages. To support the limitations noted in 6.1.1 as well as multiple end-user needs that are beyond the scope of this white paper, the drug database publishers may also offer their customers fields that use all upper case and/or all lower case text strings, in addition to the preferred mixed-case text strings, but should encourage migration as soon as feasible to the preferred mixed-case representation.

---

[64] National Council for Prescription Drug Programs, Inc. NCPDP Billing Unit Standard Fact Sheet. Publication July 2013. https://www.ncpdp.org/pdf/BUS_fact_sheet.pdf (accessed January 22, 2014).
[65] Institute for Safe Medication Practices. A teaspoon of medicine? ISMP Med Saf Alert Com/Amb Care. 2009;8(5):1-2. http://www.ismp.org/Newsletters/ambulatory/archives/200905_1.asp (accessed January 22, 2014).
[66] Institute for Safe Medication Practices. ISMP calls for elimination of "teaspoonful" and other non-metric measurements to prevent errors. http://www.ismp.org/pressroom/PR20090603.pdf (accessed January 22, 2014).

Copyrighted Materials – See Copyright Statement for Allowed Use

All drug database publishers should be encouraged to re-review drug databases, modules, and tools for use of the standardized dosing designations for oral liquid medication recommended in this white paper. Pharmacy system software companies that use drug database publishers' flat file data in their software can then adopt "mL" for use in structured Sig strings, just as "mL" is used in Application Programming Interfaces (APIs) units for alert messages. To support the limitations noted in 6.1.1 as well as multiple end-user needs that are beyond the scope of this white paper, the drug database publishers may also offer their customers fields that use all upper case and/or all lower case text strings, in addition to the preferred mixed-case text strings, but should encourage migration as soon as feasible to the preferred mixed-case representation.

6.3 **Prescribing Software Companies** (including electronic health record (EHR) with prescribing applications)

Electronic transmission of prescriptions from the prescriber to the community pharmacy affords numerous benefits to prescribers, pharmacies, and patients. The goal of e-prescribing is to have an electronic prescription arrive at the pharmacy with complete and clear instructions, eliminating the need for the pharmacy staff to interpret a prescriber's handwritten instructions and prevent transcribing errors. It has been shown to improve quality and safety by decreasing dispensing errors associated with handwritten prescriptions.

Unfortunately, some segments of the industry may not have recognized the benefits, or may not have embraced e-prescribing because of training, implementation, or software issues. To help address some of these concerns, a task group of the NCPDP e-Prescribing & Related Transactions Work Group (WG11), has produced a best practice guide for the SCRIPT standard. The implementation guide is intended for prescribing software companies, physicians, and pharmacists to assist them in the proper use of fields within the SCRIPT standard. The guide includes suggestions on the use of mL as the standard unit of measure (instead of teaspoon) as recommended by the AAP to improve pediatric medication safety.

E-prescribing can provide the additional benefit of encouraging standardized dosing designations at the point of prescribing. By incorporating standard dosing designations (units using mL and amounts using decimals and zeros appropriately), e-prescribing software may be designed so that non-metric and non-volumetric units are never presented to the prescriber in any of the structured selection menus of Sig builders, drug description menus, or quantity qualifiers. In addition, the prescriber technology vendors could even implement natural language processing and clinical decision support modules to alert their users if inappropriate values are selected.

The complete guidance may be viewed in the current *"NCPDP SCRIPT Implementation Recommendations."*[67]

[67] NCPDP SCRIPT Implementation Recommendations, http://www.ncpdp.org/members/stds-102508/SCRIPT.Implementation.Recommendations.V1.22.pdf (accessed December 17, 2013)

Copyrighted Materials – See Copyright Statement for Allowed Use

6.4 Pharmacy Leadership

NCPDP encourages community pharmacy leadership to adopt and implement the recommendations of this white paper in their pharmacies. The rationale and research cited in this white paper provide the basis for enhancing patient safety and positive medical outcomes through the use of mL as the standard unit of measure for oral liquid medications.

Nonetheless, NCPDP recognizes that the adoption and implementation of these recommendations pose a number of challenges and opportunities for the community pharmacy in the areas of pharmacy computer systems, workflow, support of pharmacy staff and patient education, and consistency across products and care settings.

6.4.1 Pharmacy System Software

Pharmacy leadership needs to make a commitment to make appropriate programming changes and create policies and procedures that will support these recommendations. There are always challenges to system changes, but such change is possible and the corporate leadership of several pharmacy chains has decided to support the use of the mL, and has started by encouraging their pharmacists to migrate prescription directions from teaspoon and tablespoon to mL units (e.g., 5 mL and 15 mL, respectively, or decimal fractions therein) and to provide appropriately marked (mL) dosing devices with all oral liquid prescription medications.

6.4.2 Workflow

Flagging of prescription receipts and sale procedures are considerations that may require changes in the workflow to allow for dispensing of calibrated dosing devices. Prescription data entry and selection of the proper Sig/direction codes for patient label directions reside in the workflow procedure and should not impede productivity and process efficiency.

6.4.3 Support of Pharmacy Staff and Patient Education

One significant way pharmacy leadership can support this initiative is to inform, educate, and empower pharmacy staff by:

- Establishing policies and procedures that support the recommended dose designations for all oral liquid medications dispensed in pharmacies and convey the preferences or policies to all the staff
- Providing pharmacies with adequate numbers of appropriately calibrated and marked dosing devices for distribution at dispensing of oral liquid prescription medication
- Sharing the expectation that staff should:
  - Provide appropriate dosing devices with oral liquid prescription medication
  - Explain to patients how to use the device to measure oral liquid medication
  - Ensure patients and caregivers understand the use of the device before leaving the pharmacy

Copyrighted Materials – See Copyright Statement for Allowed Use

- Providing ready access to this white paper (Web site link or printed copies) or other documentation of the:
  - Three white paper recommendations (See Section 2)
  - Dangers of improper dosing measurement and administration of oral liquid medications, especially in children and infants, and the rationale for the recommendations (See Section 4)
  - NABP endorsement of the use of mL and support of pharmacists exercising professional judgment to select mL as the preferred unit of measure (See Section 5)
  - USP endorsement and support of mL as the standard unit of measure for oral liquid medications (See Appendix A)
  - Other documents and resources from professional, patient safety, and standard setting organizations, and government agencies, consistent with the white paper recommendations (See Appendices A-C)
  - Call to Action for pharmacy staff in this white paper (See Section 7.1, Stakeholder Map)

Pharmacy leaders are encouraged to support pharmacist-patient counseling, communication, and education at point-of-dispensing. Community pharmacies can provide brochures or other patient-centered printed information to patients and caregivers and can emphasize these patient safety measures are being implemented to ensure proper dosing and patient safety.

6.4.4 Consistency Across Care Settings and Products

In the acute care inpatient setting and other healthcare facilities, mL is the standard oral liquid unit of measure and the use of leading zeros and avoidance of trailing zeros in dose designations is a requirement for certification by The Joint Commission. Responding to FDA and industry recommendations, OTC manufacturers are moving to the use of mL for the standard unit of measure and standard notation of decimal amounts on package labels and dosing devices packaged with oral liquid OTC medications.[68] Implementing the dose designation recommendations in this white paper will harmonize the labeling and administration of oral liquid prescription medications in the community setting with the standards used in inpatient settings and other healthcare settings, as well as the standards used for OTC medications. This standardization should decrease patient, caregiver, and health professional confusion, and therefore improve patient safety.

7. Stakeholder Call to Action: Adopt, Implement, Adhere, Communicate, and Educate

The NCPDP Task Group Call to Action maps out roles for many stakeholders, but particularly relies on local and corporate community pharmacy leadership to:

[68] Budnitz DS, Lovegrove MC, Rose KO. Adherence to Label and Device Recommendations for Over-the-Counter Pediatric Liquid Medications. *Pediatrics*, online early release, http://pediatrics.aappublications.org/content/early/2014/01/01/peds.2013-2362 (accessed January 6, 2014).

Copyrighted Materials – See Copyright Statement for Allowed Use

- Adopt and implement the recommendations in this white paper
- Communicate these as preferences or policies to all pharmacy staff
- Measure the performance of your organization in achieving these recommendations and stress accountability across your organization adhering to them
- Explore implementation of innovative patient-centered communication and education solutions that target and encourage pharmacist-to-patient conversations and education at point of dispensing
- Facilitate communication by stakeholders outside the community pharmacy system, including prescribers, with a role in patient and healthcare professional education on using standardized dosing designations for prescribed oral liquid medications.

The following "*Stakeholder Map*" identifies all the relevant stakeholders, listed alphabetically, who need to play a role in adopting, communicating, adhering, and educating. The map outlines a call to action and identifies some of the associated challenges and opportunities for each stakeholder group.

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

7.1 Stakeholder Map: Call to Action, Challenges, and Opportunities

Stakeholder(s)	Call to Action	Challenges and Opportunities
Certification Organizations – Professional and Systems	• Incorporate the white paper dose designation recommendations for oral liquid prescription medication into criteria for professional certification • Incorporate the white paper dose designation recommendations for oral liquid prescription medications into updates, inspections, and testing of pharmacy system software, drug databases, and prescribing software	• Provide education for healthcare professionals involved in dispensing medication, prescribing medication, and instructing patients and caregivers to administer medication • Provide education for system developers and designers
Dosing Device Manufacturers	Manufacture calibrated dosing devices for the pharmacy customer that have dose designations as recommended in this white paper	Call for and participate in discussion about the standardization of devices, such as elimination of extraneous markings and leading and trailing zeros

Copyrighted Materials – See Copyright Statement for Allowed Use

Stakeholder(s)	Call to Action	Challenges and Opportunities
Electronic Drug Database Publishers	• Review drug databases, modules, and tools for use of the standardized dosing designations for oral liquid medication. If not already used, update dosing designations to use mL as the standard unit of measure and to use leading zeros and to avoid the use of trailing zeros for oral liquid prescription medication • Provide electronic referential drug information products using metric units (such as "mL") in lieu of non-metric units (such as "teaspoon") • Provide quantity qualifier mappings between proprietary internal codes and NCPDP codes so that technology vendors can send accurate codes in all outbound messages • Encourage technology vendors to only use non-metric and non-generic codes while communicating prescription quantity values • Offer customers fields that use the preferred mixed case text strings rather than only upper case and/or all lower case text strings	• Provide consistency for all healthcare professionals in both inpatient and outpatient practice settings, eliminate confusion, and deliver a safer patient experience • A coordinated effort with pharmacy system software companies is required to overcome any existing challenges with field lengths designated for drug names

Copyrighted Materials – See Copyright Statement for Allowed Use

Stakeholder(s)	Call to Action	Challenges and Opportunities
Government Agencies	• Incorporate dosing designations that use mL as the standard unit of measure and use leading zeros and avoid the use of trailing zeros for oral liquid prescription medication into standards and guidances • Collaborate with standards setting organizations and device manufacturers to develop standards for dosing devices for oral liquid prescription medications aligned with existing guidelines and guidances for OTC medications	• Provide guidance to healthcare organizations and professionals to support the transition to mL as the standard unit of measure for oral liquid prescription medications • Drive elimination of units of measure that are already in use through a widespread coordinated effort to overcome any existing challenges • Provide a coordinated announcement and/or distribution mechanism that will effectively communicate to all relevant stakeholders
National Association of Boards of Pharmacy and State Boards of Pharmacy	• Reiterate supportive stance for the use of mL as the standard unit of measure for oral liquid prescription medications • Find opportunities to incorporate metric recommendations into Model Act • Provide an announcement and/or distribution mechanism that will effectively communicate to the state board of pharmacies and pharmacists	

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

Stakeholder(s)	Call to Action	Challenges and Opportunities
Pharmacists and Pharmacy Technicians	• Use professional judgment to determine the most appropriate units of measure, and most appropriate notation of decimal amounts to include in the dose designation of the prescription container label of oral liquid medications to facilitate accurate dosing • Use mL as the standard unit of measure whenever possible on prescription container labels. Avoid other abbreviations (cc, ml, ML) and the spelled-out term millimeters o When the prescription Sig contains dosing designations in mL, mL dosing instructions should be used on the prescription container label o When the prescription Sig contains dosing instructions in non-volumetric units (e.g., mg) or non-standard volumetric units (e.g., dropperful), convert the dosing instructions to mL, and use mL dosing instructions on the prescription container label • Always use leading zeros before a decimal point, and never use trailing zeros after a decimal point on prescription container labels for oral liquid medications o Do not use trailing zeros in the hundredths, or thousandths position (e.g., “2.5” mL not “2.50” mL or “2.500” mL) o Place adequate space between the dose and unit of measure (e.g., “10 mL” NOT “10mL”)	• Communicating with healthcare professionals and educating and counseling patients and caregivers takes additional time • Seek synergies and innovative solutions to improve patient education and communication at point-of-dispensing through collaboration with pharmacy system as well as other stakeholders • Periodically perform quality control checks by observing processes in the pharmacy to ensure adherence to the standardized work practices

Copyrighted Materials – See Copyright Statement for Allowed Use

Stakeholder(s)	Call to Action	Challenges and Opportunities
	• When dispensing an oral liquid medication, include a dosing device with numeric graduations and units that correspond to the container labeling, or tell patients or caregivers where an appropriate device can be obtained. • Ensure verbal patient counseling, communication and education at point-of-dispensing that use dosing designations that are consistent with the prescription container label and the dosing device • Educate patients or caregivers on how to use dosing devices correctly and ensure they have access to an appropriate dosing device before they leave the pharmacy • Educate other pharmacy staff regarding importance of using mL as the unit of measurement for all oral liquid medications	

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

Stakeholder(s)	Call to Action	Challenges and Opportunities
Pharmacy Leadership - Local and Corporate	• Commit to adopting and implementing dose designations recommendations for prescription container labels for oral liquid medications dispensed from their pharmacies o Make appropriate computer system programming changes that will support the dose designation recommendations o Make required changes in the workflow to allow for dispensing of calibrated dosing devices o Establish policies and procedures that support the recommended dose designations for all oral liquid medications dispensed in pharmacy o Convey the preferences or policies to all the staff o Provide pharmacies with adequate numbers of dosing devices that correspond with numeric graduations and dose designations on container labels for distribution at the dispensing of oral liquids o Share expectations with staff that they should distribute dosing devices with oral liquid prescription medication, explain to customers how to use the device, and ensure customers understand the use of the device before leaving the pharmacy • Inform pharmacy staff where they can access this white paper readily (Web site or printed copies) or other documentation of the white paper's recommendations and the rationale for them; the	• Seek synergies and innovative solutions to improve patient education and communication at point-of-dispensing through collaboration with both pharmacy systems, as well as other stakeholders (such as local prescribers) • Test and update pharmacy system software to ensure it incorporates the recommendations in this white paper • Educate staff regarding the importance of standardizing to use of mL as the unit of measure, the use of leading zeros, and the avoidance of trailing zeros for oral liquid prescription medications • Periodically perform quality control checks by observing processes in the pharmacy to ensure adherence to the standardized work practices

Copyrighted Materials – See Copyright Statement for Allowed Use

Stakeholder(s)	Call to Action	Challenges and Opportunities
	dangers of improper dosing; the NABP endorsement and support of pharmacists exercising professional judgment in selecting mL as the preferred unit of measure; USP's endorsement and support; other documentation and resources from professional, patient safety and standards setting organizations, and from government agencies, that are consistent with the white paper recommendations; and this white paper's call to action for pharmacy staff • Collaborate with pharmacy system software companies to incorporate the recommended labeling changes • Optimize pharmacist-patient counseling, communication and education at point-of-dispensing	

Copyrighted Materials – See Copyright Statement for Allowed Use

Stakeholder(s)	Call to Action	Challenges and Opportunities
Pharmacy System Software Companies	• Eliminate "teaspoon" and other non-metric volumetric units of measure from data files for all oral liquid medications • Modify the Sig or directions components of the systems program to be able to use mL as the standard unit of measure for oral liquid medication instead of teaspoon or other non-metric measures and to express dose amounts per the white paper recommendations o Use free text Sig in combination with standard system Sig codes o Automate the change as a system default in the "Sig file" • Assure that mnemonics, Sig codes, or any defaults used in computer systems to generate prescriptions and prescription labels produce directions using mL • Use "mL" in any alert messages, just as the drug database publishers Application Programing Interfaces (APIs) use "mL" units for alert messages • Address legacy limitations to representing milliliter in mixed case (mL) to enable universal use of mL as the standard unit of measure	• Eliminate "teaspoon" and other non-metric volumetric units of measure from data files for all oral liquid medications • Collaborate with drug database publishers on the timing of system change for the elimination of non-metric measures for liquid oral medications • Test and update pharmacy system software to ensure it incorporates the recommendations in this white paper

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

Stakeholder(s)	Call to Action	Challenges and Opportunities
Prescribing Software Companies (including EHR with prescribing applications)	• Provide default dosing designations that use mL, use leading zeros, and avoid use of trailing zeros in prescribing software • Use "mL" in dosing-related modules (such as structured Sig strings, Sig building tools, and dose screening databases) that can be embedded into workflow applications and e-prescribing whenever appropriate • Develop documentation for end users on creation of basic and complex e-prescription messages and provide training to users • Work with certification organizations to incorporate the white paper recommendations in the testing criteria • Incorporate Best Practices from the NCPDP SCRIPT Implementation Recommendations	Communicate this white paper's recommendations to all prescribers that use your prescribing software, emphasizing the patient safety benefits

Copyrighted Materials – See Copyright Statement for Allowed Use

Stakeholder(s)	Call to Action	Challenges and Opportunities
Professional Organizations and Trade Associations	Incorporate or reiterate supportive stance on the white paper dose designation recommendations for oral liquid prescription medications into policy statements or statements of professional standards	• Provide an announcement and/or distribution mechanism that would effectively communicate to all members • Obtain organizational consensus to publish support and advocate for the elimination of non-metric volumetric units of measure and adoption of the use of mL as the default unit of measure for oral liquid medications
Standards Setting Organizations	Incorporate or reiterate supportive stance on the white paper dose designation recommendations for oral liquid prescription medications	• Provide an announcement and/or distribution strategy to effectively communicate to healthcare organizations and professionals • Provide guidance to healthcare organizations and professionals to support the transition to the use of mL as the standard unit of measure for oral liquid medications, the use of leading zeros, and the avoidance of the use of trailing zeros

Copyrighted Materials – See Copyright Statement for Allowed Use

8. Conclusions

Although metric units (e.g., mg for milligrams) have been the standard unit of measure for solid dose form medications for decades, oral liquid medications continue to be prescribed, transcribed, dispensed, measured, and administered using a variety of volumetric units, which continues to lead to confusion, dosing errors and overdosing or underdosing by healthcare professionals, patients, and caregivers. Standard dosing designations used consistently on prescriptions and container labels of oral liquid medications, as well as on the dosing devices used to measure and administer them, could help improve patient safety and patient outcomes.

The adoption of this white paper's recommendations will harmonize the transcription, labeling, dispensing, measuring, and administration of oral liquid prescription medications in the community setting with standards used in hospital and other healthcare facilities, recommendations for OTC medications, and international standards of volumetric measurement. In addition, many professional and safety organizations already promote recommendations that align with the dose designation recommendations in this white paper.

The NCPDP mL Task Group Call to Action is directed first and foremost to the local and corporate pharmacy leadership, as they can catalyze many of the changes required to implement the best practices described in this white paper.

NCPDP recognizes there are challenges for pharmacy leadership to adopt and implement the recommendations, as well as for many of the other stakeholders.

A concerted effort of all stakeholders is necessary to realize the opportunities and meet and overcome the challenges, and NCPDP calls upon all the relevant stakeholders to support efforts to adopt, implement, and adhere to the recommendations in this white paper, and to educate of healthcare professionals, patients, and caregivers on how to accurately measure and administer oral liquid medications.

All stakeholders are encouraged to consider the recommendations and call to action of this white paper and to collaborate to achieve standardized dosing designations for prescription container labels of oral liquid medications dispensed from community pharmacies.

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

9. References

21 Code of Federal Regulations. CFR §290.5 Drugs; Statement of required warning

21 Code of Federal Regulations. CFR §1306.24 Labeling of substances and filling of prescriptions.

21 United States Code. USC §353 Exemptions and consideration for certain drugs, devices, and biological products (b)(2) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

21 United States Code. USC §825 Labeling and packaging (c) Warning on label.

American Academy of Pediatrics. Policy Statement – Electronic Prescribing in Pediatrics: Toward a Safer and More Effective Medication Management, Pediatrics 2013;131:824-826, April 1, 2013. http://pediatrics.aappublications.org/content/131/4/824.full.pdf (accessed January 15, 2014)

American Health Care Association, American Pharmaceutical Association, and American Society of Hospital Pharmacists. Pharmaceutical services in the long-term care facility. 7th edition, second printing. Washington, DC: 1975.

American Society of Health-System Pharmacists. Recommendations from the National Coordinating Council for Medication Error Reporting and Prevention. www.ashp.org/s_ashp/docs/files/BP07/MedMis_End_NCCMERP.pdf (accessed October 24, 2013).

American Society of Hospital Pharmacists. Guidelines for single unit packages of drugs. Approved by the ASHP Board of Directors December 2, 1966. Am J Hosp Pharm. 1971; 28:110-2.

Barker KN, Heller WM. The development of a centralized unit-dose dispensing system for UMAC. Part III: An editing center for physicians' medication orders. Am J Hosp Pharm. 1964; 21;66-7.

Bronstein AC, Spyker DA, Cantilena LR Jr, Green J, Rumack BH, Dart RC. 2011 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 29th Annual Report. Clin Toxicol (Phila). 2012 Dec;50(10):911-1164.

Bronstein AC, Spyker DA, Cantilena LR Jr, Green J, Rumack BH, Dart RC. 2010 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 28th Annual Report. Clin Toxicol (Phila). 2011 Dec;49(10):910-941.

Bronstein AC, Spyker DA, Cantilena LR Jr, Green JL, Rumack BH, Giffin SL. 2009 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 27th Annual Report. Clin Toxicol (Phila). 2010 Dec;48(10):979-1178.

Copyrighted Materials – See Copyright Statement for Allowed Use

Bronstein AC, Spyker DA, Cantilena LR Jr, Green JL, Rumack BH, Giffin SL. 2008 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 26th Annual Report. Clin Toxicol (Phila). 2009 Dec;47(10):911-1084.

Bronstein AC, Spyker DA, Cantilena LR Jr, Green JL, Rumack BH, Heard SE; American Association of Poison Control Centers. 2007 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 25th Annual Report. Clin Toxicol (Phila). 2008 Dec;46(10):927-1057.

Bronstein AC, Spyker DA, Cantilena LR Jr, Green J, Rumack BH, Heard SE. 2006 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS). Clin Toxicol (Phila). 2007 Dec;45(8):815-917.

Budnitz DS, Lovegrove MC, Rose KO. Adherence to Label and Device Recommendations for Over-the-Counter Pediatric Liquid Medications. Pediatrics, online early release, January 6, 2014. http://pediatrics.aappublications.org/content/early/2014/01/01/peds.2013-2362 (accessed January 11, 2014).

Centers for Disease Control and Prevention. The PROTECT Initiative: Advancing Children's Medication Safety. http://www.cdc.gov/medicationsafety/protect/protect_Initiative.html (accessed November 29, 2013).

Consumer Healthcare Products Association. Guideline Volumetric Measures for Dosing of Over-the-Counter Liquid Oral Drug Products for Children ≤12 Years of Age. http://www.chpa.org/voluntarycodes_volumetricmeasurepediatricliquids.aspx (accessed October 24, 2013).

Dewalt DA. Ensuring Safe and Effective Use of Medication and Health Care: Perfecting the Dismount. JAMA. 2010; 304(23):2641-2642.

Food and Drug Administration. DRAFT Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf (accessed January 14, 2014).

Food and Drug Administration. Guidance for Industry: Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm188992.pdf (accessed November 29, 2013).

Food and Drug Administration. Information for Healthcare Professionals: Long-Acting Hydrocodone-Containing Cough Product. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126196.htm (accessed October 24, 2013).

Copyrighted Materials – See Copyright Statement for Allowed Use

Food and Drug Administration. Medication Errors. http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/default.htm. (accessed November 12, 2013).

Food and Drug Administration. Nonprescription Cough and Cold Medicine Use in Children – Full Version. http://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/ucm078927.htm. (accessed October 24, 2013).

Gaunt MJ, Cohen MR. Error-prone abbreviations and dose expressions. In: Cohen MR, ed. Medication errors. 2nd ed. Washington (DC): American Pharmacists Association; 2007:165.

Hynniman CE, Conrad WF, Urch WA, Parker PF. A comparison of errors under the University of Kentucky unit dose system and traditional drug distribution systems in four hospitals. Am J Hosp Pharm. 1970; 27:802-14.

Institute for Safe Medication Practices. A teaspoon of medicine? ISMP Med Saf Alert Com/Amb Care. 2009;8(5):1-2. http://www.ismp.org/Newsletters/ambulatory/archives/200905_1.asp (accessed January 22, 2014).

Institute for Safe Medication Practices. Another TEAspoon—mL mix-up. ISMP Med Saf Alert Acute Care. 2011;16(19):3.

Institute for Safe Medication Practices. Archaic liquid measure a factor in medication errors. ISMP Med Saf Alert Com/Amb. 2012;11(7):1-2.

Institute for Safe Medication Practices. ISMP and FDA campaign to eliminate the use of error-prone abbreviations [online]. 2006. http://www.ismp.org/tools/abbreviations/. (accessed November 06, 2013).

Institute for Safe Medication Practices. ISMP calls for elimination of “teaspoonful” and other non-metric measurements to prevent errors. http://www.ismp.org/pressroom/PR20090603.pdf (accessed January 22, 2014).

Institute for Safe Medication Practices. ISMP’s list of error-prone abbreviations, symbols, and dose designations. http://www.ismp.org/Tools/errorproneabbreviations.pdf. (accessed November 06, 2013).

Institute for Safe Medication Practices. ISMP Statement on Use of Metric Measurements to Prevent Errors with Oral Liquids.

http://www.ismp.org/pressroom/PR20110808.pdf (accessed October 24, 2013).

Institute for Safe Medication Practices. Misunderstood abbreviations. ISMP Med Saf Alert Com/Amb Care. 2005 Aug;4(8):2.

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

Institute for Safe Medication Practices. Please don't sleep through this wake-up call. ISMP Med Saf Alert Acute Care. 2001;6(9):1. http://www.ismp.org/Newsletters/acutecare/articles/20010502.asp (accessed November 06, 2013).

The Joint Commission. Facts about the Official "Do Not Use" List. http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf. (accessed October 24, 2013).

National Association of Boards of Pharmacy. Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (NABP Model Act), August 2012. http://www.nabp.net/publications/model-act/ (accessed December 11, 2013).

National Association of Boards of Pharmacy. NABPLAW® Search results of state labeling requirements conducted 4/17/13.

National Council for Prescription Drug Programs, Inc. NCPDP Billing Unit Standard Fact Sheet. Publication. July 2013. https://www.ncpdp.org/pdf/BUS_fact_sheet.pdf (accessed January 22, 2014).

National Council for Prescription Drug Programs, Inc. NCPDP Recommendations for Improved Prescription Container Labels for Medicines Containing Acetaminophen. Version 1.1. http://www.ncpdp.org/Whitepaper.aspx (accessed November 29, 2013).

National Council for Prescription Drug Programs, Inc. SCRIPT Implementation Recommendations, http://www.ncpdp.org/members/stds-102508/SCRIPT.Implementation.Recommendations.V1.22.pdf (accessed December 17, 2013)

National Council for Prescription Drug Programs, Inc. Universal Medication Schedule White Paper. http://www.ncpdp.org/Whitepaper.aspx (accessed October 24, 2013).

Seifert SA, Jacobitz K. Pharmacy prescription dispensing errors reported to a regional poison control center. J Toxicol Clin Toxicol. 2002;40(7):919-23. http://www.ncbi.nlm.nih.gov/pubmed/12507062 (accessed December 19, 2013)

Shah, Rita; Blustein, Leona; Kuffner, Edward; Davis, Lisa. Communicating Doses of Pediatric Liquid Medicines to Parents/Caregivers: A Comparison of Written Dosing Directions on Prescriptions with Labels Applied by Dispensed Pharmacy.JPeds, 2013. http://www.jpeds.com/article/S0022-3476(13)01393-0/abstract (accessed December 23, 2013).

Sobhani S, Christopherson J, Ambrose PJ, Corelli RL. Accuracy of oral liquid measuring devices: comparison of dosing cup and oral dosing syringe. Ann Pharmacother. 2008;42:46-52.

Copyrighted Materials – See Copyright Statement for Allowed Use

Tzimenatos L, Bond GR; Pediatric Therapeutic Error Study Group. Severe injury or death in young children from therapeutic errors: a summary of 238 cases from the American Association of Poison Control Centers. Clin Toxicol (Phila). 2009 Apr;47(4):348-54.
United States Pharmacopeial Convention. General Notices and Requirements, Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia 9 – Prescribing and Dispensing, USP 36 – NF 31 edition May 1, 2013.

United States Pharmacopeial Convention General Notices and Requirements, Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia 10 - Preservation, Packaging, Storage, and Nomenclature, from USP 36 – NF 31 edition May 1, 2013.

Vernacchio L, Kelly JP, Kaufman DW, Mitchell AA. Medication use among children <12 years of age in the United States: results from the Slone Survey. Pediatrics. 2009 Aug;124(2):446-54. http://www.ncbi.nlm.nih.gov/pubmed/19651573 (accessed December 19, 2013)

Yin HS et al. Association between Unit of Measurement Used and Parent Medication Dosing Errors. (Under review).

Supplemental Research and References

American Academy of Pediatrics. Using liquid medicines. Available at: www.healthychildren.org/English/safety-prevention/at-home/medication-safety/Pages/Using-Liquid-Medicines.aspx.

Bond GR, Woodward RW, Ho M. The growing impact of pediatric pharmaceutical poisoning. J Pediatr. 2012;160(2):265–270, e1

Budnitz DS, Lewis LL, Shehab N, Birnkrant D. CDC and FDA response to risk of confusion in dosing Tamiflu oral suspension. N Engl J Med. 2009;361(19):1913–1914 http://www.nejm.org/doi/full/10.1056/NEJMc0909190

Budnitz DS, Salis S. Preventing medication overdoses in young children: an opportunity for harm elimination. Pediatrics. 2011; 127(6). Available at: www.pediatrics.org/cgi/content/full/127/6/e1597

Dart RC, Paul IM, Bond GR, et al. Pediatric fatalities associated with over the counter (nonprescription) cough and cold medications. Ann Emerg Med. 2009;53(4):411–417

Falagas ME, Vouloumanou EK, Plessa E, Peppas G, Rafailidis PI. Inaccuracies in dosing drugs with teaspoons and tablespoons. Int J Clin Pract. 2010;64(9):1185–1189

Copyrighted Materials – See Copyright Statement for Allowed Use

Honey BL, Condren M, Phillips C, Votruba A. Evaluation of oral medication delivery devices provided by community pharmacies. Clin Pediatr (Phila). 2013;52(5):418–422

Johnson KB, Lehmann CU; Council on Clinical Information Technology of the American Academy of Pediatrics. Electronic prescribing in pediatrics: toward safer and more effective medication management. Pediatrics. 2013;131(4). Available at www.pediatrics.org/cgi/content/full/131/4/e1350

Karch AM, Karch FE. A spoonful of medicine.Or is it more? Am J Nurs. 2000;100(11):24

Lesar TS. Tenfold medication dose prescribing errors. Ann Pharmacother. 2002; 36(12):1833–1839

Litovitz T. Implication of dispensing cups in dosing errors and pediatric poisonings: a report from the American Association of Poison Control Centers. Ann Pharmcother: 1992;26(7-8):917-918

Lokker N, Sanders L, Perrin EM, et al. Parental misinterpretations of over-the-counter pediatric cough and cold medication labels. Pediatrics. 2009;123(6):1464–1471

Madlon-Kay DJ, Mosch FS. Liquid medication dosing errors. J Fam Pract. 2000;49(8):741–744

National Council for Prescription Drug Programs. NCPDP 2012 annual report: Connecting Healthcare to Improve Patient Safety and Health Outcomes. www.ncpdp.org/annual-reports.aspx

National Coordinating Council for Medication Error Reporting and Prevention. Recommendations to enhance accuracy of prescription writing. www.nccmerp.org/council/council1996-09-04.html.

Wansink B, van Ittersum K. Spoons systematically bias dosing of liquid medicine. Ann Intern Med. 2010 5;152(1):66-7.

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

10. Appendices

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

10.1 Appendix A: Documents and Resources Consistent with the White Paper Recommendation on the Use of Milliliter (mL)

Organization	
Academic Pediatric Association (APA)	**APA Focus Volume 48, Issue 6** (December 2011). http://www.ambpeds.org/publications/newsletters/2011/newsDec2011.pdf APA Board Vote "to support and advocate for mL as the preferred unit for measurement of liquid medications."
American Academy of Family Physicians (AAFP)	**AAFP Policy - Preferred Unit of Measurement for Liquid Medications** (September 21, 2011). http://www.aafp.org/about/policies/all/preferred-unit.html "The AAFP supports a standardized approach for the use of milliliters (mL) as the preferred unit of measurement for liquid medications, in order to prevent unintended medication overdoses in children. (Board Chair 1:1)"
American Academy of Pediatrics (AAP)	**AAP Policy Statement - Electronic Prescribing in Pediatrics: Toward Safer and More Effective Medication Management**, *Pediatrics* 2013;131:824–826, April 1, 2013. http://pediatrics.aappublications.org/content/131/4/824.full.pdf "Because safety for children is paramount, e-prescribing systems used for the care of children should include…metric-only labeling instructions…" **Article in AAP News – Antidote for Medication Overdoses: Use Metric Dosing, Educate Parents**, AAP News Vol. 34 No. 12 December 1, 2013; pp. 4. http://aapnews.aappublications.org/content/34/12/4.full "Pediatricians are encouraged to use and discuss mL-based dosing when prescribing liquid medications, and to avoid dosing in teaspoons or tablespoons." **Article in AAP News – Out with Teaspoons, in with Metric Units: Pediatricians urged to prescribe liquid medications in mLs only,** AAP News Vol. 33 No. 3 March 1, 2012; pp. 10. http://aapnews.aappublications.org/content/33/3/10.full "Pediatricians are encouraged to help prevent unintentional medication overdoses by eliminating the practice of prescribing medications with volumes in teaspoons and tablespoons. Instead, metric-based dosing using milliliters (mLs) for all liquid medicine prescriptions is preferred…"
American Association of Poison Control Centers (AAPCC)	**AAPCC Resolution - Standardizing Volumetric Measures for Oral Medications Intended for Use by Children** (2010). "We encourage member poison centers, to the extent feasible, to join in educating the public about the value and importance of… measuring

Copyrighted Materials – See Copyright Statement for Allowed Use

	liquid medications using mL rather than other measuring units."
American Medical Association (AMA)	**AMA Policy H-120.968 Medication (Drug) Errors in Hospitals** http://www.ama-assn.org/resources/doc/PolicyFinder/policyfiles/HnE/H-120.968.HTM "(1) Our AMA encourages individual physicians to minimize medication errors by adhering to the following guidelines when prescribing medications:…(g) Medication orders should be clear and unambiguous. Physicians should: … (viii) and use the metric system."
American Pharmacists Association (APhA)	**APhA - Email Interview** (October 18, 2013). "APhA supports the following National Coordinating Council for Medication Error Reporting and Prevention recommendation: "…all prescription orders be written in the metric system except for therapies that use standard units such as insulin, vitamins, etc. Units should be spelled out rather than writing "U." The change to the use of the metric system from the archaic apothecary and avoirdupois systems will help avoid misinterpretations of these abbreviations and symbols, and miscalculations when converting to metric, which is used in product labeling and package inserts."
American Society of Health-System Pharmacists (ASHP)	**ASHP Statement Endorsing Use of Metric System for Prescriptions Recommendations from the National Coordinating Council for Medication Error Reporting and Prevention. Medication Misadventures–Endorsed Document** (1999. Reviewed and re-endorsed in 2005). http://www.ashp.org/DocLibrary/BestPractices/MedMisEndNCCMERP.aspx **"**All prescription orders should be written in the metric system except for therapies that use standard units such as insulin, vitamins, etc.…The change to the use of the metric system from the archaic apothecary and avoirdupois systems will help avoid misinterpretations of these abbreviations and symbols, and miscalculations when converting to metric, which is used in product labeling and package inserts." Many decades earlier, ASHP and other practice organizations (e.g., American Health Care Association (AHCA), American Pharmacists Association (APhA)) began recommending the use of metric units and metrically marked dosing devices for the measurement and administration of oral liquid medications.[69,70,71,72]

[69] American Society of Hospital Pharmacists. Guidelines for single unit packages of drugs. Approved by the ASHP Board of Directors December 2, 1966. Am J Hosp Pharm. 1971; 28:110-2.
[70] American Health Care Association, American Pharmaceutical Association, and American Society of Hospital Pharmacists. Pharmaceutical services in the long-term care facility. 7th edition, second printing. Washington, DC: 1975.
[71] Barker KN, Heller WM. The development of a centralized unit-dose dispensing system for UMAC. Part III: An editing center for physicians' medication orders. Am J Hosp Pharm. 1964; 21;66-7.
[72] Hynniman CE, Conrad WF, Urch WA, Parker PF. A comparison of errors under the University of Kentucky unit dose system and traditional drug distribution systems in four hospitals. Am J Hosp Pharm. 1970; 27:802-14.

Copyrighted Materials – See Copyright Statement for Allowed Use

Consumer Healthcare Products Association (CHPA)	**CHPA Guideline - Volumetric Measures for Dosing of Over-the-Counter Oral Liquid Drug Products for Children ≤ 12 years of Age** (Adopted November 17, 2009). http://www.chpa.org/voluntarycodes_volumetricmeasurepediatricliquids.aspx "2. Use milliliter as the preferred unit of measure in the dosing directions…4. Use the following abbreviation and text exactly: a. Abbreviations: "mL"; Full text: "teaspoonful"…Avoid use within labeling dosing directions of the following: tablespoon, cubic centimeters, cc, dram, fluid ounce, Fl. Oz., and dropper(ful)."
Food and Drug Administration (FDA)	**DRAFT FDA Guidance for Industry – Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors**, Draft Guidance issued by US HHS FDA Center for Drug Evaluation and Research (CDER) April 2013; Page 10 – Metric Measurements. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf "The dose or expression of strength **should appear in metric units of measure such as mL**, mg, and mcg, rather than apothecary or household measurements (e.g., tsp for teaspoon, TBSP for tablespoon, drams, and grains) or ratios (e.g., 1:1000). Fatal errors have occurred when healthcare providers or patients miscalculated medication doses when converting from one unit of measure to another..."
Institute for Safe Medication Practices (ISMP)	**ISMP Statement - Use of Metric Measurement to Prevent Errors with Oral Liquids** (October 2011). http://www.ismp.org/pressroom/PR20110808.pdf "The Institute for Safe Medication Practices (ISMP) is asking prescribers, pharmacists, and other healthcare professionals, as well as pharmacy computer system and e-prescribing system vendors, to only use metric measurements in prescription directions. ISMP has taken this step after careful deliberation, in order to better protect patients from harmful errors and give providers a greater level of comfort and confidence when calculating and administering doses of medication… ISMP first reported on the confusion of teaspoonfuls and mL in its newsletter in 2000, and in 2009 issued a call for practitioners to move to sole use of the metric system for measuring over-the counter (OTC) and prescription oral liquid doses, but mix-ups have continued to result in the serious injury of children and adults.… ISMP has received more than 50 reports of mL-teaspoonful errors alone, including cases where injuries required treatment or hospitalization." "Use only metric units, not teaspoon or other non-metric measurements, for all patient instructions, including those listed in prescribing and

Copyrighted Materials – See Copyright Statement for Allowed Use

	pharmacy computer systems. This should cover directions incorporated into computer system mnemonics, speed codes, or any defaults used to generate prescriptions and prescription labels." "Express doses for oral liquids using only metric weight or volume (e.g., mg or mL)—not household measures such as teaspoonfuls or tablespoonfuls, which are not an accurate volume of measure."
National Association of Boards of Pharmacy (NABP)	**NABP Model Act - Model Rules for the Practice of Pharmacy.** Section 3 Pharmacy Practice, page 84 (August 2013). http://www.nabp.net/publications/model-act/ "All Drugs Dispensed for use by inpatients of a hospital or other health care facility, whereby the Drug is not in the possession of the ultimate user prior to Administration, shall meet the following requirements….The label…shall include…the strength and volume, where appropriate, expressed in the metric system whenever possible"… "All Drugs Dispensed to ambulatory or outpatients, including Drugs Dispensed by Practitioners shall contain a label affixed to the container in which such Drug is Dispensed including…drug strength, expressed in the metric system whenever possible"…
National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP)	**Recommendations to Enhance Accuracy of Prescription Writing** (Adopted by NCCMERP 1996, Revised 2005). http://www.nccmerp.org/council/council1996-09-04.html "All prescription orders should be written in the metric system except for therapies that use standard units such as insulin, vitamins, etc. …The change to the use of the metric system from the archaic apothecary and avoirdupois systems will help avoid misinterpretations of these abbreviations and symbols, and miscalculations when converting to metric, which is used in product labeling and package inserts." **NCCMERP is an independent body comprised of 27 national organizations**: AARP, AHA, AMA, ANA, APhA, ASHP, FDA, GPhA, TJC, NABP, NCSBN, PhRMA, USP, AAPA, AGS, ASHRM, ASCP, ASMSO, APSF, DOD, DVA, IHI, ISMP, NASPA, NCPIE, NPSF, SHM. http://www.nccmerp.org/leadershipMemberOrgs.html. Actions/Decisions are those of the Council as a whole and may not reflect the views/positions of individual member organizations.
United States Pharmacopeial Convention (USP)	**General Notices and Requirements, Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia 9 – Prescribing and Dispensing**, from USP 36 – NF 31 (Edition May 1, 2013). http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/gn_usp36.pdf "9.10 Use of Metric Units. Prescriptions for compendial articles shall be written to state the quantity and/or strength desired in metric units unless

Copyrighted Materials – See Copyright Statement for Allowed Use

	otherwise indicated in the individual monograph….If an amount is prescribed by any other system of measurement, only an amount that is the metric equivalent of the prescribed amount shall be dispensed. Apothecary unit designations on labels and labeling shall not be used.”

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

10.2 Appendix B: Documents and Resources Consistent with the White Paper Recommendation on the Use of Leading Zeros and Avoidance of Trailing Zeros

Organization	
American Congress of Obstetricians and Gynecologists (ACOG)	**Improving Medication Safety. Committee Opinion No. 531. American Congress of Obstetricians and Gynecologists,** *Obstet Gynecol* 2012;120:406-10 (August 2012). http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Patient_Safety_and_Quality_Improvement/Improving_Medication_Safety One element of safely writing medication orders relates to the use of zeros and decimal points. The misusage of leading decimals and trailing zeros can be dangerous. The adage "always lead, never follow" can help mitigate errors, which can lead to 10-fold or 100-fold dosage errors (e.g., always write 0.1, never write 1.0).
American Medical Association (AMA)	**AMA Policy H-120.968 Medication (Drug) Errors in Hospitals** http://www.ama-assn.org/resources/doc/PolicyFinder/policyfiles/HnE/H-120.968.HTM "(1) Our AMA encourages individual physicians to minimize medication errors by adhering to the following guidelines when prescribing medications:…(g) Medication orders should be clear and unambiguous. Physicians should: …(v) always use a leading "0" to precede a decimal expression of less than one (e.g., 0.5 ml), but never use a terminal "0" (e.g., 5.0 ml); (vi) avoid the use of decimals when possible (e.g., prescribe 500 mg instead of 0.5 g)…
American Pharmacists Association (APhA)	**APhA - Email Interview** (October 18, 2013). "APhA supports the following National Coordinating Council for Medication Error Reporting and Prevention recommendation: ...a leading zero always precedes a decimal expression of less than one. A terminal or trailing zero should never be used after a decimal. Ten-fold errors in drug strength and dosage have occurred with decimals due to the use of a trailing zero or the absence of a leading zero."
American Society of Health-System Pharmacists (ASHP)	**ASHP Guidelines on Preventing Medication Errors in Hospitals American Journal of Hospital Pharmacy 1993;50 (2):305-314** (1993). http://www.ashp.org/DocLibrary/BestPractices/MedMisGdlHosp.aspx "5 e. Always use a leading zero before a decimal expression of less than one (e.g., 0.5 mL). Conversely, a terminal zero should never be used (e.g., 5.0 mL), since failure to see the decimal could result in a 10-fold overdose. When possible, avoid the use of decimals (e.g., prescribe 500 mg instead of 0.5 g)."

Copyrighted Materials – See Copyright Statement for Allowed Use

	ASHP Endorsed Document: Recommendations from the National **Coordinating Council for Medication Error Reporting and Prevention - Recommendations to Correct Error-Prone Aspects of Prescription Writing (**Adopted by NCCMERP 1996, revised 2005). http://www.ashp.org/DocLibrary/BestPractices/MedMisEndNCCMERP.aspx "Endorsed by ASHP Board of Directors, 1999. Endorsement reviewed by ASHP and found to still be appropriate, 2005." Please also see NCCMERP entry below.
Consumer Healthcare Products Association (CHPA)	**Guideline Volumetric Measures for Dosing of Over-the-Counter Oral Liquid Drug Products for Children ≤ 12 years of Age** (Adopted November 17, 2009). http://www.chpa.org/VoluntaryCodes_VolumetricMeasurePediatricLiquids.aspx "6. Use a format and style for expressing fractions that is consistent with the type of measure unit. For metric units, use a decimal; if <1 mL volume, use decimal with a leading zero (e.g., 0.5)."
Food and Drug Administration (FDA)	**FDA Guidance to Industry, Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products**, Guidance issued by US HHS FDA Center for Drug Evaluation and Research (CDER) Final as of May 2011. Page 4 – Recommendations. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm188992.pdf "Any decimals or fractions included on dosage delivery devices should be listed as clearly as possible. • Use leading zeroes before decimal points ("0.4" not ".4") to help avoid IO-fold dosing errors." **DRAFT FDA Guidance for Industry – Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors,** Draft Guidance issued by US HHS FDA Center for Drug Evaluation and Research (CDER) (April 2013). Page 12 – Leading and Terminal Zeros, Decimals, and Commas. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf *"9. Leading and Terminal Zeros, Decimals, and Commas* Numbers containing decimal points in the declaration of strength can lead to tenfold dosing errors when the decimal point goes unseen (e.g., 4.0 mg is seen as 40 mg, or .4 mg is read as 4 mg). To minimize such errors, the quantity of active ingredient in the statement of strength should be presented in whole numbers, and not with a decimal point that is followed by a terminal zero (e.g., 4 mg, not 4.0 mg). Conversely, decimal

Copyrighted Materials – See Copyright Statement for Allowed Use

	numbers smaller than one should always be preceded by a zero (e.g., 0.4 mg, not .4 mg). This serves to enhance the visibility of the decimal point." See also: **FDA/ISMP Campaign to Eliminate Use of Error Prone Abbreviations** on Medical Errors page http://www.fda.gov/drugs/drugsafety/medicationerrors/default.htm
Institute for Safe Medication Practices (ISMP)	**ISMP's List of Error Prone Abbreviations, Symbols, and Dose Designations** http://www.ismp.org/tools/errorproneabbreviations.pdf "Trailing zero after decimal point (e.g., 1.0 mg) – Intended meaning 1 mg, mistaken as 10 mg if the decimal point is not seen – Correction: Do not use trailing zeroes for doses expressed in whole numbers" "Naked" decimal point (e.g., .5mg) – Intended meaning 0.5 mg, mistaken as 5 mg if the decimal point is not seen – Correction: Use zero before a decimal point when the dose is less than a whole unit" **Principles Of Designing A Medication Label For Community And Mail Order Pharmacy Prescription Packages** (2010). http://www.ismp.org/tools/guidelines/labelFormats/comments/default.asp "Avoid the use of all potentially dangerous abbreviations and dose expressions (see www.ismp.org/Tools/errorproneabbreviations.pdf) including the following: i. Do not use trailing zeros (e.g., 5 mg, never 5.0 mg). ii. Use leading zeros for doses less than a whole number (e.g., 0.3 mg, never.3 mg)" **See also: ISMP and FDA Campaign to Eliminate Use of Error-Prone Abbreviations** http://www.ismp.org/tools/abbreviations/
Joint Commission (TJC)	**Joint Commission "Do Not Use" Abbreviations** (2004). http://www.jointcommission.org/assets/1/18/Official_Do_Not_Use_List_6_111.PDF http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf *"On Official "Do Not Use" list:* Applies to all orders and all medication-related documentation that is handwritten (including free-text computer entry) or on pre-printed forms. **Do Not Use:** Trailing zero (X.0 mg)* **Problem:** Decimal point is missed **Use instead:** Write X mg **Do Not Use:** Lack of leading zero (.X mg) **Problem:** Decimal point is missed **Use instead:** Write 0.X mg"
National	**Recommendations to Enhance Accuracy of Prescription Writing** (Adopted by NCCMERP 1996, Revised 2005).

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

Coordinating Council for Medication Error Reporting and Prevention (NCCMERP)	http://www.nccmerp.org/council/council1996-09-04.html The Council recommends: "6....a leading zero always precede a decimal expression of less than one. A terminal or trailing zero should never be used after a decimal. Ten-fold errors in drug strength and dosage have occurred with decimals due to the use of a trailing zero or the absence of a leading zero." **NCCMERP is an independent body comprised of 27 national organizations**: AARP, AHA, AMA, ANA, APhA, ASHP, FDA, GPhA, TJC, NABP, NCSBN, PhRMA, USP, AAPA, AGS, ASHRM, ASCP, ASMSO, APSF, DOD, DVA, IHI, ISMP, NASPA, NCPIE, NPSF, SHM. http://www.nccmerp.org/leadershipMemberOrgs.html. Actions/Decisions are those of the Council as a whole and may not reflect the views/positions of individual member organizations.
Pediatric Pharmacy Advocacy Group (PPAG) and **ISMP**	**Guidelines for Preventing Medication Errors in Pediatrics** *J Pediatr Pharmacol Ther 2001; 6:426-42.* http://www.ppag.org/attachments/files/111/Guidelines_Peds.pdf "Recommendations for Prescribers A leading zero should always precede decimal expressions less than one (i.e., 0.1 mg), but a trailing zero should never follow a whole number (i.e., 1.0 mg). Computerized Order Entry System Recommendations All decimal expressions less than one whole unit should be preceded by a leading zero (i.e., 0.1 not .1) and whole numbers should not be followed by a trailing zero (1 mg not 1.0 mg). Training for all healthcare professionals should … address what not to incorporate in a prescription (e.g., certain dangerous abbreviations, leading and trailing zeros)."
United States Pharmacopeial Convention (USP)	**General Notices and Requirements, Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia 10 - Preservation, Packaging, Storage, and Nomenclature,** from USP 36 – NF 31 (edition May 1, 2013). http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/gn_usp36.pdf "10.40.20. Use of Leading and Terminal Zeros. To help minimize the possibility of errors in the dispensing and administration of drugs, the quantity of active ingredient when expressed in whole numbers shall be shown without a decimal point that is followed by a terminal zero (e.g., express as 4 mg [not 4.0 mg]). The quantity of active ingredient when expressed as a decimal number smaller than 1 shall be shown with a zero preceding the decimal point (e.g., express as 0.2 mg [not .2 mg])."

Copyrighted Materials – See Copyright Statement for Allowed Use

World Health Organization (WHO)	**Drug and Therapeutics Committees – A Practice Guide** (2003). 5.2 Monitoring and Addressing Medication Errors http://apps.who.int/medicinedocs/en/d/Js4882e/7.2.html#Js4882e.7.2 "Some ways of preventing medication errors, particularly in hospitals, include**…**use of leading zeros for values less than 1 (0.2 instead of.2) and avoidance of trailing zeros for values more than 1 (2 instead of 2.0)."

Copyrighted Materials – See Copyright Statement for Allowed Use

10.3 Appendix C: Documents and Resources Consistent with the White Paper Recommendation on the Use of Dosing Devices for Oral Liquid Medicines

Organization	
American Academy of Pediatrics (AAP)	**AAP Policy Statement - Inaccuracies in Administering Liquid Medication** Yafe SJ, et al. *Pediatrics.* 1975; 56: 327-328. "The Committee on Drugs recommends that all physicians advise their community pharmacies to obtain and stock appropriate liquid administration devices, and insist on the use of such devices when prescribing liquid medications." **Article in AAP News – Antidote for Medication Overdoses: Use Metric Dosing, Educate Parents**, AAP News Vol. 34 No. 12 December 1, 2013; pp. 4. http://aapnews.aappublications.org/content/34/12/4.full "Additional steps that pediatric health providers can take to help reduce parent dosing errors and support PROTECT Initiative recommendations include: …parents a dosing device, such as an oral syringe, when prescribing a liquid medication." **Article in AAP News – Out with Teaspoons, in with Metric Units: Pediatricians urged to prescribe liquid medications in mLs only,** AAP News Vol. 33 No. 3 March 1, 2012; pp. 10. http://aapnews.aappublications.org/content/33/3/10.full "Pediatricians should advocate for the use of oral syringes to prevent unintentional medication overdoses. Studies have shown that syringes are used more accurately than dosing cups." "Unfortunately, household spoons are still commonly used to administer liquid medications. Therefore, pediatricians should cease prescribing liquid medications to children using teaspoon or tablespoon volumes and advocate for the use of oral syringes."
American Association of Poison Control Centers (AAPCC)	**Resolution Passed by AAPCC** (2010). "1. We encourage member poison centers, to the extent feasible, to join in educating the public about the value and importance of a) measuring medication using product-specific measuring devices when these are available and using precise measuring spoons when a product-specific device is not available…"
Consumer Healthcare Products Association (CHPA)	**Guideline Volumetric Measures for Dosing of Over-the-Counter Oral Liquid Drug Products for Children ≤ 12 years of Age** (Adopted November 17, 2009). http://www.chpa.org/voluntarycodes_volumetricmeasurepediatricliquids.aspx

Copyrighted Materials – See Copyright Statement for Allowed Use

	"**4.2 Dosing Device Accompanying the Product** A1. Provide a calibrated dosing device with all products"
Food and Drug Administration (FDA)	**Guidance for Industry – Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products** (May 2011). http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm188992.pdf "Dosage delivery devices should be included for all orally ingested OTC liquid drug products. If units of liquid measure are abbreviated on the dosage device, the abbreviation used on the device should be the same abbreviation used in the labeled dosage directions, outside packaging (carton labeling), bottle, and any accompanying written instructions."
Institute for Safe Medication Practices (ISMP)	**2014-2015 Targeted Medication Safety Best Practices for Hospitals** (2014). http://www.ismp.org/Tools/BestPractices/default.asp "**Best Practice 5: Purchase oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale**. Oral liquid dosing devices that only display the metric scale should be used. In addition, if patients are taking an oral liquid medication after discharge, supply them with (or provide a prescription for) oral syringes, to enable them to measure oral liquid volumes in mL". **Statement on Use of Metric Measurement to Prevent Errors with Oral Liquids** (October 2011). http://www.ismp.org/pressroom/PR20110808.pdf "ISMP recommends the following actions to help prevent errors: • Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters. • Coach patients on how to use and clean measuring devices; use the 'teach back' approach, and ask patients or caregivers to demonstrate their understanding."

Copyrighted Materials – See Copyright Statement for Allowed Use

10.4 Appendix D: Contributors to this White Paper

Note: The organizations listed below should not be considered endorsers of this White Paper.

WG10 Professional Pharmacy Services Co-Chairs	
Robert Franz, Pharmacy BS	Express Scriots
Scott Robertson, PharmD	Kaiser Permanente
Shelly Spiro	Spiro Consulting
mL White Paper Task Group Lead	
Dan Ramirez Pharm D	McNeil Consumer Healthcare
Sue Thompson	NCPDP Staff
mL White Paper Task Group Members	
Vishal P. Amin, PharmD	CVS Caremark
Dan Budnitz, MD, MPH, CAPT, USPHS	Centers for Disease Control and Prevention (CDC)
Michele V. Davidson, RPh	Manager, Pharmacy Technical Standards, Development & Policy, Walgreen Company
Ajit A. Dhavle, PharmD, MBA	Director, Quality Management Surescripts, LLC
Catherine Graeff, RPh., MBA	Sonora Advisory Group
Cindi Fitzpatrick, BSN, RN	Food and Drug Administration (FDA)/ Safe Use Initiative
DionNe Galloway, PharmD	Wolters Kluwer Health
Michael J. Gaunt, PharmD	Institute for Safe Medication Practices (ISMP)
Lee Hampton, MD, MSc	Centers for Disease Control and Prevention (CDC)
Eileen Lewalski, PharmD, JD	National Association of Boards of Pharmacy
Heather McComas, PharmD	Former National Association of Boards of Pharmacy

Copyrighted Materials – See Copyright Statement for Allowed Use

Gerald K. McEvoy, PharmD	Assistant Vice President American Society of Health-System Pharmacists
Patricia Milazzo, RPh	Wolters Kluwer Health
Brian Morris	Compliance and Public Affairs Officer McKesson Corporation
Hannah Sekula, PharmD	Walgreen Co
Rita Shah, PharmD	McNeil Consumer Healthcare
Shelly Spiro, RPh, FASCP	Pharmacy HIT Collaborative
Laura Topor	Granada Health, LLC
Ken Whittmore, Jr., RPh, MBA	Senior VP, Professional & Regulatory Affairs Surescripts, LLC
H. Shonna Yin, MD, MS	Assistant Professor of Pediatrics NYU School of Medicine

****Official Release****
National Council for Prescription Drug Programs, Inc.
Copyrighted Materials – See Copyright Statement for Allowed Use

National Council for Prescription Drug Programs

9240 East Raintree Drive, Scottsdale, AZ 85260
phone: 480.477.1000
fax: 480.767.1042
e-mail: ncpdp@ncpdp.org
http: www.ncpdp.org

© 2014 by NCPDP. All rights reserved.

NCPDP™

Spoonfuls Of Medicine Could Lead To Potentially Dangerous Dosing Mistakes

Published July 15, 2014
Fox News Latino

-

(AP Photo/Jessica Hill)

CHICAGO (AP) – The song says a spoonful of sugar helps the medicine go down, but a study says that kind of imprecise measurement can lead to potentially dangerous dosing mistakes.

The results, published online Monday in Pediatrics, underscore recommendations that droppers and syringes that measure in milliliters be used for liquid medicines — not spoons.

The study involved nearly 300 parents, mostly Hispanics, with children younger than 9 years old. The youngsters were treated for various illnesses at two New York City emergency rooms and sent home with prescriptions for liquid medicines, mostly antibiotics.

Parents were contacted afterward and asked by phone how they had measured the prescribed doses. They also brought their measuring devices to the researchers' offices to demonstrate doses they'd given their kids.

Parents who used spoonfuls "were 50% more likely to give their children incorrect doses than those who measured in more precise milliliter units," said Dr. Alan Mendelsohn, a co-author and associate professor at New York University's medical school.

Incorrect doses included giving too much and too little, which can both be dangerous, he said. Underdosing may not adequately treat an illness and can lead to medication-resistant infections, while overdoses may cause illness or side effects that can be life-threatening. The study doesn't include information on any ill effects from dosing mistakes.

Almost one-third of the parents gave the wrong dose and 1 in 6 used a kitchen spoon rather than a device like an oral syringe or dropper that lists doses in milliliters.

Less than half the prescriptions specified doses in milliliters. But even when they did, the medicine bottle label often listed doses in teaspoons. Parents often assume that means any similar-sized kitchen spoon, the authors said.

"Outreach to pharmacists and other health professionals is needed to promote the consistent use of milliliter units between prescriptions and bottle labels," the authors said.

TO: The Professional Practice Committee

FROM: Douglas E. Lentivech

SUBJECT: Proposed Amendment of the Regulations of the Commissioner of Education Relating Interpretation and Translation Services to Limited English Proficient (LEP) Individuals in Pharmacies and to the Establishment of Standardized Patient-Centered Data Elements for Prescription Drug Labels

DATE: June 10, 2013

AUTHORIZATION(S):

SUMMARY

Issue for Decision

Should the Board of Regents approve the addition of new sections 63.11 and 63.12 of the Regulations of the Commissioner of Education relating to the interpretation and translation services for Limited English Proficient (LEP) individuals in pharmacies, and to the establishment of standardized patient-centered data elements for prescription drug labels?

Reason(s) for Consideration

Required by State statute.

Proposed Handling

This proposed amendment is presented to the Professional Practice Committee for recommendation and the Full Board for emergency action and adoption as a permanent rule at the June 2013 meeting of the Board of Regents. A Statement of Facts and Circumstances justifying the emergency action is attached.

Procedural History

A Notice of Proposed Rule Making was published in the State Register on March 20, 2013. Four parties provided comments. An Assessment of Public Comment is attached. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

The 2012 New York State budget legislation included amendments to the Education Law, which amendments are commonly referred to as the SafeRx Law (L. 2012, c. 57, Part V). This new law, which became effective March 30 2013, includes provisions to assist Limited English Proficient (LEP) individuals who need interpretation and translation services when filling prescriptions at pharmacies. The law also requires the Commissioner of Education to develop rules and regulations to provide more patient-friendly prescription labels for all patients.

Over the course of the months following passage of this legislation the Office of the Professions sought input from interested stakeholders. In addition to receiving written comments, there were three opportunities for oral presentations, one each in Buffalo, Albany and New York City. This input, and advice from the State Board of Pharmacy, assisted in the development of the proposed regulations.

Section 6829 of the Education Law, as added by section 3 of Part V of Chapter 57 of the Laws of 2012, includes the following provisions:

- The legislation applies to covered pharmacies, which the legislation defines as a pharmacy that is part of a group of eight of eight or more pharmacies, located within New York State and owned by the same corporate entity.
- Covered pharmacies are required to provide interpretation and translation services to LEP individuals in their preferred pharmacy primary language, free of charge.
- The legislation defines the preferred pharmacy primary languages as those that are spoken by 1% or more of the population, as determined by the U.S. Census, for each region, as established by the Department, provided that no pharmacy need provide services in more than seven languages.
- Interpretation and translation services may be provided by pharmacy staff or third-party contractors.
- Pharmacies will not be liable for injuries resulting from the actions of a third party as long as the pharmacy entered into the contract reasonably and in good faith.
- Every covered pharmacy must conspicuously display a notice, in the pharmacy primary languages, notifying patients of the available interpretation and translation services.
- The legislation requires the Department to develop a process whereby a covered pharmacy may seek a waiver from these requirements if it can

demonstrate that implementation is unnecessarily burdensome when compared to the need for services.

- The legislation also requires the Commissioner, in consultation with the Department of Health, to establish translation and interpretation requirements for mail-order pharmacies; such requirements will be effective March 30, 2014. The Department anticipates that it will come before the Regents with these regulations sometime early next year.

As noted above, the law delegated to the Department the responsibility of establishing the regions to be used in determining the languages in which translation and interpretation services must be provided. The Board of Pharmacy and Department staff considered a number of options, such as dividing the State into 6-8 regions, dividing the State into an upstate and a downstate region only, dividing the State on a county-by-county basis, and considering the State in its entirety as one region. After discussions with stakeholders representing both covered pharmacies and LEP individuals, it was determined that the last option was preferred because it provided services to a large portion of the LEP population in an efficient and cost-effective manner. Establishing the State as a single region will result in four pharmacy primary languages statewide – Chinese, Italian, Russian and Spanish. This approach will expedite the adoption of standardized interpretation and translation services by covered pharmacies and will provide for more languages to be covered in nearly all upstate communities than other options.

It should be noted that New York City has a local law regarding the provision of language assistance, interpretation, and translation services to LEP individuals. Both the enacting statute and the proposed regulations contain provisions that make it clear that neither the new law nor the regulations promulgated to implement it will diminish requirements existing pursuant to this New York City law.

Additionally, in the course of the development of the proposed regulations, the Civil Rights Bureau of the State Attorney General's Office provided information concerning settlement agreements it has with seven large retail pharmacy chains pursuant to which those chains have been providing language assistance, interpretation, and translation services in approximately 10 different languages to LEP individuals throughout the state. While all but one of those agreements will be expiring in 2013, there is nothing in the law or the proposed regulation that would prohibit any pharmacy from providing language assistance, interpretation, and translation services in additional languages.

Education Law §6830, as added by section 4 of Part V of Chapter 57 of the Laws of 2012, requires the Commissioner to develop regulations requiring the use of standardized patient-centered data elements on all prescription medication labels. It also requires the Commissioner to obtain input from its Boards of Pharmacy and Medicine, consumer groups, advocates for special populations, pharmacists, physicians, other health care professionals authorized to prescribe, and other interested parties, in the development of patient-centered prescription labels. Such labeling is intended to increase patient understanding and compliance with medication regimens.

Regarding patient-centered labeling, the Boards of Pharmacy and Medicine relied, in part, on previous studies conducted by the United States Pharmacopeia and by the National Association of Boards of Pharmacy. Based on these studies, the proposed amendment requires that prescription labels must have certain, critical elements, including patient name, the drug name and directions, that must be bolded and/or highlighted and be in at least 12-point font. The proposed regulation also requires that directions for patient use be written in full sentences. Other important information must also be included on the label, including among other things, the patient's address, the pharmacy address and the name of the prescriber, but the manner in which such information is included on the label must not detract from the critical elements.

Recommendation

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

VOTED: That sections 63.11 and 63.12 of the Regulations of the Commissioner of Education be added, as submitted, effective July 3, 2013.

VOTED: That sections 63.11 and 63.12 of the Regulations of the Commissioner of Education be added, as submitted, effective June 27 2013, as an emergency action upon a finding by the Board of Regents that such action is necessary for the preservation of the public health and general welfare to ensure that the proposed amendment remains continuously in effect until it can be adopted as a permanent rule on July 3, 2013.

Timetable for Implementation

If the proposed regulations are adopted at the June Regents meeting, the emergency adoption will become effective on June 27, 2013 and the permanent rule will become effective on July 3, 2013.

STATEMENT OF FACTS AND CIRCUMSTANCES WHICH NECESSITATE EMERGENCY ACTION

The proposed amendment to the Regulations of the Commissioner of Education is necessary to implement Section V of Chapter 57 of the Laws of 2012, which amended Education Law §§6829 and 6830 to require pharmacies to provide certain interpretation and translation services, free of charge, to patients with Limited English Proficiency and to require the Commissioner of Education to establish standardized patient-centered data elements for prescription drug labels.

The proposed amendments were adopted as an emergency measure at the March 2013 meeting of the Board of Regents. Because the Board of Regents meets at fixed intervals, the earliest the proposed amendment can be presented for adoption on a non-emergency basis, after expiration of the 45-day public comment period provided for in State Administrative Procedure Act (SAPA) section 202(1) and (5), is the June 2013 Regents meeting. Furthermore, pursuant to SAPA, the earliest effective date of the proposed amendment, if adopted at the June meeting, would be July 3, 2013.

Emergency action is necessary at the June 2013 Regents meeting for the preservation of the public health and general welfare in order to ensure that the rule that was adopted as an emergency action (in order to timely implement the provisions of the new law) remains continuously in effect until the proposed amendment can be adopted as a permanent rule.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6829 and 6830 of the Education Law

Sections 63.11 and 63.12 of the Regulations of the Commissioner of Education are added, effective June 27, 2013, to read as follows:

§63.11 Interpretation and translation requirements for prescription drugs.

(a) Definitions. As used in this section:

(1) Covered pharmacy shall mean any pharmacy that is part of a group of eight or more pharmacies, located within New York State and owned by the same corporate entity.

(2) Corporate entity shall include related subsidiaries, affiliates, successors, or assignees doing business as or operating under a common name or trading symbol of the covered pharmacy.

(3) Limited English proficient individual or LEP individual shall mean an individual who identifies as being, or is evidently, unable to speak, read or write English at a level that permits such individual to understand health-related and pharmaceutical information communicated in English.

(4) Translation shall mean the conversion of a written text from one language into an equivalent written text in another language by an individual competent to do so and utilizing all necessary pharmaceutical and health-related terminology. Such translation may occur, where appropriate, in a separate document provided to an LEP individual that accompanies his or her medication.

(5) Competent oral interpretation shall mean an oral communication in which a person acting as an interpreter comprehends a message and re-expresses that message accurately in another language, utilizing all necessary pharmaceutical and

health-related terminology, so as to enable an LEP individual to receive all necessary information in the LEP individual's preferred pharmacy primary language.

(6) Pharmacy primary languages shall mean those languages, up to a maximum of seven languages other than English, spoken by one percent or more of the population of the State, as determined by the U.S. Census. If more than seven languages other than English are spoken by one percent or more of the population, the pharmacy primary languages shall be limited to seven most spoken languages, as determined by the U.S. Census.

(b) Provision of competent oral interpretation services and translation services. Except as otherwise provided in subdivision (e) of this section:

(1) For purposes of counseling an individual about his or her prescription medications or when soliciting information necessary to maintain a patient medication profile, each covered pharmacy shall provide free, competent oral interpretation services and translation services in such individual’s preferred pharmacy primary language to each LEP individual requesting such services or when filling a prescription that indicates that the individual is limited English proficient at such covered pharmacy, unless the LEP individual is offered and refuses such services.

(2) With respect to prescription medication labels, warning labels and other written materials, each covered pharmacy shall provide free, competent oral interpretation services and translation services to each LEP individual filling a prescription at such covered pharmacy in such individual’s preferred pharmacy language, unless the LEP individual is offered and refuses such services or the medication labels, warning labels and other written materials have already been translated into the language spoken by the LEP individual.

(3) Translation and competent oral interpretation shall be provided in the preferred pharmacy primary language of each LEP individual, provided that no covered pharmacy shall be required to provide translation or competent oral interpretation of more than seven languages.

(4) The services required by this subdivision may be provided by a staff member of the pharmacy or a third-party contractor. Such services shall be provided on an immediate basis but need not be provided in-person or face-to-face.

(c) Notification relating to language assistance services. Except as otherwise provided in subdivision (e) of this section:

(1) In accordance with Education Law section 6829(3), each covered pharmacy shall conspicuously post a notice to inform LEP individuals of their rights to free, competent oral interpretation services and translation services. Such notice shall include the following statement in English and in each of the pharmacy primary languages: "Point to your language. Language assistance will be provided at no cost to you."

(2) The statement in each of the pharmacy primary languages shall be in 20 point bold face, Arial type in a color that sharply contrasts with the background color of the sign. Each such statement shall be enclosed in a box, and there shall be at least a 1/4 inch clear space between adjacent boxes.

(3) The statements in each of the pharmacy primary languages shall be printed on one sign that shall be conspicuously displayed at or adjacent to each counter where prescription drug orders are dropped off and where prescriptions are picked up, and near every cash register at which payment is received for prescription drugs. Such signs

shall be positioned so that a consumer can easily point to the statement identifying the language in which such person is requesting assistance.

(d) Waivers. An application for a waiver of the provisions of subdivisions (b) and (c) of this section shall be made on a form prescribed by the department. The burden of substantiating the validity of a request for a waiver shall be on the applicant.

(1) Each application shall be specific to a registered covered pharmacy, regardless of common ownership.

(2) The applicant shall clearly document the financial or physical constraints, threat to other services provided, or other circumstances upon which the request is based.

(3) No waiver shall be granted in the absence of a showing that implementation of the provisions of subdivisions (b) and (c) of this section would be unnecessarily burdensome when compared to the need for the translation and competent oral interpretation services.

(4) The applicant shall identify alternative sources of competent oral interpretation services or translation services available for LEP individuals within a reasonable distance.

(5) In the event a request for waiver is approved, the pharmacy shall post a notice in the pharmacy primary languages informing LEP individuals of alternative sources.

(6) The duration of a waiver shall be one year and may be renewed upon approval of a new waiver application by the department.

(e) In accordance with Part V of Chapter 57 of the Laws of 2012, the provisions of this section shall preempt any contrary local law or ordinance; provided, however,

that cities with a population of 100,000 or more may retain or promulgate such local laws or ordinances imposing additional or stricter requirements relating to interpretation services or translation services in pharmacies. Nothing in this section shall diminish or impair any requirement that any pharmacy or pharmacist provide any language assistance, interpretation, or translation under any applicable federal or state law, local law or ordinance (unless preempted by this section), consent decree, or judicial settlement, judgment or order.

§63.12 Standardized patient-centered data elements to be used on all drug labels. In accordance with section 6830 of the Education Law, all prescription medicine dispensed to patients in this State must include standardized patient-centered data elements as prescribed by in this section

(a) Definitions. As used in this section:

(1) Critical elements shall consist of:

(i) patient name;

(ii) directions for use by the patient, which directions shall be structured in full sentences; and

(iii) drug name and strength.

(2) Important elements shall consist of:

(i) name, address and telephone number of the pharmacy;

(ii) patient's address;

(iii) name of prescriber;

(iv) the date of filling or refilling of the prescription; and

(v) the prescription number or other identifying number assigned to the prescription.

(b) All prescription drug labels shall contain all of the critical elements and all of the important elements.

(1) Critical elements of each prescription label shall be:

(i) emphasized by being highlighted in color, in bold type, or both: and

(ii) printed in a minimum of a 12-point font.

(2) Important elements of each prescription label and any other information contained on the label shall not be highlighted in color or in bold type, shall be legible and shall not be presented in a fashion that undermines the emphasis on the critical elements.

Assessment of Public Comment

A Notice of Proposed Rule Making was published in the State Register on March 20, 2013. Below is a list of the comments we received on the proposed amendment and the Department's responses.

Comment: One individual questioned if the requirement to provide patient information in another language obviates the need for an English-language label.

Response: The regulation requires written information in the limited English proficient patient's language in addition to an English Language label. Failure to provide an English language label would endanger the health of patients in that other providers, such as emergency medical personnel and emergency room staff, may be unable to determine the medications the patient is taking. Therefore, the Department will make this explicitly clear in a question and answer document under development that patient information must also be provided in English.

Comment: Several commenters indicated that they believe that oral and/or written translation and interpretation services should be provided in more than the four designated languages.

Response: Subdivisions (1)(c), (d) and (e) and (2) of section 6829 of the Education Law, as added by Part V of chapter 57 of the Laws of 2012 require covered pharmacies to provide translation services, both written and oral, in only those languages spoken by 1 percent or more of the population in a given region. Based on the Department's definition of New York State as one region, both written and oral services will be mandated in Chinese, Italian, Russian and Spanish only, though the Department's recommends that pharmacies provide additional transition services.

Comment: A coalition of organizations concurred with the definitions used in the regulation, except for section 63.11(a)(6) of the Regulations of the Commissioner of Education which defines pharmacy primary languages. The writers suggest the Department could use a different definition, based upon federal provisions, to require that translation services be provided in up to seven languages.

The coalition also suggests that the definition of oral translation services (8 NYCRR 63.11[b]) limits the number of the oral translation services required. It is suggested that this provision be eliminated, thereby requiring translation in a multitude of languages.

Response: The Department has reviewed and considered many suggested alternatives and determined that the regulation as drafted effectively implements the purpose and the provisions of the State statute. The suggestion that seven languages could be designated as pharmacy primary languages is inconsistent with the statutory definition of pharmacy primary language.

Comment: The coalition referenced above and another commenter sought the elimination of the waiver provision in the regulations and suggested that covered pharmacies be required to include notification of LEP services in advertisements and promotions.

Response: The Department notes that the statute explicitly requires a waiver process. The Department believes the provision is consistent with the law, and will result in limited, if any, waivers.

Comment: Two responders asked that covered pharmacies be required to establish training programs for staff, to incorporate internal tracking systems for compliance, and to report and monitor progress to the Department.

Response: The Department has reviewed and considered many of the suggested alternatives and determined that the regulation as drafted effectively implements the purpose and the provisions of the State statute, while leaving covered pharmacies sufficient flexibility to implement the new requirements in accordance with the circumstances presented. Covered pharmacies must comply with the provisions of the law and regulations, and the Department will investigate any complaint regarding non-compliance.

Comment: One commenter suggested that directions for use of medications on patient labels should incorporate full sentences and separate the dose itself from the timing of each dose; that numeric characters should be used instead of writing out numbers; and that Latin terms and medical jargon be specifically limited.

Response: Section 63.12 of the proposed amendment requires that directions be structured in full sentences. The Department considered requiring numeric characters but concluded that this should not be mandated in case a situation arose where it would be more appropriate to use numbers that are written out. The Department will, however, monitor this issue to determine whether a change should be made in the future.

Fact Sheet: Proposed State Legislation A7342 & S5000
Making It Easier to Understand How to Take Your Prescription Drugs

The Issue: Prescription drug labels are only effective if patients are able to understand them. With dozens of ways for a pharmacist to write "take once a day," it is often challenging for patients to understand and act correctly on just one prescription instruction. For those who take multiple medications, such as the elderly, this challenge is even greater. Age-related declines in vision, memory and cognitive skills means that small print and cluttered labeling are particularly problematic for the elderly. Similarly, for the over 2.4 million people in the New York who speak English less than "very well" and are therefore considered limited English proficient (LEP), the lack of translation makes labels literally incomprehensible.

The consequences of patient misunderstanding of prescription labels can be costly and dire. Unintended misuse of prescription medications causes over one million yearly "adverse drug events," resulting in visits to the emergency room, hospitalization and, in some cases, even death. Indeed, patient non-adherence with prescription instructions due to low levels of health literacy and other factors is responsible for 22% of all hospitalizations nation-wide. This problem places additional burdens on already under-resourced emergency rooms and hospitals and costs an extra $3 billion per year in healthcare spending.

The Solution: Patient advocates and pharmacy researchers agree that language barriers and information inconsistencies are the root causes of patients' confusion. Standardizing prescription labels and providing translation and interpretation services will prevent painful, costly outcomes. The proposed legislation would:

- ***Authorize the Creation of Standardized Prescription Drug Labels***. The bill would give the State Board of Pharmacy the authority to develop clear, standardized prescription drug labels. This will improve comprehension of labels by all consumers and provide unambiguous and straightforward directions for prescription drug use.
- ***Ensure that Chain/Mail Order Pharmacies Translate Standardized Prescription Drug Labels***. In addition, the bill would require pharmacies to provide written translations of the standardized prescription drug labels into the languages of patients who are LEP.
- ***Require Chain/Mail Order Pharmacies to Provide Oral Interpretation Services***. Under the bill, pharmacies would be required to have interpretation services available for patients who are LEP. The bill does not dictate how these services be provided and allows pharmacies the freedom to decide if bilingual staff, telephonic services, or other modalities of interpretation are the best option for them. This will ensure that all patients receive prescription drug information and counseling in a language they understand.
- ***Enable Physicians to Facilitate Pharmacies in Providing Language Assistance Services***. The bill would also modify prescription forms and electronic prescriptions to include a section for prescribers to indicate whether their patients are LEP, and if so, what their preferred language is. This will assist pharmacists in serving patients who are LEP by allowing them to easily determine and accommodate customers' language preferences.

Fact Sheet:
Why Prescription Medication Labels Should Be Standardized

Research shows that many patients, particularly senior citizens and those with low health literacy, have trouble reading and understanding the information contained on prescription drug labels. Given the dozens of ways pharmacists can direct patients to "take one tablet a day," the challenge of understanding prescription instructions is that much more difficult. Proposed state legislation {A.7342 (Gottfried)/S.5000 (Hannon) of 2011} will help to ensure the health and safety of all New Yorkers by requiring standardized, patient-centered labeling that all patients can understand.

There Are Over 50 Ways to Write "Take One Tablet A Day"

Here are just a few examples of the variations:

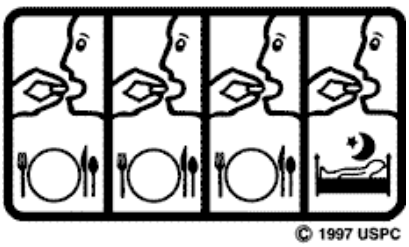
- *Take one tablet orally every day.*
- *Take one tablet by mouth once daily.*
- *Take one pill by mouth at bedtime.*
- *Take one tablet one time each day.*
- *Take one pill by mouth once each day.*
- *Take 1 tablet 1 time daily.*

For many people in New York State, understanding prescription drug instructions in difficult
Thirty-nine percent of adults in New York State have a basic or below basic literacy level. Distracting information and complex texts on prescription labels can make reading and understanding drug labels difficult even for those with higher-level literacy skills.

Standardized prescription drug labels will reduce medication errors
Creating standardized and simplified prescription labels is critical to ensuring that all individuals have equal and safe access to healthcare. For example, research shows that:

- Patients can read prescription labels printed in 12 point font better than 10 point font.
- Patients can understand numeric instruction information ("take 1 time a day") better than alphabet characters ("take once a day").
- Many people have been found to follow to medicine instructions better if those instructions are explicit and precise—i.e. "take 1 in the morning and 1 at bedtime" instead of "take 2 daily"—and if those instructions are bolded or highlighted.

Further, in some circumstances, using a standard set of icons that are closely integrated with prescription instructions and warnings has been shown to increase understanding as well. For instance, the icon to the right corresponds to an instruction to "take 4 times a day, with meals and at bedtime."



Standardization will substantially decrease likelihood of adverse drug events, lower healthcare spending, and will ease the burden on pharmacies to produce translations.

Fact Sheet:
Providing Access to Prescription Drugs in Many Languages is Easy to Do

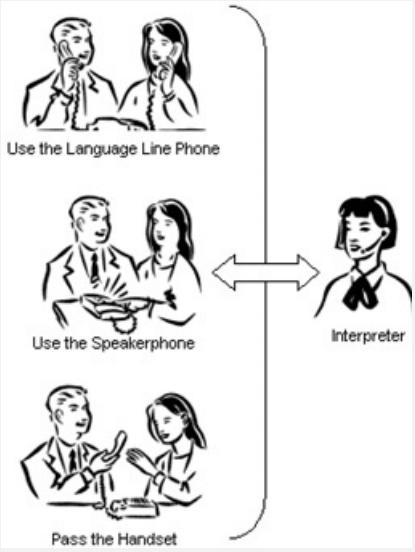
Every New Yorker should be given the opportunity to understand how to take their prescriptions. For the millions of New Yorkers who are limited English proficient (LEP), the lack of translation and interpretation services makes drug labels literally incomprehensible. The proposed state bill will help to ensure New Yorkers' health and safety by requiring chain/mail order pharmacies to provide these language assistance services.

Is it possible to provide interpretation and translation services in pharmacies?
Yes. There are existing translation and interpretation services that enable pharmacies to fill the language gap seamlessly and in a way that is consistent with a pharmacist's natural workflow. Such interpretation systems provide pharmacies with the ability to provide, in real time, medication counseling, medication instructions and auxiliary information in the patient's language. Similarly, translation systems allow the pharmacist to print on demand patient instructions, warning labels, and consumer medication information in many languages.

Aren't these types of services costly?
No. Translation and interpretation services are reasonably priced, particularly since large chain/mail order pharmacies can negotiate bulk discounts. One high-quality label translation service charges as little as $2 a day.

How It Works: Telephonic Interpretation

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



Information and visual from www.languageline.com.

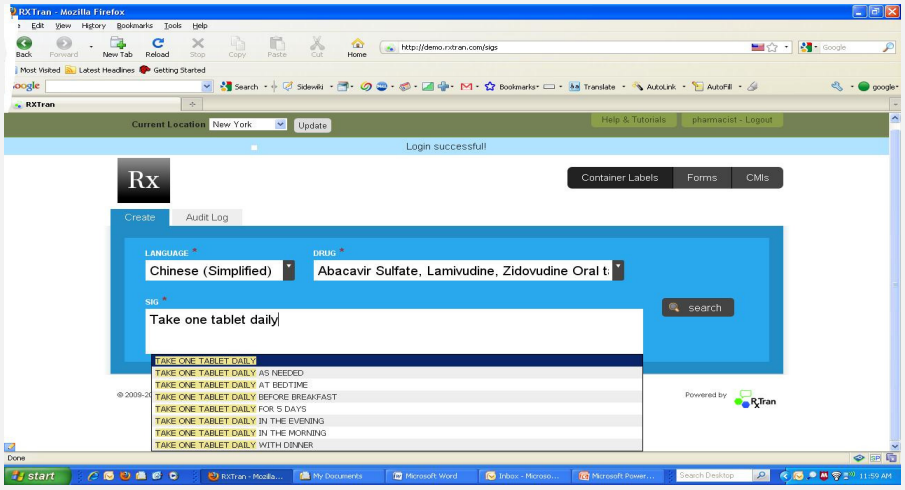
The bill requires chain/mail order pharmacies to provide translations of prescription drug labels in the "top seven languages" in New York State. What are those languages?

The top seven languages in New York State are: Spanish; Chinese; Russian; Italian; Korean; French Creole; and Yiddish. This comprises almost two million LEP individuals; about 80% of New York's LEP population. Many chain/mail order pharmacies already have the capacity to provide translations in these languages.

How It Works: Label Translation

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

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



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

Information and screenshot courtesy RxTran.

Will the bill expand negligence liability in the event of a faulty translation/interpretation for prescribers, pharmacists or pharmacies?
No. The bill itself is narrowly tailored to focus only on ensuring that chain and mail order pharmacies provide language access services. As such, the bill cannot be used to hold pharmacists liable for negligence. Further, well-established law in New York holds that no liability will be imposed on a pharmacist for negligence where the pharmacist accurately fills prescriptions as written and complies with all other laws and regulations in terms of filling prescriptions and counseling consumers. As long as chain mail order pharmacies have done due diligence in terms of selecting a reliable vendor or training staff members to provide translation and interpretation services, they will have met the standard of care expected of them.

Is this an area in which New York State can regulate? Aren't issues related to prescription medication labeling the purview of the Food & Drug Administration (FDA) and therefore preempted by Federal Law?
Yes, New York State can regulate in this area, and no, the proposed law will not be preempted by federal law. The federal government regulates prescription drug dispensing and labeling primarily through the Food, Drug, and Cosmetics Act (FDCA), 21 U.S.C.A. §§ 301, et seq. (WEST 2010). Although Congress has expressly preempted independent state regulation of food labeling and of medical devices under the FDCA, it does not expressly extend such preemption to prescription drugs.

Further, judicial analyses of similar state laws regulating food, drugs, and medical devices have consistently held that federal law does not preempt state law regulating food and/or drugs. Indeed, federal courts' recognition of drug regulation as a part of the states' traditional police power prompts a strong presumption in favor of upholding state statute when they are challenged.

Is the definition of Limited English Proficiency that is provided for in the bill, which is based on how "well" an individual speaks English, concrete enough to be workable by pharmacies and others subject to this law?
Yes. The definition is based on the definition of LEP used by the U.S. Bureau of the Census, which defines as LEP anyone who speaks English less than "very well" based on the individual's self-reporting of English language ability to census surveyors.

This definition is itself based studies conducted by the Bureau of the Census in which the agency's researchers tested the actual English proficiency of a sample population to their self-reported ability to speak English "very well," "well," "not well" and "not at all," and found a high degree of correlation between objective and subjective assessments of English language proficiency.

This definition has been used consistently over the years in other areas of law, such as in the New York State Department of Health regulations governing patients' rights in hospitals, and has posed little administrative burden or liability risk for the entities which are subject to it.

Attachment 4

2013 Survey: Translated labels in use in California pharmacies, surveys conducted by board inspectors

Survey Results Regarding Pharmacy Compliance with Translated Labels and Interpreter Availability

A total of 239 surveys were collected by Board inspectors. The results are as follows:

1. Do you provide prescription container labels with translated directions?

   a) Yes 185 (77.4%) b) No 54 (22.6%)

   Individual Comments:
   - Limited Spanish
   - No occasion has arisen
   - Spanish/French Canadian on label and as counseling information
   - Spanish
   - Spanish only

2. How do you provide the translation of the directions for use?

   a) Pharmacy staff translates the labels: 69 (37.3%)

   Individual Comment: Spanish Only

   b) The pharmacy uses the Board of Pharmacy's online translated directions for use: 5 (2.7%)

   c) The pharmacy uses computer software or online programs: 151 (81.67%)

   Comments: Spanish only; by Sigs only; no free-form Sigs can be translated on label.

   d) The pharmacy uses other means of providing translations (describe): 12 (6.5%)

   Individual Responses:
   1. Third party Language Line, although the occasion has never arisen
   2. Language Line
   3. Store employees (Spanish only). No other language translations have ever come up

3. If you translate the labels, do you also provide the English language equivalent on the label?

a) Yes 47 (26%) b) No 134 (74%)

Individual Comments:

Optional
If the software is used correctly an additional leaflet prints in English, with label information and medication information
No room/space for both
Hard copy is in English
RPh translates based on Spanish experience
Some prescribers write both English and the foreign language, so the pharmacy puts both on the label
Has never come up
Don't use often
Don't know if label provides English translation.

4. If you do not provide translated directions on the label, why?

a) The pharmacy has no requests for translated labels 28 (51.9%)

b) The pharmacy has too many patients with diverse language needs 4 (7.4%)

c) The pharmacy's software will not print in foreign language fonts 18 (33.3%)

d) The pharmacy is concerned that errors on the label will go undetected 14 (25.9%)

e) Other:

Individual Responses:

Pharmacy has not contracted with any software vendor to provide labels yet (new pharmacy).

Pharmacy has no prescription processing software at this time (new pharmacy).

5. How does the pharmacy comply with the interpreter requirements?

a) Uses pharmacy staff at this or other pharmacies to interpret 138 (57.7%)

b) Uses a telephone language service 190 (77.5%)

c) Is not compliant with current requirements to have access to an interpreter 15 (6.3%)

Individual Comments:
Is not in full compliance. Only has Spanish-speaking staff.
Both staff and rarely Language Line

2012 Survey: Readability of new prescription drug container labels

D

California State Board of Pharmacy
Patient-Centered Prescription Label Survey

Objective

To secure public comments from California consumers regarding the new patient-centered prescription labels pursuant to Senate Bill 472 (Chapter 470, Statutes of 2007).

Methodology

The consumer survey soliciting feedback regarding the readability of the new prescription drug container labels was widely distributed. An electronic version of the survey was sent to several consumer groups, who in turn distributed the survey to their ListServe contacts. The survey was also translated into Chinese and Spanish and distributed by The California Pan Ethnic Health Network (CPEHN) to the appropriate audiences. Surveys were also collected at five local Senior Scam Stopper seminars sponsored by the Contractors State Licensing Board, which are public outreach events, and a Senior Health Fair in Hayward,.

Results

A total of 1204 surveys were returned. Respondents did not always provide answers to all of the questions. Results are summarized below:

Responses to Yes/No Questions

English: 1142 Surveys Received	**YES**	**NO**
1. Are your prescription container labels easy to read?	693 (58%)	502 (42%)
2. Are the directions for taking the medicine easy to understand?	245 (20%)	95 (80%)
3. Do you know why you take each of your medicines?	1049 (87%)	149 (12%)
4. Would you like the general reason why you take the medicine to appear on the label (for pain, for infection, etc.)?	963 (80%)	232 (19%)

Chinese: 46 Surveys Received	**YES**	**NO**
1. Are your prescription container labels easy to read?	40 (87%)	5 (10%)
2. Are the directions for taking the medicine easy to understand?	45 (98%)	1 (.02%)
3. Do you know why you take each of your medicines?	42 (91%)	4 (.09%)
4. Would you like the general reason why you take the medicine to appear on the label (for pain, for infection, etc.)?	30 (65%)	4 (.09%)

Spanish: 16 Surveys Receive	**YES**	**NO**
1. Are your prescription container labels easy to read?	6 (38%)	10 (62%)
2. Are the directions for taking the medicine easy to understand?	7 (44%)	9 (56%)
3. Do you know why you take each of your medicines?	7 (44%)	9 (56%)
4. Would you like the general reason why you take the medicine to appear on the label (for pain, for infection, etc.)?	16 (100%)	0

Top responses to open-ended questions:

When asked what information on the label was most important, the top responses were:

1. Directions for use/clear dosing instructions: 539 of 1098 responses = 49%
2. Name of drug (including generic and brand name): 403 of 1098 responses = 36%
3. Side effects/warnings/interactions/contraindications: 68 of 1098 responses = 6%

When asked what changes would make the labels better, the top responses to this open-ended question was:

1. Larger font: 318 of 1180 responses = 26%
2. State purpose for taking med: 84 of 1180 responses 7%
3. Include brand name as well as generic name: 52 of 1180 responses = 4%

When asked how the information could be improved:

1. Include clear directions/dosing instructions: 123 of 574 responses = 21%
2. Larger font: 43 of 574 = 7%
3. Include purpose for taking the med: 27 of 574 = 4%

2009 Survey: Open-ended questions in English and Spanish, surveys conducted at consumer public outreach events.

California State Board of Pharmacy Prescription Label Survey

OBJECTIVE: To elicit feedback from consumers in California regarding development of patient-centered prescription drug labels pursuant to Senate Bill 472 (Chapter 470, Statutes of 2007)

METHODOLOGY: A survey was developed by the California State Board of Pharmacy (Board) 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 website 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.

RESULTS: A total of 622 surveys were received as of March 3, 2009. The majority of respondents provided one or more answers to the first two questions, but did not always provide answers to subsequent questions. Respondents gave similar answers to multiple questions within a survey (i.e., request for large print). Attached graphs reflect detailed responses; most frequent responses summarized below.

When asked what information on the prescription label was most important, the top responses were:

Directions for use (224 of 1,207 responses = 18.6%)
Name of drug; if generic, state generic name AND brand name (222 of 1,207 responses = 18.4%)
Dosage prescribed (213 of 1,207 responses = 17.6%)
Side effects/warnings/interactions/contraindications (122 of 1,207 responses = 10.1%)
Purpose of drug – state what condition medication is prescribed to treat (84 of 1,207 responses = 7%)

When asked what to change on the prescription label, the top responses were:

Print should be larger or darker (170 of 568 responses = 30%)
Nothing needs to be changed on the label (139 of 568 responses = 24.5%)
Include purpose of drug – state what condition medication is intended to treat (69 of 568 responses = 12.1%)

When asked what would make prescription labels easier to read, the top response was:

Larger or bolder print (314 of 522 responses = 60%)

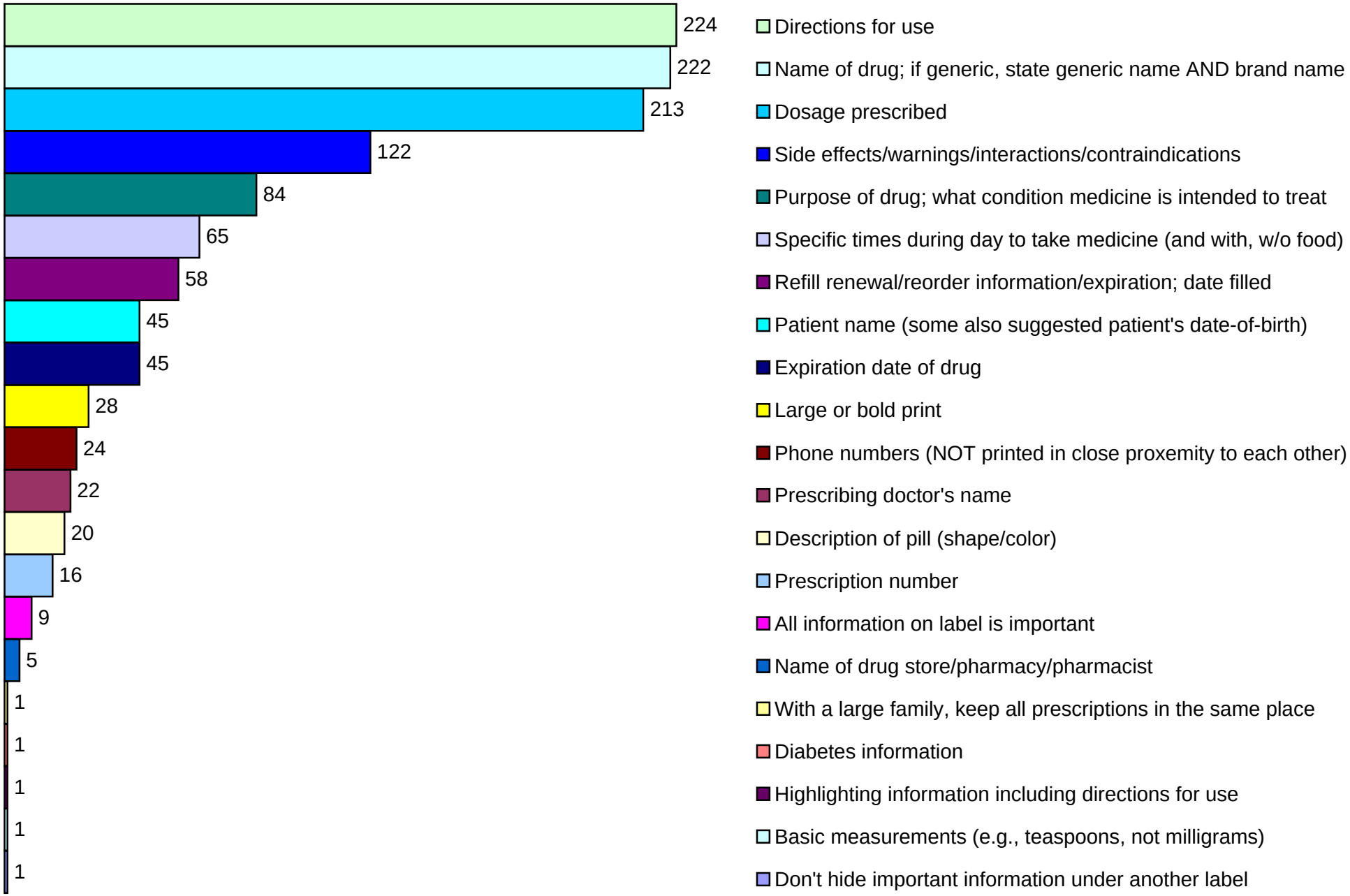
When asked for other suggestions, the top responses were:

Easy-open lids/packages should be used; no child-proof caps for seniors (20 of 134 responses = 14.9%)
Include purpose of drug - state what condition medication is intended to treat (17 of 134 responses = 12.7%)

CONCLUSIONS: Most consumers participating in this survey requested larger/bolder type font on prescription labels to increase readability. Many participants suggested that if a generic drug is provided, the prescription label should state the name of the generic drug name AND the brand-name it is generic for. They also noted that color printing and highlighting on labels brings attention to important information. Some participants suggested that the labels themselves be color-coded to help differentiate between multiple medications and family members. Many consumers want to know 'what the drug is for' and suggested that 'purpose of drug' be printed directly on prescription labels.

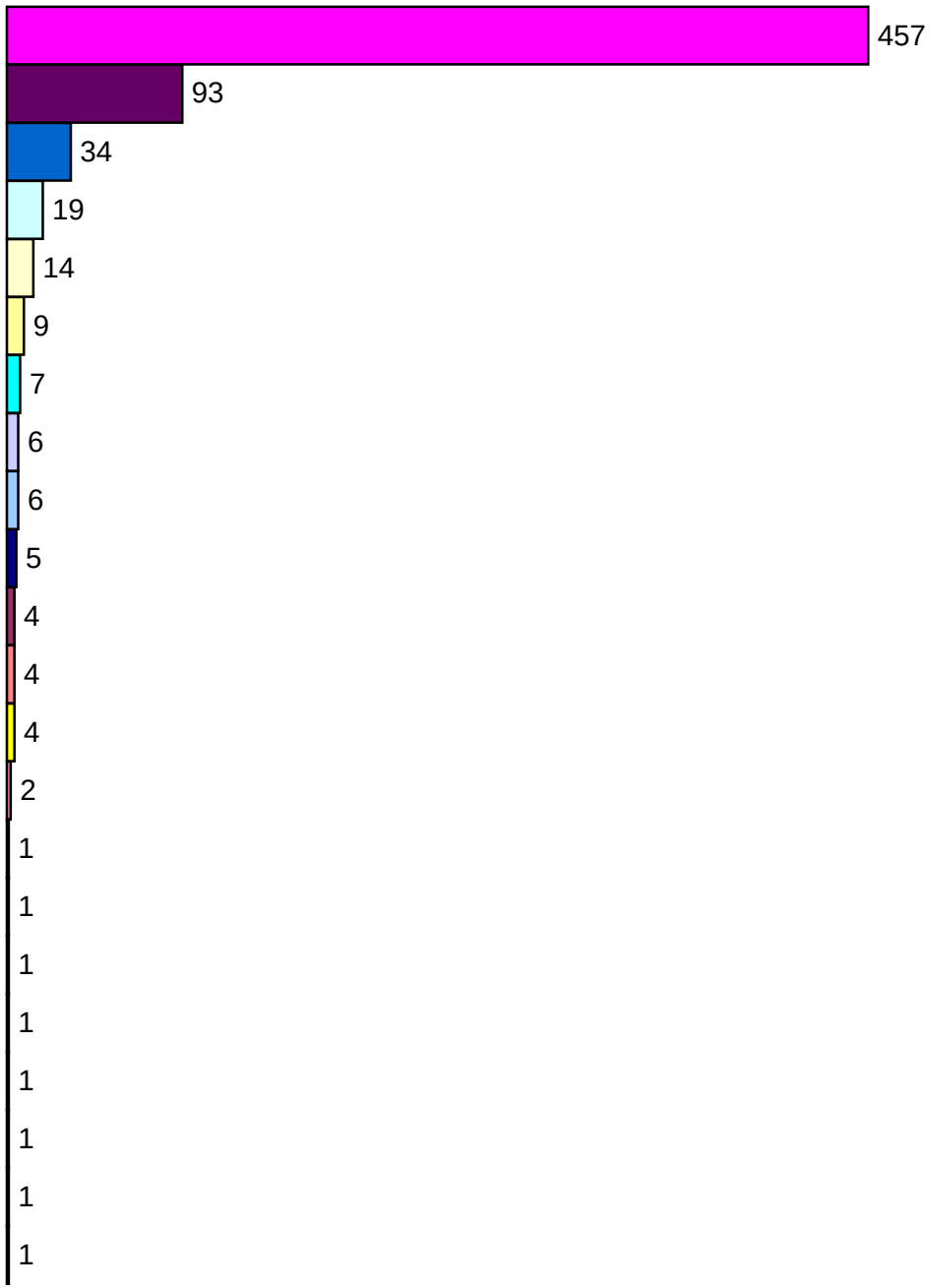
QUESTION #1: What information on the label is most important to you?

622 surveys returned (1,207 responses to Question #1) as of March 3, 2009



QUESTION #2: Do you understand the directions on the prescription label?

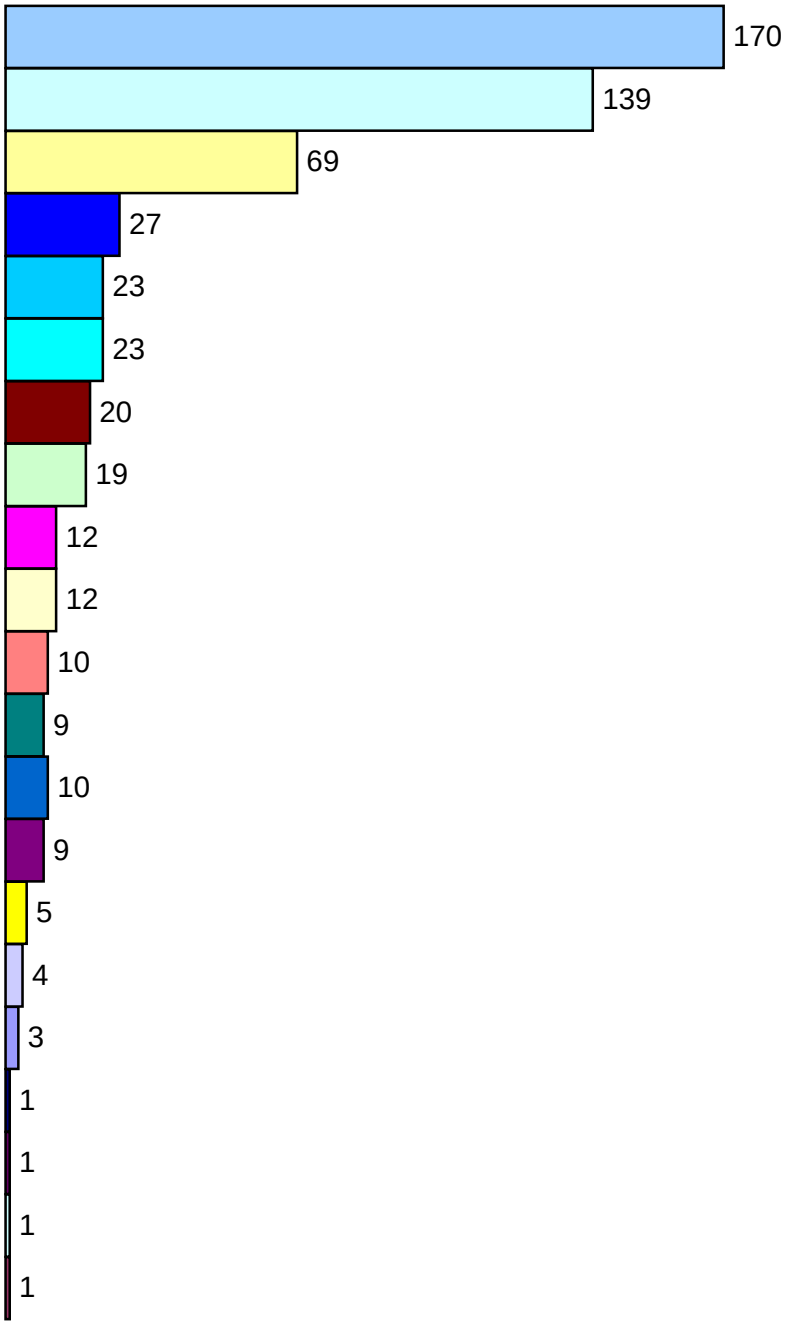
622 surveys returned (672 responses to Question #2) as of March 3, 2009



- Yes
- Usually (though print may be too small, directions/warnings unclear)
- Sometimes
- No (i.e., trouble understanding or not enough space for directions)
- Directions should state what time(s) to take medicine and how much
- Would be helpful to know whether to take with or without food
- I understand because I'm RN, Dr, health worker, have biology degree
- Not when there is a language barrier
- What does 2x (or 3x, or 4x) a day mean?
- Directions need clarity (2 pills = 1 pill twice/day or 2 pills twice/day?)
- Instructions should be in English and Spanish
- Instructions should be in English and Spanish
- Abbreviations should be eliminated
- I do not understand directions that only say "Take as directed"
- No long paragraphs on prescription label
- Label from Kaiser understandable, label from Rite Aid not as clear
- Bullets and spacing on label would be helpful
- Handout should be more readable
- Accompanying paper shouldn't be complicated - use bullets/spacing
- When I don't understand the directions, I ask the pharmacist
- Pharmacist's directions are vague during consultation
- The directions often conflict with the doctor's orders

QUESTION #3: What would you change on the prescription label?

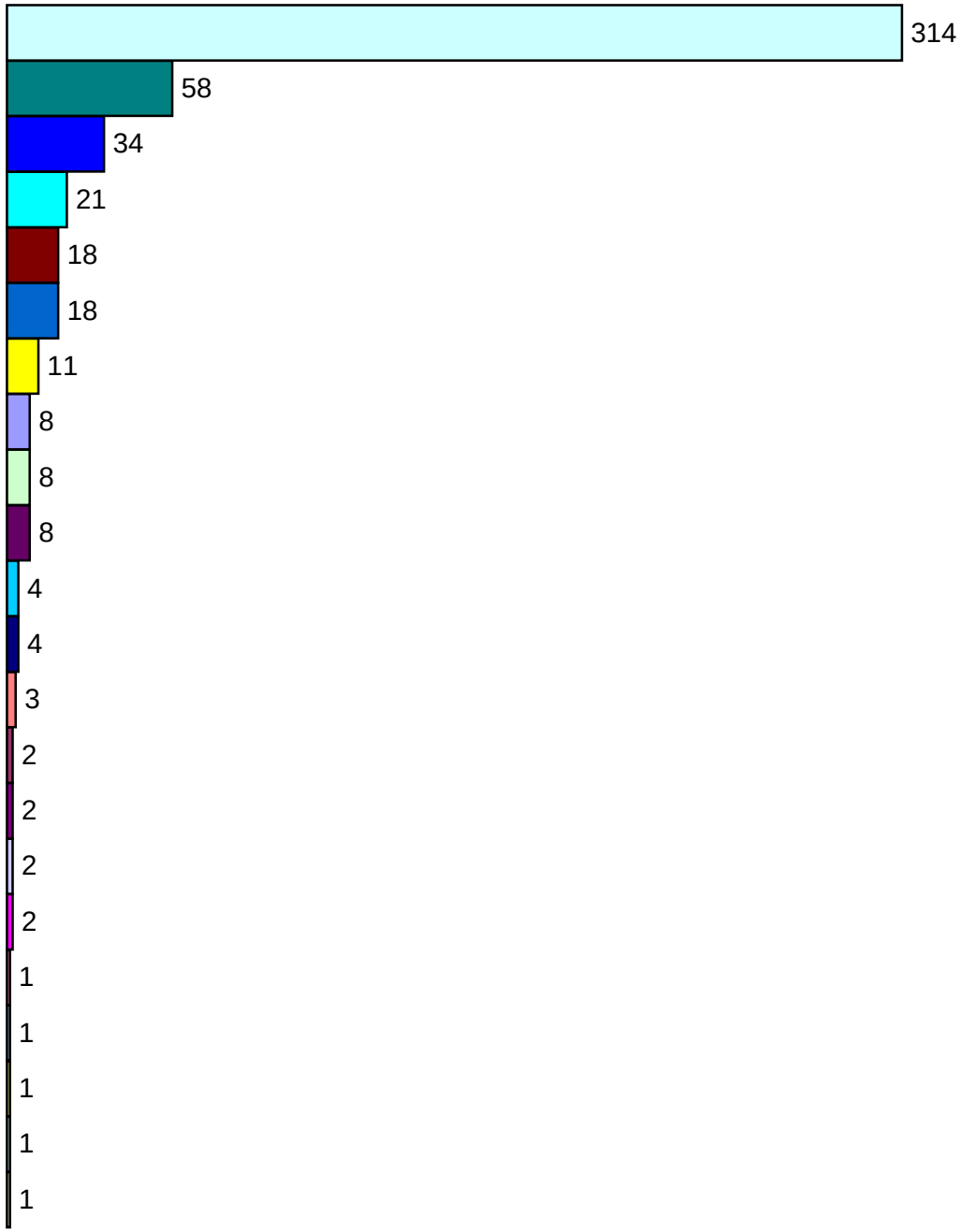
622 surveys returned (568 responses to Question #3) as of March 3, 2009



- Print should be larger or darker (legibility)
- Nothing needs to be changed (some referred to Kaiser, Target, Raley's, CVS)
- Include purpose of drug - state what condition medication is intended to treat
- Information printed should be understandable for all ages; layman's terms
- Use bold or highlighted print or capital letters; red/blue ink for warning labels
- Use different colors for different medicines, strengths/doses, family members
- Directions should include specific times (or morning/night) to take medicine
- Make warning labels easier to read or print directly on label instead of auxilliary
- Name of drug; if generic, state generic name AND brand name
- Refill info (i.e., date to reorder or if no refills remain, state "0 refills remain")
- Include direct phone numbers for easier communication with doctor/pharmacy
- Print in patient's primary language; bilingual wording
- Standardize location of info; uniform label; show information in same order
- Delete unneeded info (i.e., don't say take tab "by mouth" or show address)
- Should be less advertising on label; remove unnecessary information
- Use ink that does not disappear, fade, rub off, or smudge
- Make "fold-out" label or "lift-open flap" stating side effects or purpose of drug
- If more than 1 label, show as "label #1" and "label #2"
- Use only one color on label
- More than one name for medicine is confusing at times
- Label should not refer patient to internet web site

QUESTION #4: What would make the prescription label easier to read?

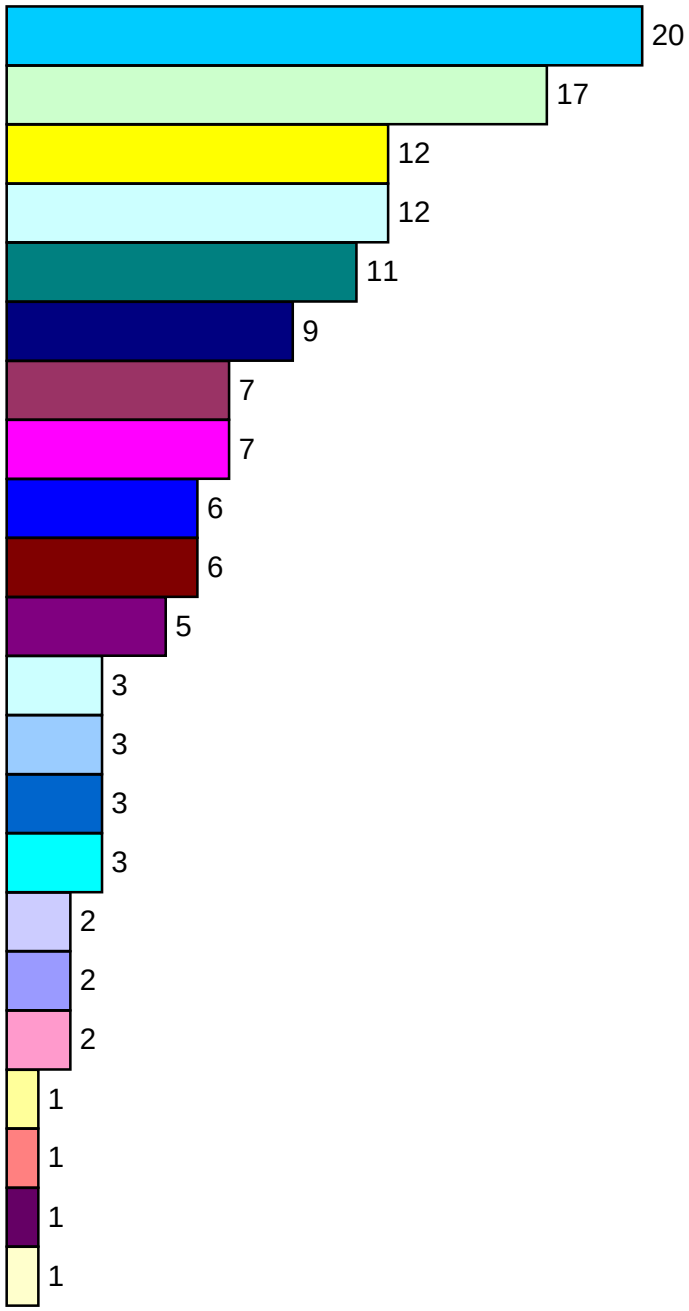
622 surveys returned (522 responses to Question #4) as of March 3, 2009



- Larger print (or bolder print)
- Highlighting directions & other info in colors (or color-coded label)
- Nothing
- Info should be in layman's terms; easy wording; don't abbreviate
- Bilingual wording
- Better description of directions (how/when to take; interactions)
- Refill renewal information including renewal expiration date
- Increase container size so large labels can have large print
- Eliminate clutter (i.e., multiple colors, icons, logos, name of PIC)
- Standard labeling for all pharmacies; standard placement of info
- Underline info or separate directions for use into different lines
- Drawings would help or symbols (or chart of meds & time to take)
- Dark background with light/flourescent print (or glow-in-the-dark)
- Print on label with ink that does not fade or disappear
- Yellow or white warning labels are easier to read than red
- Directions could be printed in all CAPS or bold
- Information on label should NOT be written by hand
- Lower and higher case letters are easier to read than ALL CAPS
- Beige background is easier for seniors to read than white
- List emergency phone number on label
- Standard placement of drug expiration date
- Print in braille for visually-imparied patients

QUESTION #5: Other suggestions?

622 surveys returned (134 responses to Question #5) as of March 3, 2009



- Easy-open lids/packages should be used; no child-proof caps for seniors
- Include purpose of drug - state what condition medication is intended to treat
- Bigger or darker font (i.e., drug expiration date, directions for use, warnings)
- Use different color for printing some info (i.e., directions for use, pharmacy phone #)
- Make directions simple/clear/understandable; print in patient's primary language
- Make bottles rectangular or square w/flat surface and directions printed on long side
- Put picture of pill on label or photo of pill or description of pill
- Side effects/interactions should be stated (i.e., dry mouth may cause dental caries)
- Different colored bottles or caps would help identify medications
- Standardize location of info so all prescriptions show information in same order
- Make label easy to remove (to recycle bottle or for privacy/security when discarding)
- Note on label when the manufacturer of the medicine changes
- Show where to return outdated meds or option to dispose via phamacy
- Don't cover prescription number with warning labels; use symbols as warnings
- Bottles should be in travel/airplane size; large bottles are clumsy and take up space
- Use top of lid for info; containers opening at bottom leave room for larger label
- Note change in size, color, shape of pills, so won't be perceived as medication error
- State what to do if you miss a dose
- Allow NP's name to appear on Rx bottle when submitting electronic prescriptions
- Labels should be waterproof
- Don't allow label to completely cover bottle; leave space to see medication remains
- Include a plan w/multiple meds (i.e., interactions, don't take with Calcium, etc.)

2009 Radio Survey: Online surveys conducted with the Pharmacy Foundation of California

Radio Surveys Conducted with the Pharmacy Foundation of California

January 2009

Pharmacy Foundation
of California

Consumer Rx Label Survey

Michael J. Negrete, PharmD
CEO, Pharmacy Foundation of California
www.PharmacyFoundation.org

Pharmacy Foundation of California

Survey Objective

- To identify key attitudes, knowledge and behaviors of California consumers related to prescription drug labels

Pharmacy Foundation of California

Methodology

- Online survey distributed by Entercom broadcasting
  - One of the five largest radio broadcasting companies in the United States
  - Nationwide portfolio of 110 stations in 23 markets, including San Francisco, Boston, Seattle, Denver, Portland, Sacramento and Kansas City
- Survey made available during January '09 on radio station websites that stream their audio

Pharmacy Foundation of California

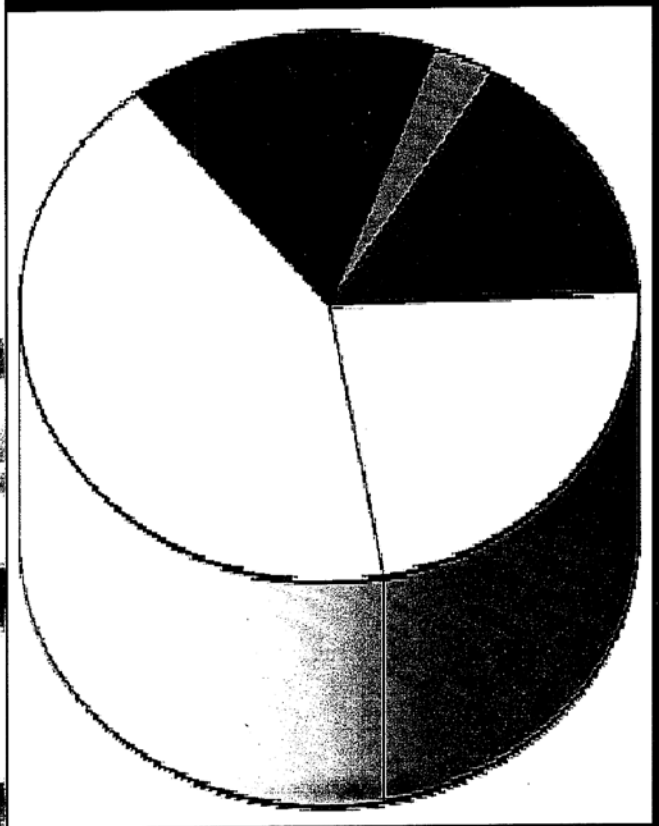
Methodology

- Survey consisted of four questions:
  - How often do you read the label on your prescription containers?
  - When you need to obtain information from the label, what do you have the most trouble with?
  - Which parts of the label are most important to you?
  - What would you change on the prescription label to improve it?

Pharmacy Foundation of California

Results

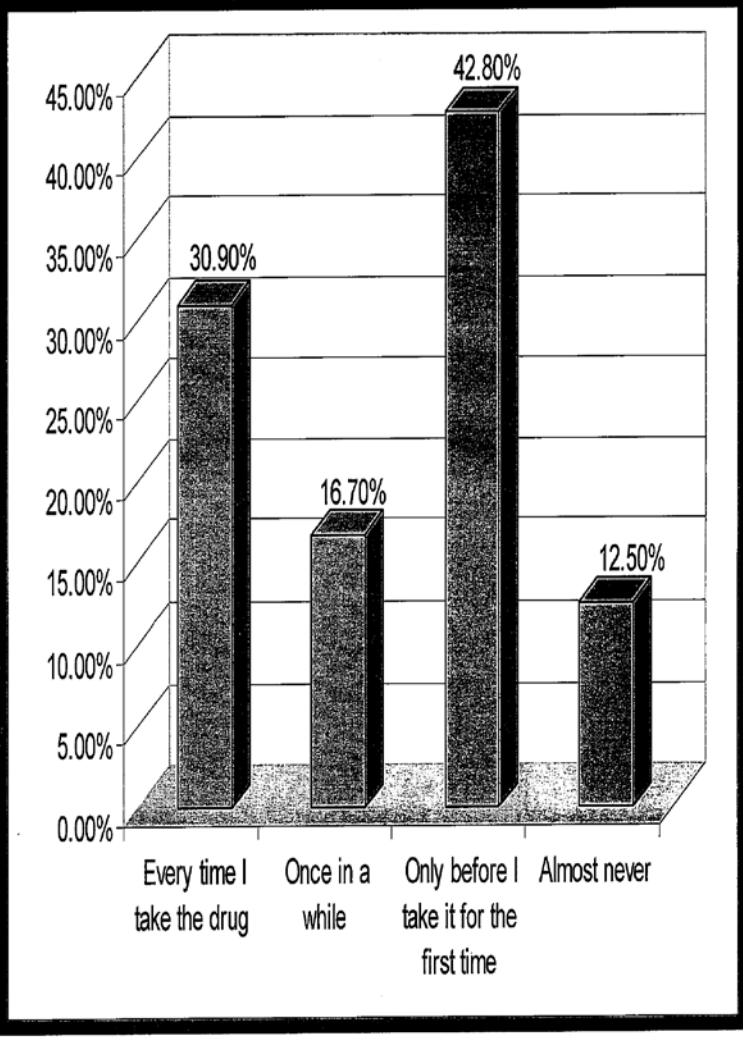
- 1,367 total responses
  - 59.6% female, 43.1% male
  - Age:



Pharmacy Foundation of California

Results

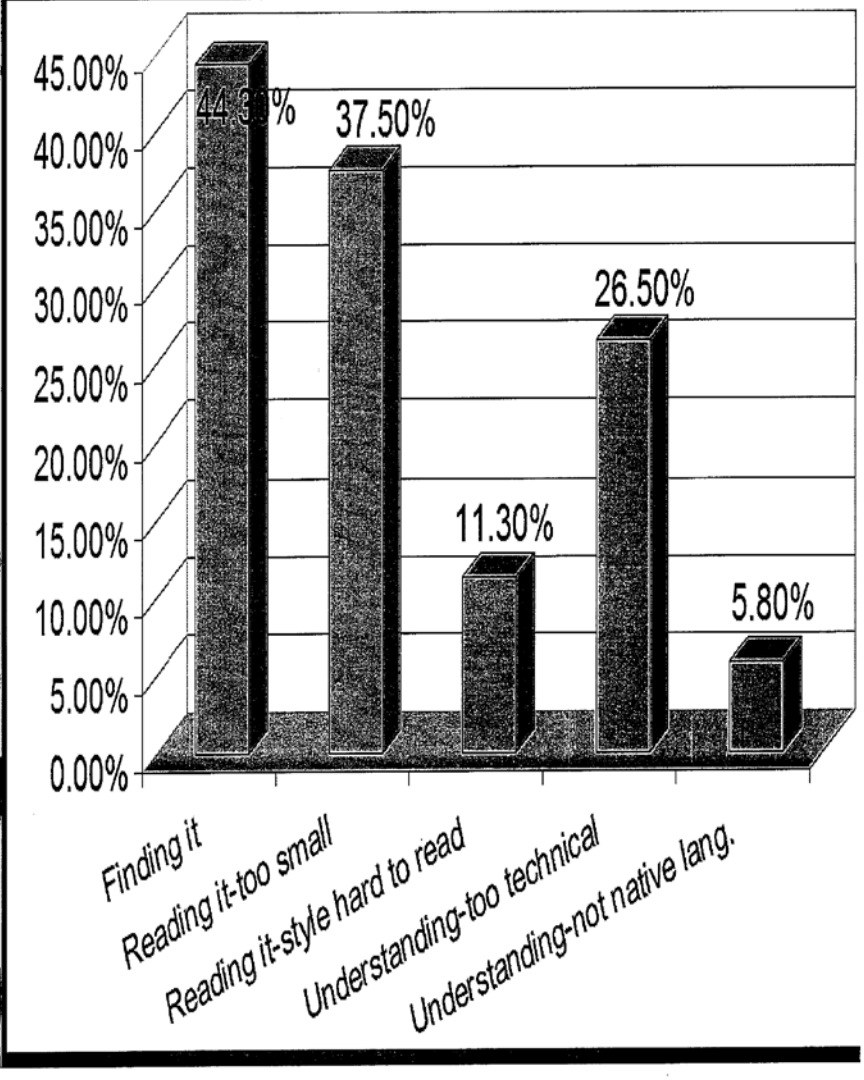
- How often do you read the label on your prescription containers?

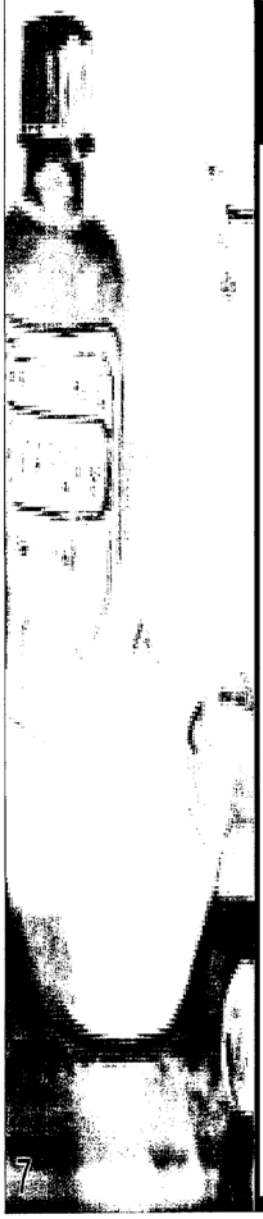


Pharmacy Foundation of California

Results

- When you need to obtain information from the label, do you have the most trouble:

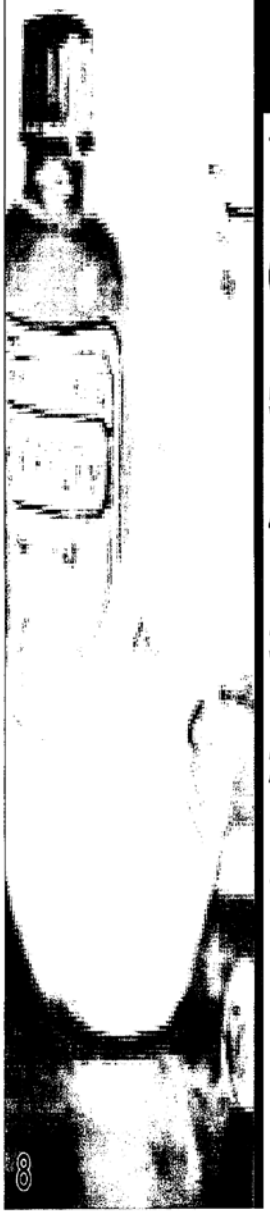


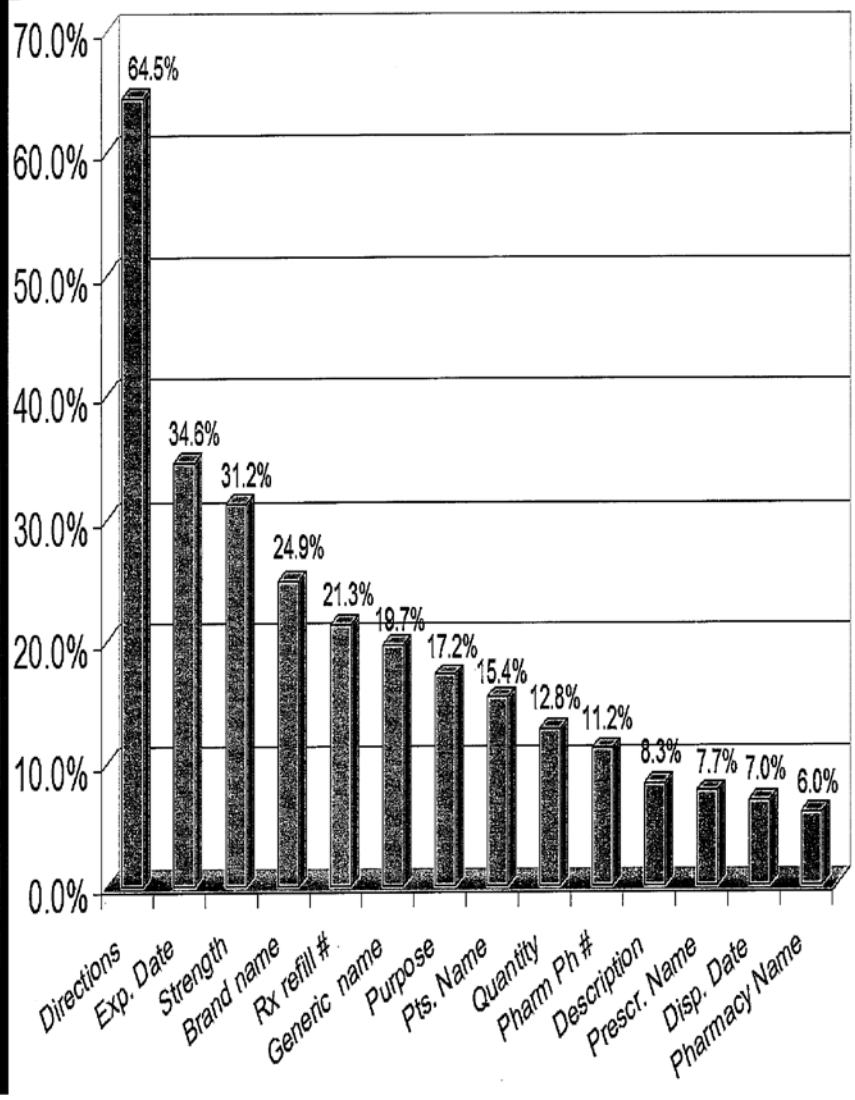


Pharmacy Foundation of California

Results

- Which parts of the label are most important to you?





Pharmacy Foundation of California

Discussion

- What would you change on the prescription label to improve it?
  - Bigger print/size
    - Drug name(s)
    - Directions
  - Clarity
  - Purpose
  - Side effects/interactions
    - On label vs. stickers
  - "Chunking" – Info should be laid out in identifiable sections

Pharmacy Foundation of California

Discussion

- Limitations
  - Representation of the sample
  - Reliability of self-reported information
- Need to encourage more frequent reading of the Rx label
- Label is crowded which requires things to be small & makes info difficult to find
- "Directions for use" is seen as particularly important

2008 AARP Survey: Survey on AARP website asking about importance, understandability and changes recommended for prescription medication labels

AARP.org

Put in Your Two Cents on Prescription Labeling

By: State: California | Source: aarp.org

The California State Board of Pharmacy is seeking public input to make prescription labels easier to understand. Recent studies show that 46 percent of patients misunderstand the prescription label that they get from the pharmacy. Mistakes based on misread labels harm at least 1.5 million people every year and costs about $1 billion dollars annually.

"With few exceptions, most prescription container labels are not terribly user friendly," said Board Executive Officer Virginia Herold. "Yet it's crucial for patients to understand the information on them for the prescriptions to be effective."

Improved labels will aid patients in taking their medicine as prescribed.

Over the next several months, the Board will hold public meetings to elicit suggestions from consumers and health care providers to improve prescription labels and make them easier to understand.

In addition, a survey has been placed on the Board of Pharmacy website to allow consumers the opportunity to provide input on such changes. Please visit www.pharmacy.ca.gov and click on the "What's New" section under "Quick Hits" for the Prescription Label Survey.

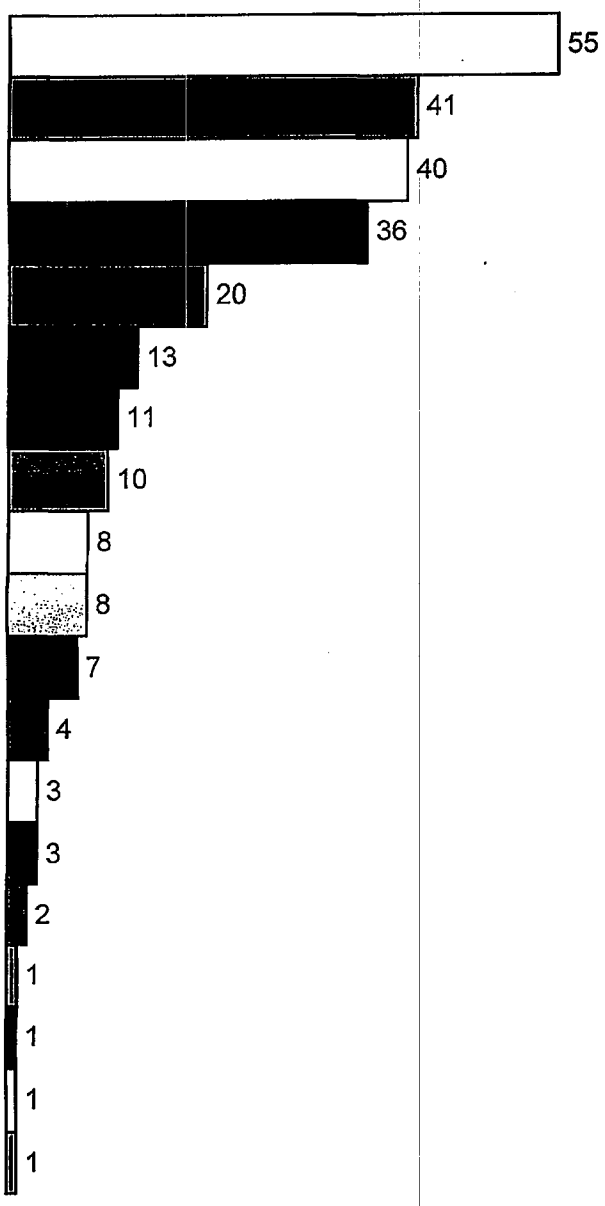
The information collected from patients will be used by the Board to develop new regulations as required by the California Patient Medication Safety Act of 2007.

Related Articles

Ask Your Doctor About these Possible Rx Alternatives

QUESTION #1: What information on the label is most important to you?

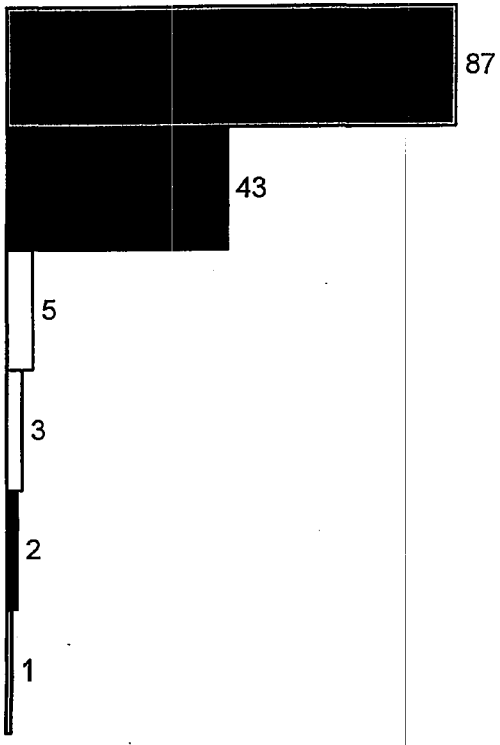
265 responses to Question #1 as of 9/26/08



- Directions for use
- Dosage prescribed
- Name of drug; if generic, state generic name AND brand name it's generic for
- Side effects/warnings/interactions
- Purpose of the drug -- what condition the medication is prescribed to treat
- Refill renewal information/expiration; date filled
- Phone numbers NOT printed in close proxemity (doctor's #, pharmacy #)
- Name of patient that medication is prescribed for
- Larger print
- Specific times during day to take medication, especially w/multiple prescriptions
- Expiration date of drug
- All information on label is important
- Description of pill (shape/color)
- Prescribing doctor's name
- Name of drug store/pharmacy
- Diabetes information
- Highlighting information including directions for use
- Basic measurements (e.g., teaspoons, not milligrams)
- Don't hide important information under another label

QUESTION #2: Do you understand the directions on the prescription label?

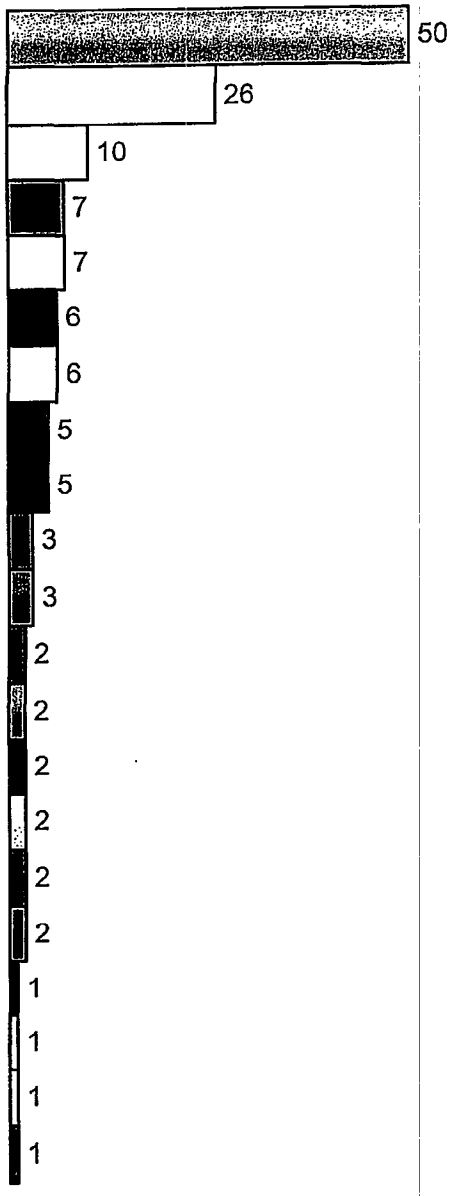
141 responses to Question #2 as of 9/26/08



- ■ Yes
- ■ Usually or sometimes (print too small, directions/warnings not clear, language barrier)
- ☐ Directions should state what time(s) of day to take medicine and how much to take
- ☐ No (trouble reading/understanding directions, not enough space for directions)
- ■ Instructions should be in English and Spanish
- ■ The directions often conflict with the doctor's orders

QUESTION #3: What would you change on the prescription label?

144 responses to Question #3 as 9/26/08



- ■ Print should be larger (or darker)
- □ Include purpose of the drug -- state what condition the medication is intended to treat
- □ Make warning labels easier to read or print warnings directly on label (instead of auxilliary)
- ■ Use bold or highlighted print or capital letters; red or blue ink for warning labels
- □ Nothing needs to be changed on the label
- ■ Directions for use should include specific times (or morning/night) to take medication
- □ Use different colors on label for different types of medication or different family members
- ■ Information printed should be understandable for all age groups; layman's terms
- ■ Delete unneeded info; shorten directions for use (i.e., do not need to say take 1 tab "by mouth")
- ■ Print in patient's primary language; bilingual wording
- ■ Include direct telephone numbers so it is easier to communicate with doctor/pharmacy
- ■ Name of drug; if generic, state generic name of drug AND brand name it is generic for
- ■ Should be less advertising printed on label; remove other unnecessary information
- ■ Include photo of pill on label
- □ Use ink that does not disappear, fade, or rub off
- ■ Standardize location of information so all prescriptions show information in same order
- ■ Make "fold-out" label with insert or "lift-open flap" stating side effects or purpose of drug
- ■ Use only one color on label
- □ More than one name for medicine is confusing at times
- □ If zero refills remain, then "0 refills remaining" should be highlighted
- ■ Label should not refer patient to internet web site

2008 Consumer Survey: Survey of attendees at public forum and consumers on readability, importance of information and suggested changes on prescription labels

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **September 26, 2008**

To: **Communication and Public Education Committee**

Subject: **Update on Consumer/Patient Surveys undertaken for SB 472 Medication Label Redesign Project**

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 2, 2011. The board is also directed to hold special public forums statewide in order to seek input from the public on the issue of prescription labels.

The first special public forum was held at a community center in Fremont on April 12, 2008. Approximately 40 people attended, though most attendees were from the pharmaceutical industry. Three attendees at the initial forum were "public" participants, so it became apparent that the board would need to find alternative venues to increase participation from consumers.

In May 2008, board staff developed a prescription label survey for distribution at public outreach events. The survey is available in English and Spanish. It is designed to elicit information from the public about prescription labels using the following questions:

1. What information on the label is most important to you?
2. Do you understand the directions on the prescription label?
3. What would you change on the prescription label?
4. What would make the prescription label easier to read?
5. Other suggestions?

Since late May, board staff have been using the survey to interview attendees at public events. Consumers have been invited to complete surveys on-site during the events, or mail them to the board using the self-addressed envelopes provided. This method of soliciting information has proved less intimidating to consumers than individually speaking at public hearings. Board staff attending the community events have also reported positive feedback when discussing this initiative with the public.

The survey can also be completed and submitted electronically on the board's Web site at https://app.dca.ca.gov/pharmacy/survey_sb472.asp. In addition, AARP has invited consumers to "Put in Your Two Cents on Prescription Labeling" in the AARP September 2008 newsletter. A copy of AARP's article is attached, and available at: http://www.aarp.org/states/ca/articles/Put_in_Your_Two_Cents_on_Prescription_Labeling.html.

The board has also provided consumers with one-page fact sheets entitled, "Do you understand the directions on your Rx medicine label?" The fact sheet provides background information related to SB 472, and printed samples of faux prescription labels as a visual aid.

A total of 175 consumers have completed surveys thus far. Attached are charts reflecting responses to each survey question. Not every consumer provided an answer to each question, while others provided multiple answers to individual questions. Many consumers gave the same response (i.e., larger font) to more than one question.

Trends have been identified in the answers provided thus far. Many responses suggest that the purpose of the drug be printed on the prescription label, and that a larger or bolder type font be used.

When asked what would make prescription labels easier to read, the top two responses were:

- Larger or bolder print
  (64 of 109 responses = 58.7%)
- Highlighting directions for use and other information in colors other than black
  (15 of 109 responses = 13.8%)

When asked what to change on the prescription label, the top two responses were:

- Print should be larger or darker
  (50 of 144 responses = 34.7%)
- Include purpose of the drug – state what condition the medication is intended to treat
  (26 of 144 responses = 18.1%)

When asked what information on the label was most important, the top two responses were:

- Directions for use
  (55 of 265 responses = 20.8%)
- Dosage prescribed
  (41 of 265 responses = 15.5%)

When asked for other suggestions, the top two responses were:

- Easy-open lids should be used; no child-proof caps for seniors
  (7 of 50 responses = 14%)
- Include purpose of the drug – state what condition the medication is intended to treat
  (6 of 50 responses = 12%)

Board staff will provide another update on the status of survey responses at the next SB 472 Medication Label Subcommittee meeting. In addition, the board will capitalize on the department-sponsored Professionals Achieving Consumer Trust Summit scheduled for November 2008 as an ideal opportunity to engage other professions in the development of a patient-centered prescription label.