



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: July 16, 2013

To: Communication and Public Education Committee

I. Public Outreach Activities to Address Prescription Drug Abuse

a. Update on Two Public CE Trainings Provided by the California State Board of Pharmacy and the Los Angeles Field Division of the U.S. Drug Enforcement Agency

The Board of Pharmacy, in conjunction with the Los Angeles Field Division of the Drug Enforcement Administration, co-hosted a seminar for pharmacists on June 26 in Downey, CA. The seminar focused on prescription drug abuse, corresponding responsibility of pharmacists, and other issues related to curtailing drug diversion. The seminar was well attended, with approximately 220 in attendance. One more seminar will be held in Downey, CA, on July 26.

b. Update on Four Public CE Trainings Provided by the California State Board of Pharmacy and the U.S. Drug Enforcement Agency Scheduled for August 2013

Four more public CE trainings on prescription drug abuse are scheduled for August. These will be co-hosted with the U.S. Department of Justice DEA Office of Diversion Control and will take place on August 16 and 17 in San Diego and August 18 and 19 in San Jose.

II. Update on implementation of 16 California Code of Regulations Section 1707.6 Notice to Consumers Poster, Video Display Format of Notice to Consumers Poster and Notice of Interpreter Availability

The Notice to Consumers poster and Notice of Interpreter Availability poster have been mailed to all licensed pharmacies in California. The posters are also available upon request from the Board and will be mailed to any pharmacy that requests them.

Foreign language versions of the Notice to Consumers poster are also available in six additional languages: Chinese, Tagalog, Korean, Spanish, Russian and Vietnamese. The printed versions of the foreign language posters can be ordered from the Board or downloaded from the Board's website under the "Publications" tab and printed on 8.5 inch x 11 inch or 11 inch by 17 inch paper.

The video display format of the Notice to Consumers is available in English or Spanish for pharmacies that request it. The video is also available for download from the Board's website under the "Publications" tab.

III. Review Requests For Approval From Three Pharmacies to Use Another Format or Display Methodology of the Board’s “Point to Your Language” Notice as Required by 16 CCR Section 1707.6(c)

Attachment 1

Board regulation requires pharmacies to prominently post the “Notice to Consumers” required by 16 CCR Section 1707.6.

In addition, Section 1707.6(c) requires every pharmacy to post or provide a “point to your language” notice that notifies consumers that interpreter services will be provided to them at no cost. That subdivision specifies that the pharmacy shall use the standardized notice provided by the Board unless the pharmacy has received prior approval of another format or display methodology. The twelve languages included in the Board’s “point to your language” notice are: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog and Vietnamese. At the February 2013 Board Meeting, the Board directed that the Communication and Public Education Committee act on all requests to use another format or display methodology of these posters.

Attachment 1 contains three requests for approval to use another format or display methodology of the “point to your language” notice as required by 16 CCR Section 1707.6(c) for review and approval by the committee:

- a. Costco requests that their pharmacies be authorized to use another format of the “point to your language” notice. Costco’s version includes the twelve languages specified in Board regulation, as well as eight additional languages: Thai, Italian, Hindi, German, French, Portuguese, Polish and Japanese.
- b. Walmart requests that their pharmacies be authorized to use another format of the “point to your language” notice. Walmart’s version includes the twelve languages specified in Board regulation, as well as the following languages: Portuguese, Polish, French (Canadian), German and Italian. Walmart’s notice also includes both “simplified” and “traditional” Cantonese and Mandarin.
- c. Riverside County Regional Medical Center requests that they be authorized to use another format of the “point to your language” notice. Riverside County’s version omits Cambodian and Armenian, but includes the following additional languages: Burmese, Polish, Portugese, French, Punjabi, Haitian Creole, Hindi, Somali, Italian and Japanese.

IV. Review and approve updated Consumer Fact Sheet on Emergency Contraception in accordance with 16 California Code of Regulations Section 1746

Attachment 2

Title 16, California Code of Regulations Section 1746 authorizes pharmacists to provide emergency contraception without a prescription to patients of any age. Pursuant to a protocol developed by the Medical Board of California, a fact sheet was to be developed and made available to patients at the time of the pharmacist consultation.

In accordance with Business and Professions Code Section 4052.3(e), the Board developed the standardized fact sheet that a pharmacist is required to provide a patient when dispensing emergency contraception.

At the April 2013 Board meeting, the Board suggested the fact sheet be modified to include the following:

- When taken as directed, emergency contraception has been shown to be safe and effective.
- If you vomit after taking emergency contraception you may need to take another dose. Before you do, contact a pharmacist or health care provider immediately.

Attachment 2 contains a copy of the fact sheet as modified by the Board in April 2013.

No action is required by the committee at this time.

V. Discussion on Assessment of Patient-Centered Prescription Label Requirements

Attachment 3

Title 16 CCR Section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. When the board promulgated these requirements, it included in subdivision (e) a requirement that the board re-evaluate the requirements by December 2013 to ensure optimal conformance with Business and Professions Code Section 4076.5.

Business and Professions Code Section 4076.5 required the board to consider the following factors when developing requirements for the patient-centered prescription label requirements:

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

The patient-centered label requirements went into effect on January 1, 2011, and since that time the board has worked to secure compliance by educating licensees, conducting surveys, distributing notices, and reviewing pharmacies' compliance with requirements. Accomplishments include:

1. Finalized regulations to update the "Notice to Consumers" poster.
2. Finalize a new "Notice to Consumers" poster and video format of the poster to explain to the public essential information about pharmacy services and taking medications and distribute these to California pharmacies.
3. Finalize regulations to require "Point to Your Language" consumer notices in pharmacies; finalize the notice itself, and distribute to California pharmacies.
4. Conduct surveys of pharmacies for compliance with label requirements.

In April 2013, this committee initiated the review of the patient-centered prescription label requirements. At this meeting, the committee will continue this discussion, and may develop recommendations for the board's consideration.

a. United States Pharmacopeia Guidelines for Prescription Drug Labels

In November 2012, the U.S. Pharmacopeial Convention (USP) published guidelines for prescription container labeling. The guidelines provide a universal approach to the format, appearance, content and language of instructions for medicines in containers dispensed by pharmacies. Review of the material in USP's guidelines would be one source of information useful for comparison of the Board's regulations with guidelines for premium presentation and focus on patient needs. It is important to note that USP's guidelines already closely resemble the Board's existing regulation requirements for patient-centered prescription container labels, specifically:

- Organize the prescription label in a patient-centered way. Feature the information patients most often seek out or need to understand about taking the medication safely.
 - Emphasize: directions
 - At the top of the label place: patient's name
 - Drug name (spell out full brand AND generic name)
 - Strength
 - Explicit and clear directions for use in simple language
- Prescription directions should follow a standard format so the patient can expect where to find information.
- Less critical information can be placed elsewhere and in a matter where it will not "supersede" critical patient information, and away from where it can be confused with dosing instructions
- Use language that it is clear, simplified, concise and familiar, and in a standardized manner. Use common terms and full sentences. Do not use unfamiliar words, Latin terms or medical jargon
- Use simplified, standardized sentences that have been developed to ensure ease understanding the directions (by seeking comment from diverse consumers)
- Separate dose from the timing of each dose to clearly explain how many pills to take and specify if there is an appropriate time to take them (morning, noon, evening, bedtime).
- Do not use alphabetic characters for numbers (not in CA's) e.g., "nine" instead of "9".
- Use standardized directions whenever possible.
- Avoid ambiguous terms such as "take as directed" (not in CA's) unless clear and unambiguous supplemental instructions and counseling are provided
- Include purpose on the label unless patient does not want it, and if used, use "purpose for use" language such as for blood pressure rather than hypertension.
- Limit auxiliary information, and only if evidence based. (not in CA's)
- Use icons only if vetted with the general public (not in CA's)
- Address limited English proficiency.
- Labels should be designed so they are easy to read. Optimize typography by using:
 - High contrast print (black print on white background)
 - Large font sizes in simple, uncondensed fonts in at least 11 point if Arial, or 12 point if Times New Roman)

- Optimize use of white space between lines (25-30 percent of font size)
- Horizontal placement of lettering only
- Sentence case
- Highlighting, bolding and other typographical cues should enhance patient-centered information, but limit the number of colors used for highlighting
- Address visual impairment (not in CA's)

Regarding addressing limited English speaking/reading patients, USP encourages directions for use in the patient's language as well as in English. Translations should be developed using high quality translation processes (CA's translated directions would fit this criterion).

b. Medical Literacy Research

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

The hope is to secure the use of directions for use in a Universal Medication Schedule into e-prescribing systems. Staff will continue to identify additional medical literacy research for the committee's consideration.

c. Surveys

The board has conducted surveys to assess California's patient-centered label requirements. Survey results are provided in Attachment 3.

1. Survey of Patient-Centered Labels in Use in California Pharmacies

The first survey was conducted in 2012 and was used to measure pharmacies' compliance with the patient-centered label requirements. It included components related to the 10- and 12-point fonts used on labels and how pharmacies have been complying with the interpreter requirements. Over the course of approximately seven months, board inspectors collected prescription labels used in California 767 pharmacies to determine compliance with the patient-centered label requirements. In general, nearly 70 percent of the labels in use as found by the board's inspectors are printed in 12-point font; 15 percent use both 10 and 12 point font on the labels; and about 15 percent are printed in 10 point.

2. Survey of Pharmacies' Compliance With Interpreter Availability

During the inspections described in the above survey, the board's inspectors also inquired how pharmacies are complying with the requirements for the availability of interpreters to provide services to limited English speaking patients.

3. Consumer Satisfaction with Prescription Labels

The board conducted a survey in 2012 to determine if consumers were satisfied with their prescription labels and how they could be improved. Several consumer groups including AARP, Consumers Union, and California Pan Ethnic Health Network (CPEHN) distributed the survey electronically. The survey was also translated into Chinese and Spanish by the board and distributed by CPEHN to the appropriate audiences. Further, surveys were distributed and collected in person at local Senior Scam Stopper seminars (public protection fairs) sponsored by the Contractors State License Board. The board received a total of 1204 completed surveys.

4. Survey of Pharmacies that Translate Labels

The board is currently surveying pharmacies to determine if they are providing consumers with translated labels, and if they are using the translation 'directions for use' that are on the board's website. A copy of the survey questions are provided in Attachment 3.

d. Language Assistance and Translations of Directions for Use

Notice to Consumers poster

Following the implementation of the patient-centered prescription label requirements, the board promulgated a regulation to amend its Notice to Consumers poster. Following approval of the regulation, the new Notice to Consumers poster was designed, printed and subsequently distributed to all board licensed pharmacies in late May 2013.

This poster has also been printed in six additional languages: Chinese, Korean, Russian, Spanish, Tagalog, and Vietnamese – which are available upon request from the Board. These translated posters are also available for download from the Board's website.

Pharmacies may also request board approval of another format or display methodology.

Interpreter Availability Poster ("Point to Your Language")

As part of the patient-centered prescription label requirements, the board developed a "Point to Your Language" poster, which is required to be posted in pharmacies at or adjacent to the pharmacy counter so that consumers can point to a language to receive interpreter services. Board regulation requires that the "point to your language" text be printed in 12 languages: Arabic, Cambodian, Farsi, Korean, Russian, Tagalog, Armenian, Cantonese, Hmong, Mandarin, Spanish and Vietnamese.

Pharmacies may request approval of another format or display methodology from the board.

Translated Directions for Use

The California Endowment, in an effort to support quality labels for those who do not read English, funded a project with national patient literacy researchers to develop and vet translations of the standardized directions for use that are posted on the board's website for use where appropriate on patient-centered prescription labels. These translations are in: Chinese, Korean, Russian, Spanish and Vietnamese.

e. At This Meeting

The committee needs to review the patient-centered prescription label requirements. Discussion should be focused on the components in Senate Bill 472 (Corbett), the enabling legislation (Business and Professions Code Section 4076.5):

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

For Discussion:

- 1. Placement of information that is “patient-centered” (i.e., patient name, name/strength of the drug, directions for use, and condition or purpose [if indicated]). Do we have the right patient-centered elements? Do we need to modify what is considered “patient centered”?***
- 2. Font size requirements. Is 10, 12 or another font / typeface appropriate?***
- 3. Use of bold text, highlighting, color and/or white space to add emphasis or set off the patient-centered items.***
- 4. Standardized directions for use.***
- 5. Translated directions for use available on the board’s website. Do we require them?***
- 6. Requirements to help patients with limited or no English proficiency understand the information on the prescription label. Are we doing enough?***
- 7. Are we doing enough to meet the needs of senior citizens?***
- 8. Should the board consider technology standards to implement patient-centered requirement?***

VI. Update on Committee's Goals for 2012/2017 to Fulfill Board's Strategic Plan

Board staff continues work on the Communication and Public Education section of the strategic plan. Following is an update of recent activity:

a. Strategic Objective 4.1 – Develop Notice to Consumers Posters and Video

The Notice to Consumers and Notice of Interpreter Availability posters were mailed to all pharmacies in California in April. Foreign language versions of the Notice to Consumers poster were also printed in six additional languages: Chinese, Tagalog, Korean, Spanish, Russian and Vietnamese.

A video display format of the Notice to Consumers poster was also produced and is available in English or Spanish for pharmacies that request it. The video is also available for download from the Board's website under the "Publications" tab.

b. Strategic Objective 4.2 – Restructure the Board's Website to Make it More User Friendly

Board staff continues to work on the new design and site architecture for the Board's website. Unit managers have provided input regarding navigation and content suggestions for their areas.

VII. Update on *The Script*

The next issue of *The Script* is undergoing legal review. The issue includes information about recent changes to pharmacy law, as well as disciplinary actions taken by the Board between July and March of 2013. The issue also includes answers to frequently asked questions and an article about the Joint Forum to Promote Appropriate Prescribing and Dispensing held in February in South San Francisco.

VIII. Update on Consumer Education Materials

Attachment 4

The following new consumer brochures have been produced in response to

1. *Prescription Drug Abuse*
2. *Prescription Drug Abuse Among Teens*
3. *Purchasing Pet Meds Safely from Online Pharmacies*

Color mock-ups of the brochures are provided in Attachment 4.

IX. Update on Media Activity: January to June 2013

Attachment 5

Media activity for the first two quarters of 2013 is provided in Attachment 5.

X. Public Outreach Activities Conducted by the Board

State government continues to be subject to travel restrictions that prohibit all but the most essential travel. The Department of Consumer Affairs must still preapprove all travel not involving enforcement issues where a travel claim will be submitted. This has restricted Board operations in all areas, including public and licensee outreach.

Recent public and licensee outreach activities performed have focused principally on educating stakeholders about e-pedigree requirements that will take effect beginning January 1, 2015, via a number of webinars hosted by various companies to help educate the pharmaceutical supply chain.

Additionally, as reported earlier in this meeting, the Board has cohosted with the Los Angeles Office of the U.S. Drug Enforcement Administration two continuing education sessions on prescription drug abuse, diversion and a pharmacist's corresponding responsibility.

The following are public outreach activities we have participated in since the April report to the Board:

- April 18: Executive Officer Herold provides a teleconference presentation on the Board's pending sterile compounding requirements to attendees at a California Conference of Local Health Officers meeting in Oakland.
- April 23: Executive Officer Herold provides a teleconferenced presentation on California's e-pedigree requirements to attendees of the LogiPharma 2013 international supply chain security conference in Geneva, Switzerland.
- May 9: Executive Officer Herold provides a teleconferenced presentation on California's e-pedigree requirements to attendees of the 3rd Annual Serialization and Traceability for Brand Protection Exl Pharma Conference.
- May 23: Executive Officer Herold provides an in-person presentation to attendees at the National Association of Boards of Pharmacy Annual Meeting in St. Louis on virtual manufacturing, virtual wholesaling (brokering) and violations affecting the quality of the US drug supply.
- May 29: Executive Officer Herold and Supervising Attorney General Joshua Room provide a webinar on California's e-pedigree requirements hosted by rfxcel.
- June 5: Executive Officer Herold provides information on California's e-pedigree requirements via a communications link at the BioLogistics Summit held in San Francisco.
- June 18: Executive Officer Herold provides a teleconferenced presentation on California's e-pedigree requirements and implementation progress at the Pharmapack North America – Serialization Technology Forum held in Philadelphia.
- June 28: Executive Officer Herold provides a two-hour webinar responding to questions about California's e-pedigree requirements to over 300 attendees hosted by Tracelink.

Attachment 1



July 9, 2013

Jan Jamison
California State Board of Pharmacy
Public Information Officer
1625 N Market Blvd N219
Sacramento, CA 95834

Re: Notice of Interpreter Availability "Point to Your Language" Notice (Section 1707.6(c))

Dear Ms. Jamison:

This letter is a formal request by Costco Wholesale for approval from the Board for an alternative form of notice pursuant to 16 California Code of Regulations Section 1707.6(c). Costco would like to use our own form of notice of interpreter services. A sample of this is included in attachment two. We would be using this in color, on an 8 ½" by 11" easel.

Thank you,

A handwritten signature in black ink, which appears to read "Jon McArthur", is placed above the typed name.

Jon McArthur
Pharmacy Compliance
Costco Wholesale
999 Lake Drive
Issaquah WA 98027

Interpretation Services Available

English Translation: Point to your language. An interpreter will be called. The interpreter is provided at no cost to you.

Arabic عربي <p>أشر إلى لغتك. وسوف يتم جلب مترجم فوري لك. سيتم تأمين المترجم الفوري مجاناً.</p>	Japanese 日本語 <p>あなたの話す言語を指して下さい。 無料で通訳を提供します。</p>
Armenian Հայերեն <p>Ցոյց տուէք ո՞ր մէկ լեզուն կը խօսիք՝ Թարգմանիչ մը կանչել կը տանք. Թարգմանիչը կը տրամադրուի անվճար.</p>	Korean 한국어 <p>귀하께서 사용하는 언어를 지적하시면 해당 언어 통역 서비스를 무료로 제공해 드립니다.</p>
Cambodian (Khmer) កម្ពុជា (ខ្មែរ) <p>សូមបង្ហាញភាសាអ្នក។ យើងនឹងហៅអ្នកបកប្រែភាសាអង់គ្លេស។ អ្នកបកប្រែភាសាខ្មែរនឹងជួយអ្នកដោយមិនគិតថ្លៃ។</p>	Mandarin 國語 <p>請指認您的語言， 以便為您提供免費的口譯服務。</p>
Cantonese 廣東話 <p>請指認您的語言， 以便為您提供免費的傳譯服務。</p>	Polish Polski <p>Proszę wskazać swój język i wezwiami tłumacza. Tłumacza zapewnimy bezpłatnie.</p>
Farsi فارسي <p>زبان مورد نظر خود را مشخص کنید. یک مترجم برای شما درخواست خواهد شد. مترجم بصورت رایگان در اختیار شما قرار می گیرد.</p>	Portuguese Português <p>Indique o seu idioma. Um intérprete será chamado. A interpretação é fornecida sem qualquer custo para você.</p>
French Français <p>Pointez vers votre langue et on appellera un interprète qui vous sera fourni gratuitement.</p>	Russian Русский <p>Укажите язык, на котором вы говорите. Вам вызовут переводчика. Услуги переводчика предоставляются бесплатно.</p>
German Deutsch <p>Zeigen Sie auf Ihre Sprache. Ein Dolmetscher wird gerufen. Der Dolmetscher ist für Sie kostenlos.</p>	Spanish Español <p>Señale su idioma y llamaremos a un intérprete. El servicio es gratuito.</p>
Hindi हिंदी <p>अपनी भाषा पर इंगित करें और एक दुभाषिया बुलाया जाएगा। दुभाषिये का प्रबन्ध आप पर बिना किसी खर्च के किया जाता है।</p>	Tagalog Tagalog <p>Ituro po ang inyong wika. Isang tagasalin ang ipagkakaloob nang libre sa inyo.</p>
Hmong Hmoob <p>Taw rau koj hom lus. Yuav hu rau ib tug neeg txhais lus. Yuav muaj neeg txhais lus yam uas koj tsis tau them dab tsi.</p>	Thai ไทย <p>ช่วยชี้ที่ภาษาที่ท่านพูด แล้วเราจะจัดหาสามให้ท่าน การใช้สามไม่ต้องเสียค่าใช้จ่าย</p>
Italian Italiano <p>Puntare sulla propria lingua. Un interprete sarà chiamato. Il servizio è gratuito.</p>	Vietnamese Tiếng Việt <p>Hãy chỉ vào ngôn ngữ của quý vị. Một thông dịch viên sẽ được gọi đến, quý vị sẽ không phải trả tiền cho thông dịch viên.</p>

Jamison, Jan@DCA

Subject: FW: Notice of Interpreter Availability Formal Request
Attachments: WalmartCASBOP-Point to Language-061913-230pmCST-RRJ.pdf

From: Shelley Tustison [<mailto:Shelley.Tustison@wal-mart.com>]
Sent: Wednesday, July 10, 2013 2:57 PM
To: Jamison, Jan@DCA
Cc: Debbie Mack
Subject: Notice of Interpreter Availability Formal Request

Ms. Jamison,

This is a formal request for approval by the California Board of Pharmacy for Walmart and Sam's Club Pharmacies to use the attached sign for the Notice of Interpreter Availability pursuant to 16 California Code of Regulations Section 1707.6(c). Please let me know if you need additional information.

Thank you,

Shelley J. Tustison, PharmD
Senior Manager, Corporate Compliance
Health and Wellness Practice Compliance
Office: 479-204-8729 Fax: 479-277-9679
Shelley.Tustison@wal-mart.com

Walmart * Compliance

The Right Way- Every Day!
702 SW 8th Street
Bentonville, AR 72716-0230
Save Money, Live Better.



Interpreter Services available at no cost to you. Please point to your language.

Spanish

Servicios de intérprete disponible sin costo alguno para usted. Por favor señale su idioma.

Russian

Вы имеете право на бесплатные услуги переводчика. Пожалуйста просим Вас указать на Ваш язык.

Portuguese (Brazilian)

Serviços de tradutor disponível para você gratuitamente. Favor apontar para o seu idioma.

Polish

Pacjenci mogą korzystać z bezpłatnych usług tłumacza. Proszę wskazać swój język.

Hmong

Peb yuav muaj tug paab txhais lug rua koj dlawb dlawb. Thov taw rua koj yaam lug.

French (Canadian)

Services d'interprète disponibles sans frais pour vous. Veuillez indiquer votre langue.

German

Sie können von kostenlosen Dolmetschdiensten Gebrauch machen. Bitte zeigen Sie auf Ihre Sprache.

Vietnamese

Dịch vụ Thông dịch luôn có sẵn miễn phí cho quý vị. Vui lòng cho biết ngôn ngữ của quý vị.

Cantonese (Simplified)

请点击这里以获得免费广东话口译服务

Cantonese (Traditional)

請點這裏以獲得免費廣東話口譯服務

Mandarin (Traditional)

請點這裏以獲得免費國語口譯服務

Mandarin (Simplified)

请点击这里以获得免费普通话口译服务

Korean

통역 서비스를 무료로 제공합니다.

Cambodian/Khmer

សំណើសេវាបកប្រែសម្រាប់ភាសាខ្មែរ
មានជូនដល់លោកអ្នកដោយមិនអស់លុយ។
សូមចង់អុលទៅភាសារបស់លោកអ្នក។

Tagalog

Mga Serbisyo ng Tagasalin nang walang gastos sa iyo. Pakituro sana ang iyong lengguwahe.

Arabic

يمكننا توفير خدمات الترجمة الفورية مجاناً. الرجاء تحديد لغتك

Farsi

خدمات ترجمه رایگان برای شما موجود است.
لطفاً به زبان خود اشاره کنید.

Armenian

Կարող ենք ամենաարագ և անվճար և՛ նաև համապատասխան լեզուներով ձեր լեզունը արձանագրել:

Italian

Servizi di interpretariato gratuiti. Indicare la lingua.



CERTIFIED LANGUAGES
INTERNATIONAL

From: [Ammee Amboya](#)
To: [Jamison, Jan@DCA](#)
Cc: [DTidwell@co.riverside.ca.us](#)
Subject: Poster Request for Approval
Date: Thursday, May 02, 2013 1:39:58 PM

Dear Ms. Jan Jamison,

Thank you very much for your time and help regarding my poster inquiries. Attached to this e-mail is a picture of the poster that we would like to use for the Riverside County Regional Medical Center (RCRMC) Pharmacy department. Address:

Riverside County Regional Medical Center
Department of Pharmacy
26520 Cactus Ave
Moreno Valley, CA 92555
(951) 486-4000

If you have any questions, concerns, or suggestions, you can contact me at amboya@usc.edu / (808) 250-7420 or my supervisor, Dr. Davalyn Tidwell at DTidwell@co.riverside.ca.us.

Again, thank you.

Sincerely,
Ammee Amboya
Pharm.D. Candidate 2013
USC School of Pharmacy

Attachment 2



Key Facts About Emergency Contraception

Emergency Contraception (EC) is a safe and effective way to prevent pregnancy after sex.

Consider using Emergency Contraception (EC) if:

- You had unprotected sex, or
- You think your contraceptive didn't work.

What are Emergency Contraceptive pills?

Emergency Contraceptive pills contain the same medication as regular birth control pills, and help to prevent pregnancy. There are three basic types of Emergency Contraceptive pills:

- Progestin-only pills (Plan B® One-Step, Next Choice®)
- Ulipristate acetate (ella®)
- High doses of regular oral contraceptive pills

Don't wait! Take EC as soon as possible.

- It is best to take EC as soon as possible; the sooner you take EC the more effective it is.
- It has been shown to be effective for up to 5 days.
- For more information talk to your pharmacist or doctor.

When taken as directed Emergency Contraception has been shown to be safe and effective.

- Emergency Contraception may reduce the risk of pregnancy by up to 89 percent.
- The effectiveness of EC varies based on the type used and when it is taken.
- EC is only recommended as a backup and should not be used as your primary method of birth control.
- Emergency Contraceptive pills do not protect against sexually transmitted infections, including HIV/AIDS.

What EC does.

- Emergency Contraceptive pills prevent pregnancy.
- Emergency Contraceptive pills are not effective after pregnancy has occurred and they will not harm the developing fetus.
- Emergency Contraceptive pills are NOT the same as RU-486 (the abortion pill)
- Using Emergency Contraceptive pills will not affect a woman's ability to become pregnancy in the future.

Follow-Up after taking Emergency Contraceptive pills

- If you vomit after taking emergency contraception you may need to take another dose. Before you do, contact a pharmacist or healthcare provider immediately.
- If you do not get a normal period within three weeks, take a pregnancy test.
- It is important to visit your doctor or clinic for a regular birth control method and information about preventing sexually transmitted infections.
- Medical providers or your pharmacist can provide Emergency Contraception for future use if needed.

In California, women and men may receive free family planning services through Family PACT based on income.

If you don't have a doctor or clinic, call 1-800-942-1054 to find a Family PACT provider near you.

Under the Affordable Care Act (ACA), Emergency Contraception may be covered with a prescription.



Approved by the California State Board of Pharmacy
Revised July 2013 • Printed by Pharmacy Access Partnership

Attachment 3

Summary

Patient-Centered Labeling Inspections

DATE: April - August 2012

This survey is intended to be used during inspections of all pharmacies. Unless otherwise indicated, please use tally marks. Sections 1-4 should always be completed. Section 5 will only be used if the pharmacy is compliant and indicated as such in section 4.

1	Number of Inspections	767
----------	------------------------------	------------

2	Patient-Centered Label (B&P 4076[a] & CCR 1707.5[a][1][A] - [D])			
		Chain Store	Community	Clinic
	Compliant	355	339	1
	Noncompliant	13	67	7
	Corrections issued	13	49	7

3	The label is usually printed in...	Chain Store	Community	Clinic
	10-point font is the default	40	73	0
	12-point font is the default	280	161	1
	Both 10-point & 12-point font appear on the label	47	138	0

Please tally the number in sections 2 and 3 of the survey. This survey is designed to measure compliance with the patient-centered labeling requirements (section 2). Section 3 is designed to identify if pharmacies are defaulting to the larger or smaller font, or using a combination of sizes on the patient-centered elements.

4	Interpretative Services (CCR 1707.5[d])			
		Chain Store	Community	Clinic
	Compliant (all 12 languages available)	349	253	0
	Noncompliant	23	150	1
	Corrections issued	23	146	1

5	If compliant, interpretative services provided by	Chain Store	Community	Clinic
	Staff only	17	2	0
	Telephone (e.g. language line)	68	51	0
	Combination of staff and telephone	260	199	43
	Other, please specify	0	1	0

Please tally the number of pharmacies compliant and non-compliant in Section 4. Complete Section 5 section only if the pharmacy is compliant with the interpretative services provisions.

Other: Internal system with video conference - UC Davis

**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 have also been collected at local Senior Scam Stopper seminars sponsored by the Contractors State Licensing Board.

Results

A total of 1204 surveys were received. 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	502
2. Are the directions for taking the medicine easy to understand?	245	959
3. Do you know why you take each of your medicines?	1049	149
4. Would you like the general reason why you take the medicine to appear on the label (for pain, for infection, etc.)?	963	232
Chinese: 46 Surveys Received	YES	NO
1. Are your prescription container labels easy to read?	40	5
2. Are the directions for taking the medicine easy to understand?	45	1
3. Do you know why you take each of your medicines?	42	4
4. Would you like the general reason why you take the medicine to appear on the label (for pain, for infection, etc.)?	30	4

Spanish: 16 Surveys Received	YES	NO
1. Are your prescription container labels easy to read?	6	10
2. Are the directions for taking the medicine easy to understand?	7	9
3. Do you know why you take each of your medicines?	7	9
4. Would you like the general reason why you take the medicine to appear on the label (for pain, for infection, etc.)?	16	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 were:

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%

Survey Questions Regarding Translated Labels:

1. Do you provide prescription container labels with translated directions?
 - a) Yes
 - b) No (if no, go to question 4)

2. How do you provide the translation of the directions for use?
 - a) Pharmacy staff translates the labels
 - b) The pharmacy uses the Board of Pharmacy's online translated directions for use
 - c) The pharmacy uses computer software or online programs
 - d) The pharmacy uses other means of providing translations (describe):

3. If you translate the labels, do you also provide the English language equivalent on the label?
 - a) Yes
 - b) No

4. If you do not provide translated directions on the label, why?
 - a) The pharmacy has no requests for translated labels
 - b) The pharmacy has too many patients with diverse language needs
 - c) The pharmacy's software will not print in foreign language fonts
 - d) The pharmacy is concerned that errors on the label will go undetected
 - e) Other: _____

5. How does the pharmacy comply with the interpreter requirements?
 - a) Uses pharmacy staff at this or other pharmacies to interpret
 - b) Uses a telephone language service
 - c) Is not compliant with current requirements to have access to an interpreter

Inspector: _____ Date _____

Pharmacy: _____

**Point to your language.
It's your right. Interpreter services will be provided at no cost.**

ARABIC	<p align="center">اختر لغتك.</p> <p align="center">يتم تقديم خدمات الترجمة الفورية لك عند الطلب دون أي تكلفة.</p>	<p>Նշեք ձեր լեզուն:</p> <p>Թարգմանչի ծառայություններն անվճար կտրամադրվեն ձեզ՝ ըստ պահանջի:</p>	ARMENIAN
CAMBODIAN	<p>ចូរចង្អុលទៅកាន់ភាសារបស់អ្នក ។</p> <p>មានផ្តល់សេវាកម្មបកប្រែភាសាដល់អ្នកតាមការស្នើសុំ ដោយឥតគិតថ្លៃ ។</p>	<p align="right">廣州話</p> <p>指向您的語言。</p> <p>將根據您的要求免費為您提供翻譯服務。</p>	CANTONESE
FARSI	<p align="center">زبان خود را مشخص کنید.</p> <p align="center">خدمات ترجمه شفاهی بر حسب درخواست شما به صورت رایگان فراهم خواهد شد.</p>	<p>Taw rau koj yam lus.</p> <p>Kev pab cuam neeg txhais lus yuav muaj pub rau koj raws li kev thov yam tsis yuav nqi.</p>	HMONG
KOREAN	<p>언어를 지정해 주십시오.</p> <p>요청 시 통역 서비스를 무료로 제공해 드립니다.</p>	<p>指向您的语言。</p> <p>官話</p> <p>将根据您的要求免费为您提供翻译服务。</p>	MANDARIN
RUSSIAN	<p>Указать на ваш язык.</p> <p>Услуги переводчика будут бесплатно предоставлены Вам по требованию.</p>	<p>Indique su idioma.</p> <p>Se le proporcionarán servicios de intérprete sin costo si lo solicita.</p>	SPANISH
TAGALOG	<p>Ituro ang iyong wika.</p> <p>Ang serbisyo ng interpreter ay ibibigay sa iyo kapag hihilingin nang walang bayad.</p>	<p>Xin hãy chỉ vào ngôn ngữ của quý vị.</p> <p>Dịch vụ thông dịch sẽ được cung cấp cho quý vị miễn phí theo yêu cầu.</p>	VIETNAMESE



BE AWARE AND TAKE CARE:
Talk to your pharmacist!
 CALIFORNIA STATE BOARD OF PHARMACY



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 hazard-

ous. 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).

Universal Medication Schedule White Paper

April 2013 DRAFT

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Universal Medication Schedule White Paper

Version 1.0

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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.

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.

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

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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.¹The 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

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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

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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.

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.

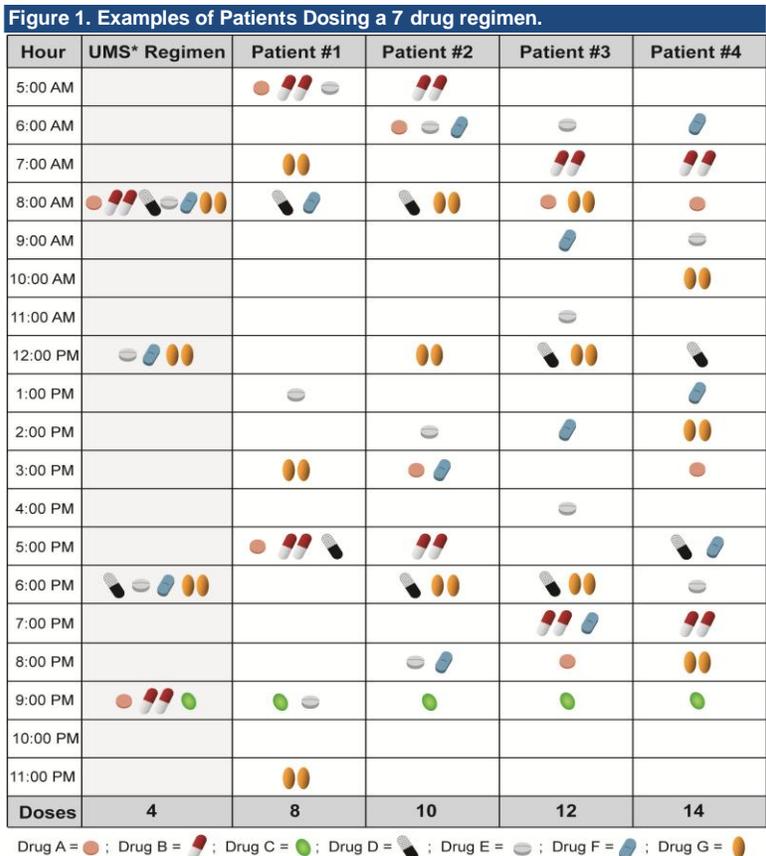
The Universal Medication Schedule (UMS)

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.

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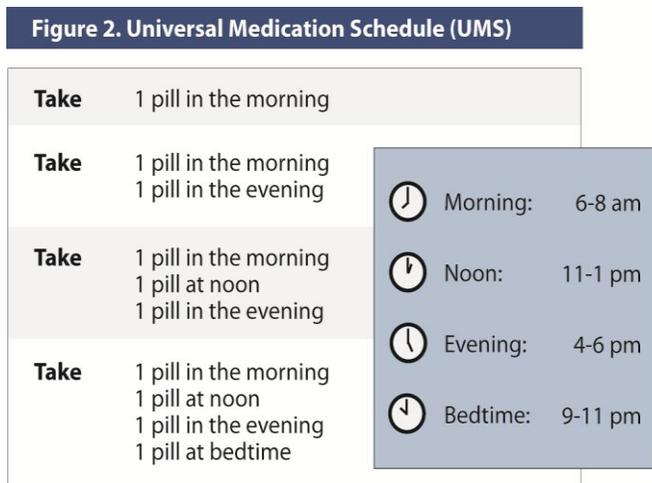
Limited Literacy. Numerous studies have found limited literacy to be significantly associated with patients' poorer recall of medication names and indications, inadequate understanding and demonstrated use of prescription instructions and precautions.^{11-13,38-42} The study team at Northwestern recently 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

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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.*



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

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.

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.

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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;

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- 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

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.

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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).

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*".

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}

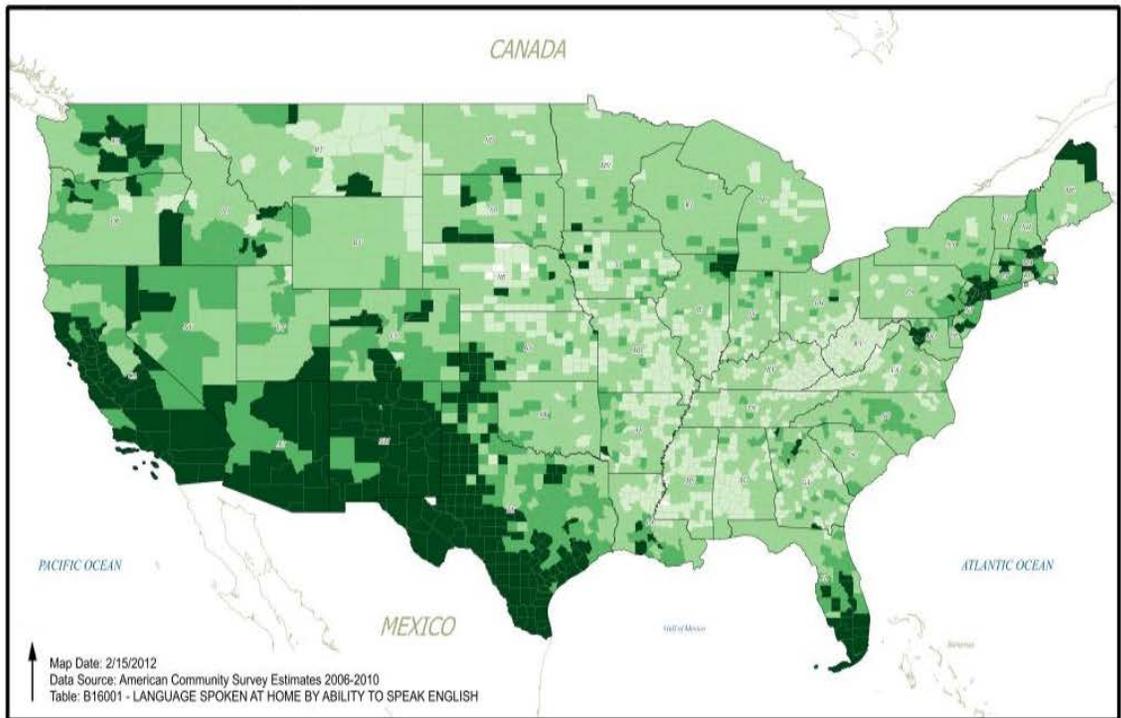
It should be noted that several states have requirements related to translations of prescription labels, and other items. Translations can occur via printed materials or with

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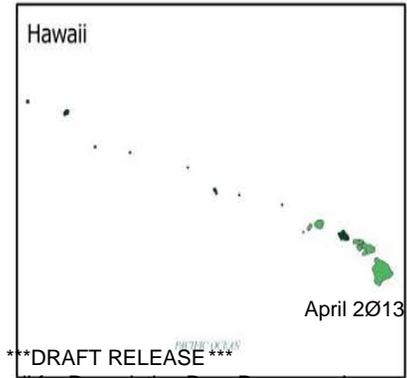
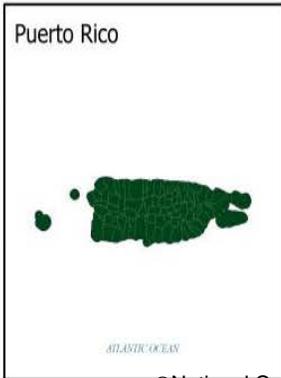
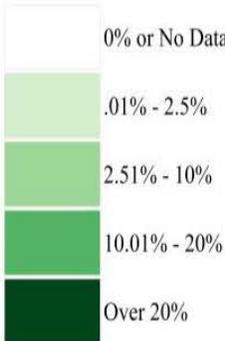
the use of interpreters. New York's requirements, as an example, are specific to pharmacies with a minimum of eight locations. The law requires that pharmacies provide free interpretation and translation services to customers with limited English proficiency (LEP) who request the services or fill a prescription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



Population Speak Other Language At Home



Version 1.0

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

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- 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.

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.

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

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- (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;*

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- (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

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

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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.

Pharmacy Name:	Date Filled: MM/DD/YY	Cautions:
Phone:	Rx No.:	
Purpose:		Description:
Patient Q. Name		
Prescriber:		
Take 1 tablet in the morning and 2 tablets at bedtime.		
Drug Name and Strength		
Generic for:	Qty:	
Discard after: MM/DD/YY	Refills:	

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.

(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-point 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

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(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 2011 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. 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.

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:

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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/qbk_pdf/pp_qbk.pdf

Research Validated	A program, activity or strategy that has the highest degree of proven effectiveness supported by objective and comprehensive research and
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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	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ 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.

JOURNAL OF YOUNG PHARMACISTS:

<http://www.jyoungpharm.in/article.asp?issn=0975-1483;year=2010;volume=2;issue=1;spage=107;epage=111;aui=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.

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- 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 <ul style="list-style-type: none">• 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.
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APPENDIX D. TARGET CLEARRX IMPLEMENTATION

ClearRx: The Future of Pharmacy

Target Introduces Innovation with Safety and Design for Guests

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.”



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.

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;

Version 1.0

April 2013

DRAFT RELEASE

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Universal Medication Schedule White Paper

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)

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):

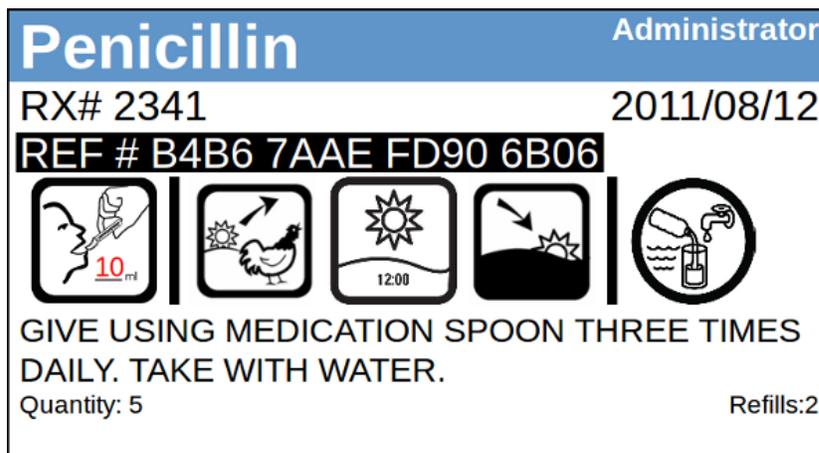
- A label with customizable size
- A medication information sheet for one medication
- A prescription calendar that combines all medicines
- A storyboard of a medication

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)

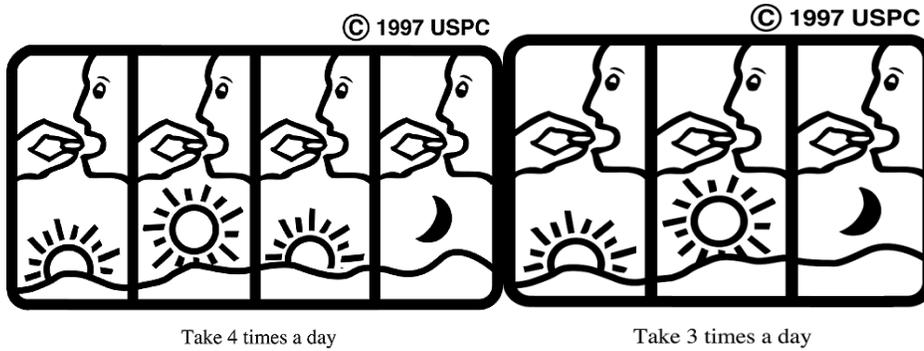


The same type of simple imagery could be added to prescription labels:

Universal Medication Schedule White Paper

	Morning:	6-8 am
	Noon:	11-1 pm
	Evening:	4-6 pm
	Bedtime:	9-11 pm

The US Pharmacopeial provided the following sample pictograms:



Universal Medication Schedule White Paper



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

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14 ENDNOTES

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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 hazard-

ous. 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).

Attachment 4

California State Board of Pharmacy

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Prescription Drug Abuse

What you need to know to avoid addiction and overdose



What are prescription drugs?

Prescription drugs are medicines your doctor prescribes for you.

What is prescription drug abuse?

Prescription drug abuse is:

- Taking a prescription drug for nonmedical reasons.
- Taking more of a prescription drug than you should.
- Taking someone else's prescription drug.
- Giving your prescription drug to someone else.

Death from an overdose of prescription painkillers has become a national epidemic. The National Institute on Drug Abuse reports that while the use of illegal drugs is down, abuse of prescription drugs continues to rise. More people die from prescription drug overdose than from car accidents.

Which prescription drugs are most often abused?

Three types of prescription drugs are most often abused:

Opioids - Opioid abuse is the fastest growing drug problem in the United States. Opioids are painkillers and are often prescribed to treat pain after medical or dental procedures or physical injuries. Some people also feel euphoria when taking opioids, which can lead to addiction and abuse. Common opioids include hydrocodone (Vicodin), oxycodone (OxyContin, Percocet), morphine (Kadian, Avinza), and codeine.

Depressants - Depressants are sedatives or tranquilizers. They work on the central nervous system to slow brain activity and create a feeling of calm. Some of the most common depressants are Valium, Halcion and ProSom. Depressants are not prescribed for long-term use because of the risk of addiction.

Stimulants - Stimulants increase energy, attention and alertness. They can also raise the heart rate, blood pressure and breathing, which can lead to paranoia and anger. Stimulants can also heighten the effects of dopamine and norepinephrine in the brain and cause a feeling of euphoria, which contributes to abuse.



Spotting prescription drug abuse

Signs of prescription drug abuse vary depending on the drug used. If you recognize any of the following symptoms in yourself or someone you know, talk to a doctor or medical professional as soon as possible. Identifying prescription drug abuse early could prevent addiction or serious health problems.

Signs of opioid abuse

Low blood pressure
Reduced breathing
Confusion
Depression
Constipation

Signs of depressant abuse

Involuntary and rapid eye movements
Poor judgment
Drowsiness
Unsteady gait
Confusion

Signs of stimulant abuse

High blood pressure
Irregular heartbeat
Weight loss
Agitation
Irritability
Insomnia

Other signs of prescription drug abuse

- Taking higher doses than prescribed.
- Excessive mood swings.
- Needing more or less sleep.
- Stealing or selling prescriptions.
- Appearing to be high, unusually energetic, or sedated.
- Poor decision making.
- Continually losing prescriptions so more prescriptions must be written.
- Seeking prescriptions from more than one doctor.

Guidelines for using prescription drugs safely

- Always follow the directions carefully.
- Don't increase or decrease doses without talking with your doctor first.
- Never stop taking prescription drugs on your own.
- Don't crush or break pills (especially if they are time-released).
- Be clear about the drug's effects on driving and other daily tasks.
- Learn about possible interactions of the prescription drugs with alcohol or other prescription and over-the-counter drugs.
- Talk honestly with your doctor about any history of substance abuse.
- Never allow other people to use your prescription medications and don't take theirs.

How to help someone who is addicted to prescription drugs

If you notice any of the warning signs and suspect that a family member or close friend is abusing prescription drugs, talk to the person about your concerns. Don't be surprised if the person denies it, since people with addiction often have trouble acknowledging their illness. You should also talk to your healthcare provider, who can give you a referral to a drug treatment program.



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Prescription Drug Abuse Among Teens

What every parent should know



Every day, more than 2,000 teenagers in the United States take a prescription drug to get high according to The Partnership at Drugfree.org. Unfortunately, many teens believe that because prescription drugs are legal and dispensed by a doctor, they must be safe. Many parents believe that, too.

What many parents and teens don't understand is that abusing prescription drugs can easily escalate to addiction or even death.

Prescription painkillers are among the most commonly abused drugs. Many times, they are crushed, snorted, or injected, making them even more risky. In fact, opioid painkillers act on the same sites of the brain as heroin and can easily lead to addiction or overdose.

Why do teens abuse prescription drugs?

Teens abuse prescription drugs for many reasons, including to get high, to relax, to treat pain, to fit in with their peers, or to stay alert in school.

Why are prescription drugs so dangerous?

Teens who take prescription drugs without a prescription often take more than the recommended dose or recklessly combine them with other pills or alcohol. The results can be deadly.

Teens who abuse prescription drugs may be more prone to engage in other risky behaviors. According to findings from multiple national surveys, teens who said they have used prescription painkillers for nonmedical reasons were more likely to smoke pot or cigarettes or to binge drink than those who had taken the medication only under a doctor's care.

How do teens get prescription drugs?

Unfortunately, prescription drugs are often easy to get. Many people leave their unused prescription drugs in a bathroom medicine cabinet, where teens can help themselves. Some teens are prescribed pain medication for a medical condition and use the drugs to get high. Others steal the drugs from friends or relatives.

Watch for telltale signs

Parents should watch for signs that may indicate drug use, such as:

- Sudden weight loss or gain.
- Increased energy, restlessness, or inability to sleep.
- Slow or slurred speech.
- Excessive talking.
- Nausea and vomiting.
- Constricted pupils.
- Slowed breathing.
- Dizziness.
- Anxiety.
- Chest pain with palpitations.

Commonly abused drugs

Narcotic pain medications, including Vicodin, OxyContin, and Percocet, are the drugs most commonly abused by teens. These drugs are often referred to as cash, tango, schoolboy, or monkey. Taking just one large dose can suppress breathing and cause death.

Depressants, including Valium and Xanax, are often called reds, yellows, downers, and roofies. Taking these drugs with other medication or alcohol can slow the heart and breathing enough to cause death.

Stimulants, such as Adderall and Ritalin, are referred to as speed, uppers, blow, crack, and crystal. Overuse of these drugs can result in irregular heartbeat, dangerously high body temperature, heart failure, and seizures.

Keep your teen safe

Keep your prescription drugs in a secure place your children don't know about.

Talk to your children about the dangers of abusing prescription drugs. Make sure they understand that prescription medications can be just as deadly as street drugs if abused.

Dispose of any unused or expired prescription drugs. Use a marker to black out personal information on the label, mix the drugs with water, and put the bottle in a margarine tub or other empty container before throwing it in the garbage. Or, find a local prescription drug take-back event in your community.

Educate yourself about the dangers of prescription drug abuse and share what you've learned.



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Pet Medications

What to know before
buying pet drugs online



Buying your pet's medications online can be convenient and economical. Many of these pet medication websites are legitimate, reputable pharmacies that follow State and Federal laws. However, some websites may be unlicensed and unable to buy medicines from legitimate sellers. Instead, they sell outdated, mislabeled, or counterfeit drugs and products.



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BE AWARE AND TAKE CARE:
Talk to your pharmacist!

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Look for the red flags

Avoid shopping at an online pet pharmacy if:

- 1 The site's prices are noticeably lower than your veterinarian or other online sites.
- 2 The pharmacy does not require a prescription from a veterinarian.
- 3 The site has no licensed pharmacist available to answer your questions.
- 4 There is no physical address, phone number, or other contact information listed.

Know how to protect yourself

Before you buy drugs for your pet from an online veterinary pharmacy, there are a few things you can do to protect yourself, and your pet.

Look for the Vet-VIPPS seal. This stands for Veterinary-Verified Internet Pharmacy Practice Site, which is an accreditation program of the National Association of Boards of Pharmacy. The accreditation requires a review of all policies and procedures as well as an onsite inspection of all facilities used by the site to receive, review, and dispense medicine.



Ask your veterinarian to recommend trusted online pet pharmacies.

Always make sure you have a prescription for any prescription medications you buy.

Inspect your order

After you have received your order, be sure to inspect the drug container and its contents. Is it the drug you ordered? If you have ordered the drug before, does it look the same? If you have any questions about what you received or the dosing instructions, be sure to contact your veterinarian.

Taking these few precautions can help keep your pet healthy and safe.

If you suspect a pet pharmacy is operating illegally, contact the California State Board of Pharmacy. You can also notify the U.S. Food and Drug Administration Center for Veterinary Medicine 888-FDA-VETS, or the National Association of Boards of Pharmacy at custserv@nabp.net or online at www.nabp.net.

Attachment 5

Agenda Item IX – Attachment 5

Update on Media Activity – January to June 2013

Compounding

03/27/13	Chelsey Conaboy	The Boston Globe	Pallimed Pharmacy - Compounding Issues
05/09/13	Greg Jones	Work Comp Central	General Compounding Issues

ePedigree

4/29/2013	Alaina Busch	FDA News	FDA track and trace system
5/28/2013		Life Science Reader	Impact of Federal ePedigree legislation on CA's proposed program

Prescription Drug Abuse

01/17/13	Ms. Klein	LA Times	Scheduling of Hydrocodone
02/06/13	Lisa Bartley	KABC-TV Los Angeles	Investigation into overprescribing at Costco
02/14/13	Gregg Jones	Work Comp Central	Is BOP interested in overseeing CURES Program?
03/01/13	Jaimie Fletcher	OC Register	Pacifica Pharmacy Appeal

Rx Drug Costs

03/04/13 Michelle Katz World News Tonight RX Drug Prices

Emergency Contraception Regulations

06/11/13 Monte Moren LA Times EC Regs

Grey Market Activity

02/26/13 Michael Tomsic NPR, Charlotte, N.C. Gray Market Drugs

Pharmacy Errors

06/25/13 Adeline Yee KOVR Channel 13 Interviewed Giny re: consumer who experienced 3-week delay in receiving cancer meds from Express Scripts.