



## COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Deborah Veale, Chair  
Ramón Castellblanch, Vice Chair  
Ryan Brooks, Public Member  
Lavanza Butler, Professional Member  
Ricardo Sanchez, Public Member

Report of the Communication and Public Education Committee Meeting held May 25, 2016. A copy of the minutes from the meeting is provided in **Attachment 9**.

**a. Update and Discussion on the Development of a Revised Patient Consultation Survey Questionnaire**

At the October 2015 Board Meeting, President Gutierrez asked the committee to develop a broader survey for licensees about patient consultation. At the May 2016 Communication and Public Education Committee Meeting, Division of Program & Policy Review Chief Tracy Montez, Ph.D., of the Department of Consumer Affairs addressed the committee and her office's ability to develop the patient consultation survey for the board's licensees. During the meeting, the committee provided basic parameters to Dr. Montez regarding the survey including: intent, privacy for participants, and addressing various practice settings that must be addressed.

The committee directed board staff to work with Dr. Montez's team and develop the agreement for the completion of the survey. The committee directed Dr. Castellblanch and board staff to work with Dr. Montez's team on the development, administration and completion of the survey. The committee agreed to a target date of September 2016 for the committee to review the survey at the next Communication and Public Education Committee meeting.

**Update**

Board staff recently met with Dr. Montez's team to develop the agreement for the completion of the study. Dr. Montez's team will develop the agreement deliverables and a timeline for board staff review.

**b. Discussion on Current Patient Consultation Practices and Actions the Board Can Take to Educate Consumers and Licensees on Appropriate Patient Consultations**

The committee discussed the importance of educating consumers and licensees on appropriate patient consultations. The committee agreed in waiting for the results of the upcoming patient consultation survey and board strategic planning sessions before moving forward.

Ms. Herold suggested the possibility of developing a video demonstrating what a good consultation looks like and perhaps what a bad consultation looks like as a tool for consumers and pharmacists. Chairperson Veale suggested a university competition to develop such a video.

Dr. Castellblanch inquired about the availability of the Notice to Consumers (NTC) in other languages. Board staff indicated the NTC is available for download from the board's website in full color in six languages on legal-size paper, in addition to English. Dr. Castellblanch asked that, at minimum, a Spanish version be available in a full poster size. Chairperson Veale directed board staff to have larger NTC posters printed and available in Spanish. Ms. Veale asked board staff to bring to the next board meeting the large NTC posters in English and Spanish as well as the legal size posters translated in the other languages available on the board's website.

#### Update

Board staff has worked with the Department of General Services' Office of State Publishing for the production of a large poster sized NTC in Spanish. As of July 12, 2016, the board's website has been updated to allow ordering of a poster-size NTC in English and Spanish.

### **c. Update and Discussion on Prescription Label Translations of Directions for Use**

#### **1. Update on the Communication Plan**

#### **Attachment 1**

Assembly Bill (AB) 1073 (Ting) was signed by the Governor on October 11, 2015, and the provisions went into effect on January 1, 2016. The law requires a pharmacist to use professional judgment to provide a patient with appropriately worded directions for use on a prescription label consistent with the prescriber's instructions.

The bill also requires a prescriber to provide existing translated directions for use on a label when appropriate, if requested. Dispensers are not *required* to provide translated directions for use beyond what the board has made available. However, the bill does *authorize* a dispenser to provide his or her own translated directions for use to comply with the requirement. Veterinarians are exempt from the requirement to provide translated directions for use.

At the January 2016 Communication and Public Education Committee Meeting, the committee directed board staff to develop a communication plan and provide an update to the committee. The committee directed board staff to release a public service announcement about the change in law immediately.

Board staff released the public service announcement on February 10, 2016. The release was translated into Chinese, Korean, Vietnamese, Russian and Spanish. Overall, the release was sent to over 800 media outlets, as follows:

- 499 media outlets received the English and translated press releases;

- 272 media outlets received the Spanish translated press release;
- 33 media outlets received the Chinese translated press release;
- 17 media outlets received the Vietnamese translated press release;
- 12 media outlets received the Korean translated press release; and
- 3 media outlets received the Russian translated press release.

As part of the Communication Plan – Phase I, the information from the public service announcement was added to the board’s website on the homepage. Additionally, board staff contacted the Department of Consumer Affairs’ (DCA) Public Affairs Office for assistance in disseminating the message through DCA’s website, Facebook and Twitter accounts. The board’s Spring 2016 edition of *The Script* also included an article on this topic.

A copy of the board’s web page, translated press releases, DCA’s webpage search function showing “label translations,” DCA’s Facebook post and Tweet, and the board’s newsletter article is included in **Attachment 1**.

As part of the Communication Plan – Phase II, board staff recommended and the committee directed board staff to disseminate information regarding the availability of written translations as part of a specific ***Did You Know?*** Campaign, to be implemented as follows:

- Flyer/Fact Sheet Development – Develop in concert with the DCA Office of Publications, Design and Editing. Identify fact sheet and tag line materials translated into the five languages and post these on the board’s website.
- Follow Up Press Release – Reiterate the message through a follow-up Press Release with Flyer/Fact Sheet directed to audiences of the five languages identified in the law.

#### Update

Board staff is working with California Pan-Ethnic Health Network (CPEHN) as a collaborative partner for Phase II of the Communication Plan. Board and CPEHN staff have had two telephone conferences to develop the flyer/fact sheet. Once the flyer/fact sheet has been developed, the two organizations will work together to increase distribution and consumer awareness.

## **2. Proposed Draft Regulation Language for Board Consideration**

### **Attachment 2**

At the January 2016 meeting, the committee discussed developing draft regulation language requiring pharmacies to post information for consumers regarding the availability of written translations. At the May 2016 meeting, the committee reviewed language to require the Point to Your Language notice to include a translated direction for the consumer to ask about translations available.

**Committee Recommendation (Motion):** Direct board staff to provide draft language for 16 CCR 1707.6(c) as discussed in the committee to reflect the addition of prescription labels being available in Spanish, Chinese, Korean, Vietnamese and Russian and provide prescription labels may be available for other languages referenced in 16 CCR 1707.6(c) and recommend draft to the board for consideration.

Update

Based on the committee's comments and directions, board staff revised the draft language. The revised language is provided below and may be found in **Attachment 2**.

***Draft Proposal to Amend Section 1707.6 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:***

**§ 1707.6. Notice to Consumers.**

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

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

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

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

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

*Before* taking your medicine, be sure you know: the name of the medicine and

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

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

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

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

“Point to your language. Interpreter services will be provided to you upon request at no cost. Ask the pharmacist what translations may be available for prescription labels.” This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, ~~Cantonese~~, Farsi, Hmong, ~~Korean~~, ~~Mandarin~~, ~~Russian~~, ~~Spanish~~, and Tagalog, ~~and Vietnamese~~.

“Point to your language. Interpreter services will be provided to you upon request at no cost. Ask the pharmacist what translations are available for prescription labels.” This text shall be repeated in at least the following languages: Chinese, Korean, Russian, Spanish, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

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

Note: Authority cited: Sections 4005, 4076.6 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5, 4076.6 and 4122, Business and Professions Code.

d. **Update on Development of FAQs Received From [ask.inspector@dca.ca.gov](mailto:ask.inspector@dca.ca.gov)**

**Attachment 3**

Licensees are now able to call and ask general questions of pharmacy inspectors. Inspectors answer calls on Tuesdays and Thursdays from 8:00 am to 4:30 pm. In addition, licensees may submit an email inquiry to an inspector at [ask.inspector@dca.ca.gov](mailto:ask.inspector@dca.ca.gov). The board is developing an FAQ to be posted on the board's website concerning the most frequent questions and issues.

FAQs are not intended as, nor should they be construed to be legal advice. The information is intended to provide guidance to the reader on relevant legal sections that should be considered when using professional judgment to determine an appropriate course of action. Should a licensee require legal advice or detailed research, the licensee is encouraged to contact an attorney or other source.

Board staff has been drafting FAQs to add to the board's website as a reference for licensees. The challenge with many of the drafted FAQs is that it is difficult to create a full response as a written response has implications in what is said and what is not said too. An update on the draft FAQs was provided at the meeting and is included in **Attachment 3**.

e. **Discussion and Consideration of Naloxone Related Matters**

**Attachment 4**

**1. Sample Naloxone Labels**

Pursuant to title 16 CCR section 1743.6 (c)(5), the board is required to provide on the board's website sample naloxone labels. The committee reviewed the sample naloxone labels at the meeting. The committee requested the labels provided on the board's website include labels for a specific patient's name and also for an unknown patient's name as "recipient."

Update

Board staff updated the sample naloxone labels to reflect both a specific patient's name and an unknown patient's name as recipient. A copy of the updated naloxone labels is included in **Attachment 4**.

**2. Communication to the California Healing Art Boards Regarding Naloxone**

The committee discussed reaching to out to California healing arts boards regarding naloxone access, regulation and protocol. This would proactively inform physicians, nurses, physician assistants, and others about naloxone access, the existing protocol and the pharmacist's role in dispensing naloxone.

Executive Officer Virginia Herold reported to the committee she has shared this information with the Medical Board of California, and has talked to the Dental Board and their association. Ms. Herold also spoke on May 20, 2016, about the naloxone protocol at an opioid abuse event sponsored by the Sacramento County Medical Association.

Additionally, the Summer 2016 edition of *The Script* is scheduled to include an article that can be shared with other healing arts boards for their respective newsletters.

The committee discussed the roadblocks to the furnishing and dispensing of naloxone including insurance billing with anonymous patient names, time required for protocol completion and anonymous patient medication records.

The committee also discussed the status of the updated naloxone fact sheet which is under development. Board staff reported the San Francisco Department of Public Health was working in concert with the California Department of Public Health to update the information. The San Francisco Department of Public Health anticipates the updated naloxone fact sheet be available by the end of July 2016.

### **3. Need for Naloxone FAQs**

Chairperson Veale requested the board address insurance and billing questions in the FAQs and requested a draft FAQs for the board to consider at the July 2016 board meeting.

#### Update

Board staff drafted Naloxone FAQs for board consideration with an insurance and billing question. The draft Naloxone FAQs is included in **Attachment 4**.

## **f. Update and Discussion on SB 493 Implementation**

**Attachment 5**

### **1. Immunization Protocol: Sample Administration Records for Immunizations**

In July 2015, the board initiated a formal rulemaking to add Title16 CCR section 1746.4 to specify the requirements for a pharmacist to administer vaccinations. In June 2016 near the end of the rulemaking process, the board modified the protocol to ensure all pharmacist-provided immunizations were subject to a single set of requirements. The 15-day comment period ended on June 25, 2016, and the board adopted the final regulation text at the July 1, 2016, Board Meeting. A copy of the adopted regulation language is provided in **Attachment 5**.

Pursuant to the board-adopted final text, the board is required to maintain on the board's website an example of an appropriate vaccine administration record once the regulation is approved by the Office of Administrative Law.

The committee reviewed multiple samples of immunization records including: The California Immunization Record (yellow card) - California Department of Public Health; The California School Immunization Record - California Department of Public Health; and Immunization and Development Milestones for Your Child from Birth Through 6 Years Old - Centers for Disease Control and Prevention. Copies of the considered records are included in **Attachment 5**.

Staff reviewed the sample immunization record formats and recommended using the California Department of Public Health's yellow card. The yellow card is a widely recognized immunization record used in California and has space to write in immunizations given beyond school age (e.g., HPV, shingles, etc.). Staff felt the other two formats presented limitations.

**Committee Recommendation (Motion):** Recommend that the board post on the board's website The California Immunization Record (yellow card) developed by the California Department of Public Health as the board recommended vaccine record upon approval of pending adoption of regulation 16 CCR 1746.4.

**2. Self-Administered Hormonal Contraception Matters: Documents Available to Memorialize Prescriptions Furnished by a Pharmacist as a Drug Order**

Pursuant to 16 CCR 1746.1 (b)(11), the protocol for pharmacists furnishing self-administered hormonal contraception requires that each hormonal contraception furnished by a pharmacist in accordance with the protocol shall be documented in a patient medication record as required by 16 CCR 1717 and 1707.1. These records are required to be maintained for a period of at least three years from the date of dispense.

The committee reviewed a sample document that records hormonal contraception furnished by a pharmacist along with a copy of a self-screening questionnaire. A copy of the document may be found in **Attachment 5**.

Chairperson Veale recommended that the words "refer patient to" be removed from the second page of the document. Ms. Veale asked the board's counsel review the document and report back to the committee.

**3. Nicotine Replacement Therapy Matters: Discussion of The DCA Page: News from the Department of Consumer Affairs Blog Article – Pharmacists Can Help You Quit Smoking**

*The DCA Page* is the department's blog page. On March 29, 2016, *The DCA Page* featured an article about the nicotine replacement therapy regulation. A copy of the blog is included in **Attachment 5**.

**g. Discussion on the Development of FAQs for SB 493-Related Items**

At the April 2016 Board Meeting, the board requested that the Communication and Public Education Committee coordinate the development of FAQs for SB 493-related items.

The committee determined to hold the discussion at the September 2016 Communication and Public Education Committee meeting.

**h. Update and Discussion on CURES 2.0 and Communication to Licensees**

**Attachment 6**

The committee reviewed and discussed the board's outreach to licensees regarding the requirement for pharmacists to be registered for CURES 2.0 by July 1, 2016.

- In February 2016, the board mailed a reminder postcard to pharmacists to register for CURES 2.0 by July 1, 2016.
- In April 2016, the board issued a subscriber alert announcing a DOJ tip sheet as well as a reminder that all pharmacists with active California licenses need to be registered to access CURES 2.0 by July 1, 2016.

Additionally, the Department of Justice (DOJ) has published on their website publications and training videos to assist in the registration process:

<http://oag.ca.gov/cures/publications> .

Update

At the end of May 2016, the board mailed letters to licensed pharmacists who were not registered in CURES according to DOJ records.

Included in **Attachment 6** are the following documents: DOJ tip sheet, a copy of the DOJ CURES 2.0 Publication and Training Video landing page, the board's subscriber alert, and the board's letter to pharmacists.

**i. Update and Discussion on Resources Available on the Board's Website**

At prior meetings, the committee reviewed multiple items for posting on the board's website as a resource for consumers and licensees during the meeting. The committee directed the board to post on the board's website Drug Diversion Toolkit: Patient Counseling – A Pharmacist's Responsibility to Ensure Compliance by Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain. The committee directed staff to continue to reach out to Consumer Reports for approval to post their article on the board's website. The committee directed board staff to develop a draft policy for posting resources on the board's website and bring back to the committee.

Update

The board's website has been updated to include links for the Drug Diversion Toolkit:

Patient Counseling – A Pharmacist’s Responsibility to Ensure Compliance by CMS and the CDC Guideline for Prescribing Opioids for Chronic Pain at:

[http://www.pharmacy.ca.gov/publications/pubs\\_for\\_licensees.shtml](http://www.pharmacy.ca.gov/publications/pubs_for_licensees.shtml)

Board staff drafted guidelines for posting information to the board’s website for consideration at the September 2016 Communication and Public Education Committee Meeting.

**j. Discussion and Consideration of the United States Access Board’s Recommendations Related to Prescription Labels for Visually-Impaired and Elderly Patients**

**Attachment 7**

As part of the U.S. Food and Drug Administration Safety and Innovation Act signed by President Obama on July 9, 2012, an “Access Board” was authorized to convene a stakeholder working group to develop best practices for making information on prescription drug container labels accessible to people who are blind, visually impaired or who are elderly. Guidelines were developed and are posted on the website where prescription label samples are provided.

A copy of the draft summary and the United States Access Board’s Working Group Recommendations entitled *Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly* is provided in **Attachment 7**.

**k. Proposal to Develop a Consolidated List of Drug Take Back Locations for the Board’s Website**

Dr. Castellblanch reported he found the consolidated website assembled by the DEA for a list of drug take back locations for consumers. The committee directed board staff to work with Dr. Castellblanch on posting the link to the board’s website.

The board’s website has been updated to include this link entitled “DEA Drug Takeback Program” and can be found at the board’s website:

<http://www.pharmacy.ca.gov/consumers/information.shtml>

**l. Discussion on a Possible Regulatory Change to Require the Collection of Pharmacists’ Email Addresses**

**Attachment 8**

At the April 2016 Board Meeting, the board asked the Communication and Public Education Committee to discuss a possible requirement to collect pharmacists email addresses. The committee discussed the options of (1) requiring a pharmacist to maintain an email address with the board and (2) requiring pharmacists to sign up for email notification with the board’s subscriber list.

**Committee Recommendation (Motion):** Recommend that the board pursue a requirement as a condition of license renewal, a pharmacist with an email address shall sign up for the board's email alert system, and self-certify on the renewal form that he or she has met this requirement.

#### Update

Based on the committee's comments and directions, board staff revised the draft language which has been provided below and in **Attachment 8**.

***Draft Proposal to Amend Section 1732.5 of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:***

***§ 1732.5. Renewal Requirements for Pharmacist.***

- (a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.
- (b) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.
- (c) All pharmacists with an email address shall subscribe to the board's email notification system and shall self-certify enrollment to the board in writing at the time of license renewal.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

**m. Update on *The Script* Newsletter**

Board staff continues to work on articles for the Summer 2016 issue of *The Script*.

**n. Update on Media Activity**

The board's Executive Officer (unless otherwise noted) participated in the following media interviews and requests for information.

- **Ventura County Star**, April 13, 2016: Tom Kiskan, Hormonal contraception regulation
- **The Verge**, April 13, 2016: Lindsey Smith, Prescription writing and filling by doctors and pharmacists using smart phone applications
- **HECHO EN CALIFORNIA on KIQI 1010 am/San Francisco & KATD 990 am/Sacramento**, April 15, 2016: Isabel Gutierrez, interview for radio program: Hormonal contraception regulation
- **One Medical Group**, May 6, 2016: Maria Hunt, Hormonal contraception regulation
- **San Jose Mercury News**, May 11, 2016: Tracy Seipel, End of Life Option
- **KQED**, May 13, 2016: Kelly Dunleavy O'Mara, Self-Administered Hormonal

Contraception

- **San Francisco Examiner**, June 16, 2016: Robyn Purchia, pending drug take-back regulations.
- **Redding Searchlight Record**, June 28, 2016: Amber Sandhu, pharmacist training for dispensing self-administered hormonal contraception.

**o. Update on Public Outreach Activities Conducted by the Board**

A list of major public outreach activities provided by the board's staff is listed below:

- April 29-30: Executive Officer Virginia Herold spoke at the CPhA Annual Meeting.
- May 15: Executive Officer Herold provided a CE presentation to 500 individuals on regulation of wholesalers and third-party logistics providers by the states under federal provisions of the federal Drug Quality Security Act at the National Association of Boards of Pharmacy annual meeting in San Diego.
- May 20: Executive Officer Herold provided a presentation on CURES at an annual prescription drug abuse symposium at California State University Sacramento sponsored by the Sacramento Medical Association.
- June 21: Executive Officer Herold provided training to new or newly reappointed board members on board member/executive officer working relationships as part of DCA's required board member orientation training.
- June 28: Executive Officer Herold and Supervising Inspector Michael Ignacio provided a presentation on sterile compounding for the California Hospital Association.
- June 29: Executive Officer Herold provided information on the Board of Pharmacy's role in regulating the profession to UOP second year pharmacy school students.

**p. Review and Discussion of News or Journal Articles**

The committee reviewed the news or journal articles on medication-related topics. The articles are available in the committee packet for the May 2016 Communication and Public Education Committee Meeting.

**q. Future Meeting Dates**

- September 8, 2016
- December 1, 2016

# **Attachment 1**

# **Update on the Communication Plan**

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DEPARTMENT OF CONSUMER AFFAIRS  
BOARD OF PHARMACY

## Patients Can Now Request Translations on the Directions for Use on Certain Prescription Labels

On February 10, 2016, the board released the press release announcing the new 2016 requirement for prescription labels. The press release was translated into Chinese, Korean, Russian, Spanish and Vietnamese. Copies of the translated press releases are available below. The press release was sent to over 800 media outlets including:

- 499 media outlets received the English and translated press releases (below)
- 272 media outlets received the [Spanish translated press release](#)
- 33 media outlets received the [Chinese translated press release](#)
- 17 media outlets received the [Vietnamese translated press release](#)
- 12 media outlets received the [Korean translated press release](#)
- 3 media outlets received the [Russian translated press release](#)

NEWS RELEASE  
February 10, 2016  
CONTACT: Debbie Damoth  
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[Debbie.Damoth@dca.ca.gov](mailto:Debbie.Damoth@dca.ca.gov)

### Translations on Prescription Drug Labels Patients Can Now Request Translations on the Directions for Use on Certain Prescriptions Labels

Being able to read a prescription label is an essential element of being able to understand how to take medication appropriately.

In January 2016 new California requirements for prescription labels took effect that establish a mechanism by which patients with limited English skills may often obtain translated directions on their prescription container labels or as a supplement to the label.

This law was sponsored by the California Board of Pharmacy and authored by Assembly Member Ting as AB 1073.

The law recognizes that many dispensers already provide translations on prescription containers and the enacted legislation allows this practice to continue. This law creates another opportunity for consumers to receive translations. Consumers interested in receiving such translations should request this service from their pharmacy.

In some cases, a translation may not be available for the pharmacy to provide. In such cases, the board strongly encourages consumers to use the free interpreter services available at the pharmacy to ensure they understand how to safely take medications.

Additional information about this new law as well as other changes to pharmacy law can be found on the board's website via the following link - - [http://www.pharmacy.ca.gov/laws\\_regs/new\\_laws.pdf](http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf)

*The California Board of Pharmacy protects and promotes the health and safety of California by pursuing the highest quality of pharmacist care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation and enforcement.*

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## Junta de Farmacias del Estado

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BUSINESS, CONSUMER SERVICES and HOUSING AGENCY  
DEPARTAMENTO DE ASUNTOS DEL CONSUMIDOR  
GOBERNADOR EDMUND G. BROWN JR.

COMUNICADO DE PRENSA  
10 de febrero de 2016

CONTACTO: Debbie Damoth  
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### Traducción de las etiquetas de medicamentos con receta Los pacientes ahora pueden solicitar la traducción de las instrucciones de uso de ciertos medicamentos con receta

Ser capaz de leer la etiqueta del medicamento es fundamental para poder entender cómo tomarlo de manera apropiada.

En enero de 2016 entraron en vigencia en California nuevos requisitos para las etiquetas de medicamentos con receta, los cuales establecen un mecanismo por el cual los pacientes con conocimientos limitados de inglés podrán por lo general obtener las indicaciones traducidas en las etiquetas de los envases de sus medicamentos recetados o como un suplemento a la etiqueta.

Esta ley fue patrocinada por la Junta de Farmacias de California y redactada por el miembro de la asamblea Ting como el proyecto de ley AB 1073.

La ley reconoce que muchos expendedores de medicamentos ya ofrecen traducciones en los envases y la legislación promulgada permite que esta práctica continúe. Esta ley crea una nueva oportunidad para que los consumidores reciban traducciones. Los consumidores que estén interesados en recibir este tipo de traducciones, deben solicitar este servicio a su farmacia.

En algunos casos, puede que la farmacia no cuente con una traducción disponible para proporcionarle. En tales casos, la junta recomienda encarecidamente a los consumidores que utilicen los servicios de interpretación gratuitos disponibles en la farmacia con el fin de garantizar que entiendan cómo tomar los medicamentos de forma segura.

Se puede encontrar más información acerca de esta nueva ley, así como de otros cambios en la ley de farmacias, en la página web de la junta a través del siguiente enlace:  
[http://www.pharmacy.ca.gov/laws\\_regs/new\\_laws.pdf](http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf)

*La Junta de Farmacias de California protege y promueve la salud y seguridad de California, buscando la más alta calidad de atención farmacéutica y el uso adecuado de los productos farmacéuticos a través de la educación, comunicación, concesión de licencias, legislación, regulación y aplicación de las normas.*

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EDMUND G. BROWN JR. 州長

新聞稿

二零一六年二月三日

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### 處方藥標籤翻譯

患者即起可要求特定處方藥標籤中的使用說明翻譯

擁有閱讀處方藥標籤的能力是了解正確用藥方式的重要一環。

加州對處方藥標籤的新要求於二零一六年一月正式生效，其建立一個讓具備有限英語能力的患者可以在一般情況下從處方藥罐標籤中，或是在藥罐標籤外的補充信息中獲得使用說明翻譯的機制。

此法案由加州藥劑局(California Board of Pharmacy)贊助，並由丁議員以 AB 1073 法案為名提出。

目前法律認知許多藥劑師已經在處方藥罐上提供翻譯，而此法案的設定讓藥劑師們能夠繼續提供此服務。此法案為消費者提供獲取翻譯的機會。任何有意獲取翻譯的消費者皆可向藥局提出要求。

在某些情況下，藥局可能無法提供特定藥物的標籤翻譯。若遇到此情況，加州藥劑局強烈建議消費者善加利用藥局提供的免費翻譯服務以確保消費者對正確用藥的了解。

關於此法案的額外訊息及其它藥劑法的修改皆可於加州藥劑局的網站上找到，以下為連結  
-- [http://www.pharmacy.ca.gov/laws\\_regs/new\\_laws.pdf](http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf)

加州藥劑局透過追求最高品質的藥劑師服務以及通過教育、溝通、授權、立法、條例和法規執行以確保正確用藥的方式，保護及推廣加州的健康與安全。

###



## Hội đồng Dược Tiểu bang California

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[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

CƠ QUAN KINH DOANH, CHĂM SÓC KHÁCH HÀNG và NHÀ Ở

PHÒNG DỊCH VỤ KHÁCH HÀNG

THỐNG ĐỐC EDMUND G. BROWN JR.

### THÔNG CÁO BÁO CHÍ

10 Tháng Hai, 2016

LIÊN HỆ: Debbie Damoth

(916) 574-7935

[Debbie.Damoth@dca.ca.gov](mailto:Debbie.Damoth@dca.ca.gov)

### Dịch Thuật Nhãn Thuốc Theo Toa Bệnh Nhân Giờ Đây Có Thể Yêu Cầu Bản Dịch Hướng Dẫn Sử Dụng Trên Nhãn Thuốc Theo Toa Nhất Định

Có khả năng đọc nhãn thuốc theo toa là một yếu tố cần thiết để có thể biết cách sử dụng thuốc thích hợp.

Trong tháng 1 năm 2016, các điều luật mới có hiệu lực tại California đối với nhãn thuốc theo toa giúp thiết lập cơ chế mà theo đó bệnh nhân với kỹ năng tiếng Anh hạn chế thường có thể được cung cấp các hướng dẫn đã được dịch trên nhãn thuốc theo toa hoặc như một bổ sung trên nhãn.

Luật này được bảo trợ bởi Hội đồng Dược California và do Thành viên Hội đồng Ting soạn thảo với tên gọi AB 1073.

Luật này nhận thấy nhiều hãng bào chế đã cung cấp bản dịch trên vỏ hộp thuốc theo toa và luật ban hành cho phép việc thực hành này được tiếp tục. Luật này cũng tạo cơ hội khác để người tiêu dùng nhận được bản dịch. Người tiêu dùng quan tâm đến việc được cung cấp bản dịch nên yêu cầu dịch vụ này từ hiệu thuốc của mình.

Trong một số trường hợp, một bản dịch có thể không có sẵn để hiệu thuốc cung cấp. Trong những trường hợp như vậy, hội đồng mạnh mẽ khuyến khích người tiêu dùng sử dụng các dịch vụ thông dịch miễn phí có sẵn tại hiệu thuốc để đảm bảo hiểu rõ cách dùng thuốc an toàn.

Thông tin thêm về điều luật mới này cũng như các thay đổi khác về luật dược có thể được tìm thấy trên trang web của hội đồng thông qua liên kết sau đây - -  
[http://www.pharmacy.ca.gov/laws\\_regs/new\\_laws.pdf](http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf)

*Hội đồng Dược California bảo vệ và thúc đẩy sức khỏe và sự an toàn của California bằng cách theo đuổi chất lượng cao nhất về sự chăm sóc của dược sĩ và việc sử dụng dược phẩm thích hợp thông qua giáo dục, truyền thông, cấp phép, pháp luật, quy định và thực thi.*

###



## 캘리포니아 약사위원회

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팩스: (916) 574-8618

www.pharmacy.ca.gov

산업, 소비자 서비스 및 주택청

소비자부

GOVERNOR EDMUND G. BROWN JR.

보도 자료

2016 년 2 월 3 일

연락처: Debbie Damoth

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### 처방약 라벨에 대한 번역

지금부터 환자들은 특정 처방약 라벨에 있는 복용법에 대한 번역을 요청하실 수 있습니다.

처방약 라벨을 읽을 수 있다는 것은 약을 적절하게 복용하는 법을 이해하기 위한 필수적인 요소입니다.

2016 년 1 월에, 영어를 미숙하게 이해하는 환자들이 처방약 용기 라벨이나 라벨에 추가된 부록을 통해 번역된 복용법을 자주 제공받을 수 있는 메커니즘을 수립시키는 새로운 캘리포니아 처방약 라벨 요건이 발효되었습니다.

이 법률은 캘리포니아 약사위원회의 후원을 받았으며 국회의원 텅에 의해 AB 1073 법안으로 발의되었습니다.

이 법률은 이미 많은 제약 공급자들이 처방약 용기에 번역을 제공하고 있다는 점을 인지하고 법률을 제정함으로써 이러한 관행을 유지해가고자 합니다. 이러한 법률은 소비자들이 번역을 제공받을 수 있는 새로운 기회를 창출합니다. 이러한 번역을 제공받고 싶으신 소비자는 해당 약국에 이러한 서비스를 요청하셔야 합니다.

어떤 경우 약국에서 번역을 제공하는 것이 가능하지 않을 수도 있습니다. 이러한 경우, 위원회에서는 약을 안전하게 복용하는 법을 확실히 이해할 수 있도록 해당 약국에서 제공하는 무료 통역 서비스를 이용하시기를 소비자께 강력히 권고드립니다.

약사법 개정안과 더불어 이 새로운 법률에 대한 추가적인 정보를 원하시면 다음 링크를 통해서 위원회의 웹사이트에서 찾아보실 수 있습니다- [http://www.pharmacy.ca.gov/laws\\_regs/new\\_laws.pdf](http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf)

*캘리포니아 약사위원회는 고품질의 약사 서비스와 교육, 커뮤니케이션, 인허가, 법률의 제정, 규제와 집행을 통한 제약의 적절한 사용을 추구함으로써 캘리포니아의 건강과 안전을 보호하고 촉진하고 있습니다.*

###



## Фармацевтическое управление

### штата Калифорния

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Факс: (916) 574-8618  
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АГЕНТСТВО ПО ВЕДЕНИЮ БИЗНЕСА, ОБСЛУЖИВАНИЮ ПОТРЕБИТЕЛЕЙ И НЕДВИЖИМОСТИ

УПРАВЛЕНИЕ ПО ДЕЛАМ ПОТРЕБИТЕЛЕЙ  
УПРАВЛЯЮЩИЙ ЭДМУНД Г. БРАУН МЛ.

ПРЕСС-РЕЛИЗ  
от 10 февраля 2016 года

КОНТАКТНОЕ ЛИЦО: Дебби Дамос  
(916) 574-7935  
Debbie.Damoth@dca.ca.gov

Перевод инструкций по применению лекарственных препаратов, отпускаемых по рецепту  
Теперь пациенты могут запросить перевод инструкций по применению определенных лекарственных  
средств рецептурного отпуска

Умение правильно прочесть инструкцию к лекарственному препарату – это залог верного  
понимания способа его применения.

В январе 2016 года вступили в силу новые требования штата Калифорния в отношении инструкций  
к лекарственным препаратам рецептурного отпуска. Согласно указанным требованиям, пациенты,  
не владеющие английским языком, могут получить перевод инструкции к лекарственному  
средству прямо на его упаковке или в качестве приложения к нему.

Автором Закона под номером АВ 1073 стал Член Ассамблеи Фил Тинг при поддержке  
Фармацевтического управления штата Калифорния.

Закон признает тот факт, что многие фармацевты уже предлагают своим клиентам оригинальные  
упаковки с переводом инструкций, а введенный в действие Закон позволяет и в дальнейшем  
поддерживать эту практику. Этот Закон дает потребителю еще одну возможность получить  
перевод. Он может попросить перевод лекарственного средства в своей аптеке.

В некоторых случаях аптека не может предоставить клиенту готовый перевод. В данной ситуации  
Управление настоятельно рекомендует воспользоваться бесплатными услугами перевода,  
предоставляемыми аптекой, для правильного и безопасного приема лекарственного препарата.

Более подробно о новом Законе, а также законодательных изменениях в фармацевтической  
области, можно прочитать на сайте Управления по адресу:  
[http://www.pharmacy.ca.gov/laws\\_regs/new\\_laws.pdf](http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf)

*Фармацевтическое управление штата Калифорния обеспечивает здоровье и безопасность  
жителей Калифорнии благодаря использованию высоких стандартов качества в  
фармацевтической области. Для осведомленности населения о надлежащем использовании  
лекарственных препаратов используются образовательные программы, информационные  
материалы, лицензии, законодательная база, различные методы регулирования и контроля  
соблюдения.*

###



## ➔ Department of Consumer Affairs Search Results

About 397 results (0.28 seconds)

### [Patient-Centered Labels Information, Translations, and Sample Labels](#)

Patient-Centered **Labels** Information, **Translations**, and Sample **Labels** ... the new **labels** on **prescription medication** containers you received from pharmacies?

[www.pharmacy.ca.gov/publications/labels\\_info.shtml](http://www.pharmacy.ca.gov/publications/labels_info.shtml)

### [Patients Can Now Request Translations on the Directions for Use on ...](#)

Feb 10, 2016 ... The press release was **translated** into Chinese, Korean, Russian, Spanish and Vietnamese. Copies ... **Translations** on **Prescription Drug Labels**

[www.pharmacy.ca.gov/publications/label\\_press\\_release.shtml](http://www.pharmacy.ca.gov/publications/label_press_release.shtml)

### [Translations of Pill Directions](#)

**Translations** of Pill Directions. Press Release Announcing the New 2016 Requirement for **Prescription Labels**. Disclaimer. The California Endowment, in an ...

[www.pharmacy.ca.gov/publications/translations.shtml](http://www.pharmacy.ca.gov/publications/translations.shtml)



### [Meeting Materials](#)

File Format: PDF/Adobe Acrobat

Jan 13, 2015 ... Translation of Labels and the Use of Translated Directions Available ... proposal to require on a **prescription label translated** "directions for use".

[www.pharmacy.ca.gov/meetings/agendas/.../15\\_jan\\_pub\\_mat.pdf](http://www.pharmacy.ca.gov/meetings/agendas/.../15_jan_pub_mat.pdf)



## California Department of Consumer Affairs

February 11 · 🌐

Patients can now request translations in five languages on the directions for use on certain prescription labels. The request can be made for Spanish, Russian, Chinese, Korean and Vietnamese. Check out the Board of Pharmacy's latest news releases here:



 **DCA**  
@DCAnews

 Follow

Patients can now request translations in five languages on the directions for use on certain prescription labels.

[pharmacy.ca.gov/publications/l...](http://pharmacy.ca.gov/publications/l...)

RETWEETS

2



3:20 PM - 11 Feb 2016



# Translation on Prescription Drug Labels

## AB 1073 (Ting), Chapter 784, Statutes of 2015



Being able to read a prescription label is an essential element of being able to understand how to take medication appropriately.

In January 2016 new California requirements for prescription labels took effect that establish a mechanism by which patients with limited English skills may often obtain translated directions on their prescription container labels or as a supplement to the label.

This law was authored by Assembly Member Ting as AB 1073, and amends Business and Professions Code sections 4076 and 4199, and creates new section 4076.6. The text of the new requirements can be viewed from this link:

[http://www.pharmacy.ca.gov/publications/labels\\_info.shtml](http://www.pharmacy.ca.gov/publications/labels_info.shtml)

The law recognizes that many dispensers already provide translations on prescription containers. The enacted legislation allows this practice to continue.

The requirements of the new law implement the following key components:

1. A pharmacist must use professional judgment when selecting the wording of directions that appear on a prescription container label in any language.

The specific requirement is:

4076(e) A pharmacist shall use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions, consistent with the prescriber's instructions. (Business and Professions Code section 4076(e))

2. A dispenser must provide translated directions for use on a prescription container when requested by the patient or a patient's representative, provided:
  - a) The dispenser believes that a standardized direction for use (as listed in the board's patient-centered regulation) is appropriate for the patient's prescribed medication (this list also appears on page 5 of this newsletter). If so the board has translated the 15 standardized directions for use into five languages -- Spanish, Vietnamese, Korean, Russian and Chinese. These translation are available from: <http://www.pharmacy.ca.gov/publications/translations.shtml>

Translations into additional languages or translations of additional directions are not required.

- b) The dispenser may provide his/her/its own translations in place of the translations available from the board,

And

- c) The dispenser is responsible for the accuracy of the **English** directions provided to the patient.

3. The translated direction should, whenever possible, appear in the patient-centered area of the prescription container or label. When this occurs the English version should appear, whenever possible, on the prescription container or label in or outside the patient-centered area. When the English translation cannot be printed on the prescription container or label, the English translation may be provided on a supplemental sheet.

A translated direction may be provided on a supplemental sheet when it cannot be added to the prescription container or label. In this case, the label shall contain the English version of the direction. (Per existing law, such direction should be in the patient centered portion of the container or label.)

*See Translation on Rx Label Page 5*

## Translation on Rx Label

Continued from Page 4

### Where can I find the translated directions for use?

Pharmacies may use translated directions for use that are available on the board's website when appropriate. The translations of certain standardized directions for use are found in Board regulation 1707.5(a)(1) and are available in multiple languages on the Board's website at <http://www.pharmacy.ca.gov/publications/translations.shtml>. The English version of the standardized directions are:

- (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
- (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

# **Attachment 2**

**Proposed Draft  
Regulation Language  
for Consideration**

***Draft Proposal to Amend Section 1707.6 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:***

**§ 1707.6. Notice to Consumers.**

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

(b) The notice shall contain the following text:

**NOTICE TO CONSUMERS**

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

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

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

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

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

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

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

“Point to your language. Interpreter services will be provided to you upon request at no cost. Ask the pharmacist what translations may be available for prescription labels.” This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, ~~Cantonese~~, Farsi, Hmong, ~~Korean~~, ~~Mandarin~~, Russian, Spanish, and Tagalog, ~~and~~ Vietnamese.

“Point to your language. Interpreter services will be provided to you upon request at no cost. Ask the pharmacist what translations are available for prescription labels.” This text shall be repeated in at least the following languages: Chinese, Korean, Russian, Spanish, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

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

Note: Authority cited: Sections 4005, 4076.6 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5, 4076.6 and 4122, Business and Professions Code.

# **Attachment 3**

## Frequently Asked Questions

As part of its licensee education efforts, the board restored a service whereby a board inspector and board staff are available to respond to verbal and written inquiries from the board and board licensees. To ensure that all licensees receive the benefits of service, the board has developed these FAQs.

It is important to note that the questions and answers below are not intended, nor should they be construed as legal advice. The answers provided are intended to provide guidance to the reader on relevant legal sections that should be considered when using professional judgement in determining the appropriate course of action. Should you require legal advice or detailed research, you will need to contact an attorney or another source.

**Question:** Does a pharmacist have to perform a final verification by physically inspecting the patient's medication if was filled by a pharmacy technician or an intern?

**Answer:** There are a few sections of law that address this question and the answer varies based on various factors: Relevant legal references include:

1. Section 1726 of Title 16 of the California Code of Regulations states a pharmacist supervising an intern be responsible for all professional activities performed by the intern under his or her supervision, including the correct dispensing of a prescription.
2. Section 1793.7 of Title 16 of the California Code of Regulations states any function performed by a pharmacy technician in connection with dispensing of a prescription, including repackaging from bulk, must be verified and documented in writing by a pharmacist.

**Question:** What is the pharmacist to intern ratio?

**Answer:** Business and Professions Code Section 4114(b) provides that a pharmacist may not supervise more than two interns at one time.

**Question:** What is the pharmacist to pharmacy technician ratio in a community pharmacy?

**Answer:** Business and Professions Code Section 4115(f)(1) specifies that a pharmacy with only one pharmacist shall have no more than one pharmacy technician performing pharmacy technician functions. The ratio of pharmacy technicians increases for each additional pharmacist to a ratio not to exceed 2 technicians:1 pharmacist for pharmacy technicians performing duties specified as pharmacy technician duties.

**Question:** How do I identify the dates of the renewal period within which I must earn 30 units of continuing education (CE) to renew my pharmacist license?

**Answer:** The expiration date of a pharmacist's license occurs every two years generally in the birth month of the pharmacist. To calculate the renewal period: the renewal period ends on the expiration

date of the license (which would fall on the last day of the birth month). The next renewal period begins the next day, or the first of the next month.

**Example:** A pharmacist's license expires October 31, 2017. The current renewal period runs November 1, 2015 through October 31, 2017, within which the pharmacist must have earned 30 units of CE to renew the license in an active status. The next renewal period will be November 1, 2017 through October 31, 2019. Please note that California law requires pharmacists to keep CE certificates for four years.

**Question:** Is it possible to purchase pen needles over-the-counter in California?

**Answer:** Business and Professions Code Section 4145.5(a) provides the authority for a pharmacist or physician to furnish hypodermic needles and syringes for human use, without a prescription or permit, with the following restrictions:

- The person is known to the furnisher and the furnisher has previously been provided with a prescription or other proof of legitimate medication need requiring a hypodermic needle or syringe to administer a medicine or treatment.

**Question:** Who is responsible for notifying the consumer of a recalled prescription drug?

**Answer:** The recall process from an FDA-approved drug is voluntary by the manufacturer, unless the FDA issues a mandatory recall to the manufacturer. The most serious recalls, where the drug product is being recalled from the pharmacy or patient, often are released through the media. The FDA does not mandate that the pharmacy contact the patient. However, California Code of Regulations Section, 1735.5(c)(2) specifies that if a drug has been compounded by an out-of-state pharmacy doing business in California, the pharmacy must have policies and procedures in place for handling recalled compounded drugs.

**Question:** Can a Schedule II controlled substance be refilled?

**Answer:** Health & Safety Code Section 11200 (c) prohibits the refilling of a Schedule II controlled substance.

**Question:** How long is a controlled substance prescription good for?

**Answer:** Health & Safety Code Section 11200 (a) specifies that no person shall dispense or refill a controlled substance more than six months (180 days) after the date written.

**Question:** How many times can a Schedule III or IV controlled substance be filled?

**Answer:** Health & Safety Code Section 11200 (b) specifies that no prescription for a Schedule III or Schedule IV controlled substance may be refilled more than five times. Further, this section also creates a limit of 120-day total supply of refills for a Schedule III or Schedule IV controlled substance prescription.

**Question:** Where is the law that establishes the requirement for a pharmacist to exercise corresponding responsibility?

**Answer:** Health & Safety Code Section 11153 (a) provides that the responsibility for the proper prescribing and dispensing of controlled substances is upon both the prescribing practitioner AND a corresponding responsibility rests with the pharmacist who fills the prescription.

NOTE: Additional information about corresponding responsibility can be found using the following link - - [http://www.pharmacy.ca.gov/publications/corresponding\\_responsibility.pdf](http://www.pharmacy.ca.gov/publications/corresponding_responsibility.pdf)

**Question:** Am I required to apply for registration to the CURES system?

**Answer:** Health & Safety Code Section 11165.1 (a)(1)(A)(ii) requires a pharmacist, on or before July 1, 2016, or upon licensure, to submit an application to the Department of Justice to obtain approval to access the CURES system.

**Question:** How often does a pharmacy need to report controlled substances dispensing information to CURES?

**Answer:** Health & Safety Code Section 11165 (d) specifies that a dispensing pharmacy must report information to the Department of Justice as soon as reasonably possible, but not longer than seven days after the controlled substance is dispensed.

# **Attachment 4**

**Sample  
Naloxone  
Labels**

Sample Naloxone Labels

[http://www.pharmacy.ca.gov/licenses/naloxone\\_info.shtml](http://www.pharmacy.ca.gov/licenses/naloxone_info.shtml)

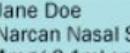
 1625 N. Market Blvd. Sacramento, CA 95834 (555) 555-9810	Provider: Roger Brown RPH <b>Single Dose Vial</b> Quantity: 2 Vials
	Expires: 04/01/2016 Rx# 06197 1234567 DATE FILLED: 04/01/2015 ORIG RX DATE: 04/01/2015 RPH: RB Store DEAR# 875555555
<b>RECIPIENT</b> Naloxone, Injection 0.4mg/1mL, Single Dose Vial Manufacturer: Hospira Call 911. Inject 1mL into upper arm or thigh muscle for opioid overdose. May repeat after 3 minutes if patient not breathing.	
Judith Johnson 5673 EVERGREEN AVE DAVIS, CA 95615 (555) 555-7889	

 1625 N. Market Blvd. Sacramento, CA 95834 (555) 555-9810	Provider: Roger Brown RPH <b>Syringe</b> Quantity: 2 Syringes
	Expires: 04/01/2016 Rx# 06198 1234567 DATE FILLED: 04/01/2015 ORIG RX DATE: 04/01/2015 RPH: RB Store DEAR# 875555555
<b>RECIPIENT</b> 3mL syringe with 25G x 1" needle Manufacturer: BD Call 911. Use to withdraw naloxone from vial and inject 1mL into upper arm or thigh muscle for opioid overdose. Use a new syringe for each dose.	
Judith Johnson 5673 EVERGREEN AVE DAVIS, CA 95615 (555) 555-7889	

John Doe Naloxone, Intranasal 1mg/1mL, 2mL Needleless Syringe Manufacturer: Amphastar Call 911. Attach white cone. Spray ½ of syringe (1mL) into each nostril for opioid overdose. May repeat in 3 minutes if patient not breathing.	Rx# 06197 1234567 DATE FILLED: 04/01/2015 ORIG RX DATE: 04/01/2015 RPH: RB Store DEAR# 875555555
	Alan Smith 73 Main St. Sacramento, CA 95835 (555) 555-4789
Provider: Roger Brown RPH Quantity: 2 Syringes <b>Prefilled Needleless Syringe</b> Expires: 04/01/2016	
 1625 N. Market Blvd. Sacramento, CA 95834 (555) 555-9810	

John Doe Mucosal Atomization Device (MAD) Manufacturer: LMA Call 911. Screw onto naloxone needleless syringe to administer drug into nose. Then insert white cone into nostril. Spray ½ of syringe (1mL) into each nostril.	Rx# 06198 1234567 DATE FILLED: 04/01/2015 ORIG RX DATE: 04/01/2015 RPH: RB Store DEAR# 875555555
	Alan Smith 73 Main St. Sacramento, CA 95835 (555) 555-4789
Provider: Roger Brown RPH Quantity: 2 MAD <b>Mucosal Atomization Device</b> Expires: 04/01/2016	
 1625 N. Market Blvd. Sacramento, CA 95834 (555) 555-9810	

 1625 N. Market Blvd. Sacramento, CA 95834 (555) 555-9810	<b>RECIPIENT</b> Evzio 0.4mg/0.4mL, 2 auto-injectors Manufacturer: Kaleo Call 911. For opioid overdose, remove cover and red cap. Press black end firmly against outer thigh to inject. May repeat in 3 minutes if patient is not breathing.
	Rx# 06197 1234567 DATE FILLED: 04/01/2015 ORIG RX DATE: 04/01/2015 RPH: RB Store DEAR# 875555555
Provider: Roger Brown RPH Quantity: 2 auto-injectors <b>Auto-Injector</b> Expires: 04/01/2016	
SARALATHA GONZALEZ 4206 ELPI STREET BLK GROVE, CA 95728 (352) 555-1234	

 1625 N. Market Blvd. Sacramento, CA 95834 (555) 555-9810	Rx# 06198 1234567 DATE FILLED: 04/01/2015 ORIG RX DATE: 04/01/2015 RPH: RB Store DEAR# 875555555
	Denise Camp 73 Main St. Sacramento, CA 95835 (555) 555-4789
<b>RECIPIENT</b> Narcan Nasal Spray 4mg/ 0.1ml sprayer Manufacturer: Adapt Pharma Call 911. Administer a single spray intranasally into one nostril for opioid overdose. May repeat in 3 minutes if patient is not breathing.	
Provider: Roger Brown RPH Quantity: 2 Nasal Sprays <b>Prefilled Nasal Spray</b> Expires: 04/01/2016	
 1625 N. Market Blvd. Sacramento, CA 95834 (555) 555-9810	

**Sample  
Naloxone  
FAQs**

## ***FAQ for Naloxone Protocol***

**Q: What is an opioid?**

A: An opioid means naturally derived opiates as well as synthetic and semi-synthetic opioids.

**Q: Who is the recipient?**

A: A recipient is the person to whom the naloxone is furnished.

**Q: Who is the patient?**

A: If the recipient is the person to whom the naloxone would be administered, the naloxone recipient is the patient for purposes of this protocol and notification may be required under the protocol.

**Q: What training or continuing education (CE) is required prior to furnishing naloxone?**

A: Pharmacists using the protocol have two options to meet the required training/CE prior to administering naloxone:

1. The pharmacist must have successfully completed a minimum of one hour of an approved CE program specific to all routes of naloxone administration as identified in 16 CCR 1746.3 (c)(4); or,
2. The pharmacist must have successfully completed an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

**Q: Is the pharmacist required to screen the recipient prior to furnishing naloxone in accordance with the protocol?**

A: Yes. The pharmacist must screen the recipient using the following questions:

1. Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question 2.);
2. Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacists may continue);
3. Whether the person to whom the naloxone would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)

**Q: Are screening questions available in different translations? Where can I get the translated versions?**

A: Yes, the screening questions are available translated into Spanish, Traditional Chinese, Korean, Russian, Tagalog, and Vietnamese. The translated screening questions may be downloaded from the board's website: [http://www.pharmacy.ca.gov/licensing/naloxone\\_info.shtml](http://www.pharmacy.ca.gov/licensing/naloxone_info.shtml)

**Q: Is the pharmacist required to provide the recipient with information and training? If so, what type of information and training is required?**

A: Yes, the pharmacist is required to provide the recipient with training. Training must include the following topics: opioid overdose prevention, recognition, response and administration of the antidote naloxone.

**Q: What is required to be provided to the recipient when naloxone is furnished?**

A: When a pharmacist provides naloxone to a recipient, the following must be provided to the recipient:

1. The pharmacist shall provide the recipient with appropriate counseling and information on the furnished naloxone including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.
2. The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at the time of furnishing naloxone.
3. The pharmacist shall answer any questions the recipient may have about naloxone.

**Q: When the pharmacist provides patient consultation to the recipient of the naloxone, is the recipient allowed to waive the patient consultation?**

A: No. The recipient is not allowed to waive the patient consultation for naloxone.

**Q: When a pharmacist is advising the recipient on the route of administration for naloxone, what information should be considered by the pharmacist?**

A: The pharmacist should consider the following information when advising a recipient on the route of administration for naloxone:

1. Formulation available;
2. How likely the particular route of administration can be administered;
3. The setting;
4. Local context.

**Q: What forms of naloxone may the pharmacist provide to the recipient?**

A: The pharmacist may supply naloxone in the following forms:

1. Intramuscular injection;
2. Intranasal spray;
3. Auto-injector; or
4. Any FDA-approved product form.

**Q: Are there special requirements for naloxone prescription labels?**

A: The pharmacist shall label the naloxone in accordance with law and regulations. Labels should include the expiration date for the naloxone furnished.

**Q: Does the board have sample naloxone labels available?**

A: Yes. The board's sample naloxone labels can be found at:

[http://www.pharmacy.ca.gov/licensing/naloxone\\_labels.shtml](http://www.pharmacy.ca.gov/licensing/naloxone_labels.shtml)

**Q: Is the pharmacist required to provide the naloxone fact sheet upon furnishing naloxone?**

A: Yes, the pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the board. It can be found at: [http://www.pharmacy.ca.gov/licensing/naloxone\\_info.shtml](http://www.pharmacy.ca.gov/licensing/naloxone_info.shtml)

**Q: Is the board approved naloxone fact sheet available in different translations?**

A: Yes, the board approved naloxone fact sheet is available translated into Spanish, Traditional Chinese, Korean, Russian, Tagalog, and Vietnamese. They can be found at:

[http://www.pharmacy.ca.gov/licensing/naloxone\\_info.shtml](http://www.pharmacy.ca.gov/licensing/naloxone_info.shtml)

**Q: Is the pharmacist required to give notification if the patient gives verbal or written consent they were furnished naloxone?**

A: If the recipient is also the patient, the pharmacist is required to notify a patient's primary care provider (PCP) of any drug(s) and/or device(s) furnished or enter appropriate information in a patient record system share with the PCP as allowed by the patient and PCP.

**Q: Is the pharmacist required to give notification if the patient does not have a PCP or chooses not to give notification consent?**

A: If the recipient is also the patient, the pharmacist is required to provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult a health care provider of the patient's choice.

**Q: How long is documentation of furnishing naloxone required?**

A: Documentation of each naloxone product furnished by a pharmacist pursuant to this protocol is required to be documented in the naloxone recipient's medication record and stored for at least three years from date of dispensing.

**Q: Is patient privacy required for naloxone furnished to recipients/patients?**

A: Yes, patient privacy is required for naloxone furnished to recipients/patients in accordance with the pharmacy or health care facility's policies and procedures.

**Q: Can insurance be billed for naloxone furnished to a recipient on behalf of a patient?**

A: Check with the appropriate insurance for their billing procedures on naloxone.

# **Attachment 5**

# **Immunization Protocol**

## BOARD OF PHARMACY

### Order of Adoption

**Add and Adopt** §1746.4, which is new regulation text as follows:

#### **§1746.4 Pharmacists Initiating and Administering Vaccines.**

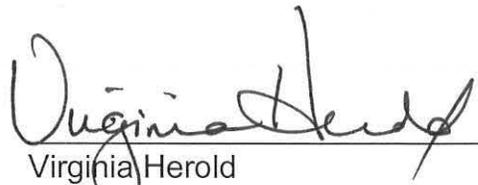
- (a) A pharmacist initiating and/or administering vaccines pursuant to sections 4052 or 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.
- (b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:
  - (1) Completion of an approved immunization training program, and
  - (2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

- (c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.
- (d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. If known, notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.
- (e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 14 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.
- (f) Documentation: For each vaccine administered by a pharmacist, a patient vaccine administration record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a

vaccine administration record, which fully documents the vaccines administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code, Section 120440, Health and Safety Code, and Sections 300aa – 25, Title 42, United States Code.



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Virginia Herold  
Executive Officer  
California State Board of Pharmacy

**Sample  
Administration  
Records for  
Immunizations**



# CALIFORNIA SCHOOL IMMUNIZATION RECORD

This record is part of the student's permanent record (cumulative folder) as defined in Section 49068 of the Education Code and shall transfer with that record. Local health departments shall have access to this record in schools, child care facilities, and family day care homes.

This record must be completed by school and child care personnel from an immunization record provided by parent or guardian. See reverse side for instructions.



Student Name \_\_\_\_\_ Birthdate \_\_\_\_\_ Place of Birth \_\_\_\_\_  
 Sex:  M  F  
 Race/Ethnicity:  
 White, not Hispanic  
 Hispanic  
 Black  
 Other:  
 Address \_\_\_\_\_ City \_\_\_\_\_ ZIP \_\_\_\_\_  
 Daytime \_\_\_\_\_ Nighttime \_\_\_\_\_

VACCINE	DATE EACH DOSE WAS GIVEN					
	1st	2nd	3rd	4th	5th	Booster
POLIO (OPV or IPV)						
DTP/DTaP/DT/Td (Diphtheria, tetanus and [acellular] pertussis OR tetanus and diphtheria only)						
MMR (Measles, mumps, and rubella)						
HIB (Required only for child care and preschool)						
HEPATITIS B						
VARICELLA (Chickenpox)						
HEPATITIS A (Not required)						

**I. DOCUMENTATION**  
 I certify that I reviewed a record of this child's immunizations and transcribed it accurately:  
 Date \_\_\_\_\_  
 Staff Signature \_\_\_\_\_

Record Presented was:  
 Yellow California Immunization Record  
 Out-of-state school record  
 Other immunization record  
 Specify: \_\_\_\_\_

**II. STATUS OF REQUIREMENTS**  
 A. All Requirements are met.  
 Date \_\_\_\_\_  
 B. Currently up-to-date, but more doses are due later. Needs follow-up.  
 Exemption was granted for:  
 C. Medical Reasons—Permanent  
 D. Medical Reasons—Temporary  
 E. Personal Beliefs

**III. 7th GRADE ENTRY**  
 A. All Requirements are met. Name \_\_\_\_\_ Date \_\_\_\_\_  
 B. Currently up-to-date, but more doses are due later. Needs follow-up. Name \_\_\_\_\_ Date \_\_\_\_\_

TB SKIN TESTS	Type*	Date given	Date read	mm indur	Impression	CHEST X-RAY (Necessary if skin test positive)	
						Impression	Film date:
	<input type="checkbox"/> PPD-Mantoux <input type="checkbox"/> Other				<input type="checkbox"/> Pos <input type="checkbox"/> Neg	<input type="checkbox"/> normal <input type="checkbox"/> abnormal	Person is free of communicable tuberculosis: <input type="checkbox"/> yes <input type="checkbox"/> no
	<input type="checkbox"/> PPD-Mantoux <input type="checkbox"/> Other				<input type="checkbox"/> Pos <input type="checkbox"/> Neg		

# Immunizations and Developmental Milestones for Your Child from Birth Through 6 Years Old

continues on back page

Child's Name \_\_\_\_\_ Birth Date \_\_\_\_\_

	1 MONTH	2 MONTHS	4 MONTHS	6 MONTHS
<b>Recommended Immunizations</b>	<input type="radio"/> HepB <sup>1</sup>	<input type="radio"/> RV <input type="radio"/> DTaP <input type="radio"/> Hib <input type="radio"/> PCV <input type="radio"/> IPV	<input type="radio"/> RV <input type="radio"/> DTaP <input type="radio"/> Hib <input type="radio"/> PCV <input type="radio"/> IPV	<input type="radio"/> HepB <input type="radio"/> RV <input type="radio"/> DTaP <input type="radio"/> Hib <input type="radio"/> PCV <input type="radio"/> IPV
<b>Milestones*</b>	<input type="radio"/> Starts to smile <input type="radio"/> Raises head when on tummy <input type="radio"/> Calms down when rocked, cradled or sung to <input type="radio"/> Recognizes caregiver's voice <input type="radio"/> Turns head toward breast or bottle <input type="radio"/> Communicates through body language, fussing or crying	<input type="radio"/> Begins to smile at people <input type="radio"/> Coos, makes gurgling sounds <input type="radio"/> Begins to follow things with eyes <input type="radio"/> Can hold head up	<input type="radio"/> Babbles with expression <input type="radio"/> Likes to play with people <input type="radio"/> Reaches for toy with one hand <input type="radio"/> Brings hands to mouth	<input type="radio"/> Knows familiar faces <input type="radio"/> Responds to own name <input type="radio"/> Brings things to mouth <input type="radio"/> Rolls over in both directions
<b>Growth</b>	WEIGHT / PERCENTILE _____ LENGTH / PERCENTILE _____ HEAD CIRCUMFERENCE _____	WEIGHT / PERCENTILE _____ LENGTH / PERCENTILE _____ HEAD CIRCUMFERENCE _____	WEIGHT / PERCENTILE _____ LENGTH / PERCENTILE _____ HEAD CIRCUMFERENCE _____	WEIGHT / PERCENTILE _____ LENGTH / PERCENTILE _____ HEAD CIRCUMFERENCE _____

Shaded boxes indicate the vaccine can be given during shown age range.

VISIT DATE \_\_\_\_\_

<sup>1</sup> The second dose of HepB may be given either at the 1 month or 2 month visit.  
<sup>2</sup> Two doses given at least four weeks apart are recommended for children aged 6 months through 8 years of age who are getting a flu vaccine for the first time and for some other children in this age group.  
 \* Milestones adapted from *Caring for your baby and young child*, Birth to age 5, Fifth Edition, edited by Steven Sholov and Tanya Kemner Altman © 1991, 1993, 1998, 2004, 2009 by the American Academy of Pediatrics and Bright Futures: Guidelines for health supervision of infants, children, and adolescents, Third Edition, edited by Joseph Hagan, Jr., Judith S. Shaw, and Paula M. Duncan, 2008, Elk Grove Village, IL: American Academy of Pediatrics. If your child has any medical conditions that put him at risk for infections or is traveling outside the United States, talk to your child's doctor about additional vaccines that he may need.



**U.S. Department of Health and Human Services**  
 Centers for Disease Control and Prevention

**AMERICAN ACADEMY OF FAMILY PHYSICIANS**  
 STRONG MEDICINE FOR AMERICA

**American Academy of Pediatrics**  
 DEDICATED TO THE HEALTH OF ALL CHILDREN



**Self-Administered  
Hormonal  
Contraception**

**Documents Available  
to Memorialize  
Prescriptions Furnished  
by a Pharmacist as a  
Drug Order**

## Hormonal Contraceptive Self-Screening Questionnaire

Name: \_\_\_\_\_ Date of Birth \_\_\_\_\_

Address: \_\_\_\_\_ Phone: \_\_\_\_\_

Allergies to Medications?  Yes  No If yes, list them here: \_\_\_\_\_

Are you interested in a starting/changing to a new contraceptive  Yes  No  Maybe

Do you have a preferred method of birth control that you would like to use?  Continue my current method

A pill taken daily  A patch changed weekly  A vaginal ring changed monthly  A shot every 3 months

Other Long term method like an IUD or implant  Not sure

Do you want your health care provider to receive a notice regarding this visit?  Yes  No If yes who: \_\_\_\_\_

1	Do you think you might be pregnant now?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2	What was the first day of your last menstrual period?	___/___/___
3	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, what kind of reaction occurred?	_____
	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, which one do you use?	_____
4	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5	Do you smoke cigarettes?	Yes <input type="checkbox"/> No <input type="checkbox"/>

### Medical History:

6	Have you given birth within the past 6 weeks?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7	Are you currently breastfeeding an infant less than 1 month of age?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8	Do you have diabetes?	Yes <input type="checkbox"/> No <input type="checkbox"/>
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes <input type="checkbox"/> No <input type="checkbox"/>
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/> No <input type="checkbox"/>
12	Have you ever had a blood clot in your leg or lung?	Yes <input type="checkbox"/> No <input type="checkbox"/>
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes <input type="checkbox"/> No <input type="checkbox"/>
14	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/> No <input type="checkbox"/>
15	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
16	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/> No <input type="checkbox"/>
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/> No <input type="checkbox"/>
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, list them here:	
20	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, list them here:	

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

*Pharmacy  
use only*

Eligible for pharmacist services

BP Reading \_\_\_\_\_/\_\_\_\_\_

Refer Patient to:

Pharmacist Name \_\_\_\_\_ Pharmacist Signature \_\_\_\_\_

Notes:

Pharmacy 123  
456 Main Street  
My Town, California  
(XXX) 333-4444

Name: \_\_\_\_\_

Date: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

Contraceptive selected: \_\_\_\_\_

Sig:

Refills:

\_\_\_\_\_  
Furnishing pharmacist printed name

\_\_\_\_\_  
Signature of furnishing pharmacist

NPI number: \_\_\_\_\_:

**The DCA Page:  
News from the  
Department of  
Consumer Affairs**

**Blog Article**

**Pharmacists Can Help  
You Quit Smoking**

# Pharmacists Can Help You Quit Smoking

Posted on **March 29, 2016** by **DCAStaffWriter**



It just got a lot easier to kick the nicotine habit now that products to help you quit smoking are available from your local pharmacy without a prescription.

“Quitting smoking is difficult to do, but important to patient health. Pharmacists can now offer greater assistance to individuals who have decided to quit smoking,” said Virginia Herold, California State Board of Pharmacy executive officer.

Board of Pharmacy regulations went into effect in late January that allow pharmacists to furnish smoking cessation products without a prescription. Before they can provide the products, pharmacists are required to complete two hours of approved continuing education on nicotine replacement therapy and must then receive ongoing training.

Before dispensing, your pharmacist must ask questions to determine if nicotine replacement products are safe for you. Your pharmacist will ask about your current tobacco use and attempts to quit; if you’ve suffered a recent heart attack; if you have a history of heart problems; if you have frequent chest pain or unstable angina; or if you have nasal allergies or have been diagnosed with temporal mandibular joint (TMJ). Women will be asked if they are pregnant or plan to become pregnant.

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A pharmacist will use his or her professional judgment and the responses to your questions to determine whether to furnish the products or refer you to a health care professional.

According to the Centers for Disease Control (CDC), in 2014 nearly 17 out of every 100 Americans – or 40 million people – smoked cigarettes. The CDC says cigarette smoking kills 480,000 in the U.S. every year and is the leading cause of preventable disease and death. Along with those deaths, more than 16 million Americans live with smoking-related diseases. Quitting smoking is an important step to improving your health and life expectancy.

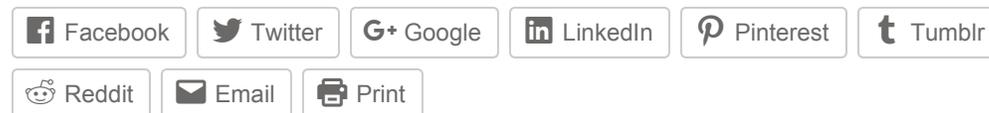
Pharmacists received authority to provide nicotine replacement products with the passage of SB 493 (Hernandez). The Board of Pharmacy and Medical Board of California then developed protocols for pharmacists to follow. Ask your pharmacist if he or she can work with you to help you kick the smoking habit and start on a path to better health.

Click here to view the regulation:

[http://www.pharmacy.ca.gov/laws\\_regs/1746\\_2\\_00a.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_2_00a.pdf).

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# **Attachment 6**

# CURES 2.0

REGISTRATION TIPS TO ~~X~~ SUCCESSFULLY REGISTER

## MEDICAL DOCTORS

### License Type

**Your license type is the letter in front of your license number on your license wallet card.**

For example, if your wallet card reads G12345,  
select "Medical Doctor (MD) - Type G" as your license type.

## OSTEOPATHIC DOCTORS

### License Type

**Your license type is "Osteopathic Doctor (DO) – Type A."**

### License Number

**The prefix "20A" reflects your license type. It is not part of your license number and should not be included in the license number field.**

For example, if your wallet card reads 20A1234,  
enter "1234" as your license number.

## PODIATRIC DOCTORS

### License Board

**Select the "Board of Podiatric Medicine" as your licensing board,  
NOT "Medical Board of California."**

## NURSE MIDWIVES / NURSE PRACTITIONERS

### License Number

**Make sure to register using your Nurse Midwife Furnishing license number or your Nurse Practitioner Furnishing license number and NOT your Registered Nurse license number.**

The Nurse Midwife Furnishing license or Nurse Practitioner Furnishing license is your qualifying license for access to the CURES database.

## PHYSICIAN ASSISTANTS

### License Board

**Select the "Physician Assistant Committee" as your licensing board,  
NOT "Medical Board of California."**

## ALL APPLICANTS

### Social Security Number (SSN) and Individual Tax Identification Number (ITIN)

Choose between these options based upon **what is on file with your licensing board**.

To be approved, the information you enter into the CURES online registration form must **EXACTLY** match records on file with your licensing board.

A business ITIN number should never be used, because it will not match records on file for you.

### Prescriber Name Validation

For prescribers to be approved, their last name, as entered into the CURES online registration form, must match their name on file with the Drug Enforcement Agency.

### Security Questions and Answers

Please make a note of your security question answers for later retrieval.

The answer **CANNOT** be part of the question (a word, part of a word, or a single letter.)

For example, if the security question contains the word **PET**, an answer of **PET** will not be accepted. If the security question contains the word **WHERE**, an answer of **ER** will not be accepted.

**Do not use abbreviations or single letter answers.**

### Reapplying after Denial

Once denied, applicants must reapply.

The CURES program cannot edit information submitted by applicants.

Upon receipt of a denial, review your User Registration Confirmation page printout for accuracy and compliance with these tips before reapplying.

If the information you entered is correct, contact your licensing board to verify that the date of birth and SSN or ITIN it has on file for you is accurate.

### Approval/Denial Timeframe

Applicants should receive an approval or denial within 48 hours.

If you have not received an email by then, check your spam/junk email folder before contacting the CURES program.

## FIRST-TIME LOGIN TIPS

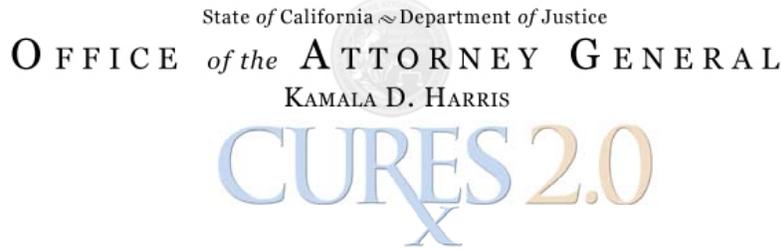
### Entering Primary Address

To enter the address, **CLICK THE PENCIL ICON**.

After inserting address, **CLICK THE CHECKMARK** to confirm address entry.

### Entering Phone Type – (Required Field)

Make sure to select phone type (home, office, or cell.)



## PUBLICATIONS AND TRAINING VIDEOS

CURES 2.0 (Controlled Substance Utilization Review and Evaluation System) is a database of Schedule II, III and IV controlled substance prescriptions dispensed in California serving the public health, regulatory oversight agencies, and law enforcement. CURES 2.0 is committed to the reduction of prescription drug abuse and diversion without affecting legitimate medical practice or patient care.

### Publications

Annual Report to the California Legislature

[CURES 2.0 Annual Grant Report for 2015, pdf](#)

[CURES 2.0 Annual Private Donations Report for 2015, pdf](#)

CURES 2.0 User Training Documents

[CURES 2.0 Prescriber and Dispenser User Guide, pdf](#)

[CURES Registration Instructions for Prescribers and Dispensers, pdf](#)

[CURES 2.0 Registration Tips and Tricks, pdf](#)

### CURES 2.0 Training Videos

Prescriber and Dispenser Users:

[Registration Part 1](#)

[Registration Part 2](#)

[Patient Activity Report \(PAR\) Search](#)

[Update User Profile](#)

[Manage Delegates](#)

[Patient Treatment Exclusivity Compact](#)

[Peer-to-Peer Communication](#)

All Users:

[Log-In and Navigation](#)

[Change Password](#)

[Forgot Password](#)

[Forgot User ID](#)



California State Board of Pharmacy Subscriber Alert - Message (HTML)

You forwarded this message on 4/11/2016 11:18 AM.

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV> on behalf of Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV> Sent: Wed 4/6/2016 10:51 AM  
To: PHARM-GENERAL@DCALISTS.CA.GOV  
Cc:  
Subject: California State Board of Pharmacy Subscriber Alert

The Department of Justice recently released a CURES 2.0 registration tip sheet to help individuals register or access the system. Pharmacists would be included under "All Applicants" on page 2.

As a reminder, all pharmacists with active California licenses need to be registered to access CURES by July 1, 2016.

The tip sheet can be accessed at: [http://www.pharmacy.ca.gov/licensing/cures\\_tips.pdf](http://www.pharmacy.ca.gov/licensing/cures_tips.pdf)

Information about CURES registration can also be obtained from: <http://www.pharmacy.ca.gov/licensing/cures.shtml>

----- To unsubscribe from this email list please click on the link below and follow the instructions on the web page.

<https://www.dca.ca.gov/webapps/pharmacy/subscribe.php>

**California State Board of Pharmacy**

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

May 2016

Important Notice

XXXXXXXXXX  
XXXXXXXXXX

Dear California Pharmacist:

The board is sending this letter to you to ensure you have taken action required by California law. Please read the information below; based on information we reviewed May 10, 2016, we do not believe you are currently compliant.

The requirement:

By July 1, 2016, all pharmacists licensed by the California State Board of Pharmacy with active licenses must have applied to become registered to access California's prescription drug monitoring program, the Controlled Substance Utilization Review and Evaluation system (CURES). CURES tracks Schedule II, III and IV controlled substances dispensed by California pharmacies. (See California Health and Safety Code sections 11165, 11165.1)

According to records from the California Department of Justice, as of May 2016 you are not registered to access CURES.

To apply for registration to access CURES, go to:

<https://cures.doj.ca.gov/registration/confirmEmailPnDRegistration.xhtml>

If you have questions or would like to view training videos, go to:

<http://oag.ca.gov/cures/publications>

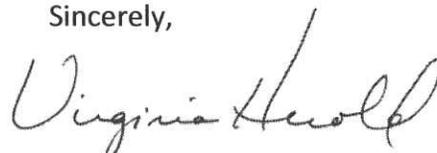
If you believe you are registered and took action before May 2016 to become registered, please contact Lisa Henry at the Board of Pharmacy at 916- 574-7977. Alternatively, you may wish to simply re-register using the link provided above.

Finally, please be aware that to keep abreast of new laws, regulations and board information, you may join the board's email alert system through this link:

<https://www.dca.ca.gov/webapps/pharmacy/subscribe.php>

Thank you for your attention to this matter.

Sincerely,



VIRGINIA HEROLD

Executive Officer

**Attachment +**

## **Summary of Best Practices for Making Prescription Drug Labels Accessible To Patients Who are Blind, Visually Impaired or Elderly**

The following best practices are recommended to make it easier for people who are blind, visually impaired or elderly to access label information on prescription drug containers.

The recommended best practices were developed by a working group of consumer and drug industry advocates convened by the United States Access Board under the Food and Drug Administration Safety and Innovation Act (Public Law 112-144, 126 Stat. 993).

The working group said that people who cannot read printed prescription labels because of visual impairment “all too often take the wrong medication, the wrong amount, at the wrong time and under the wrong instructions.” The group also noted that most people who become blind or visually impaired “do so after age 60” – a time when many take multiple medications and have physical and cognitive conditions that increase the need for “safe, consistent, reliable and independent access” to drug label information.

- Encourage patients to communicate their needs to pharmacists.
- Follow universal patient-centered prescription drug container label standards.
- Make container labels available in audible, braille and large-print formats. Explain the choices and provide the format selected by the patient.
- Ensure that duplicate accessible labels preserve the integrity of the print prescription label.
- Subject accessible prescription labels to the same quality control processes used for print labels to ensure accuracy and patient safety.
- Maintain patient privacy (HIPPA rules) when preparing accessible drug labels.
- Keep a sufficient inventory of supplies to provide accessible labels.
- Provide drugs with an accessible label within the same time frame as would be provided to patients without visual impairments.
- Don't impose an extra fee to cover the cost of providing an accessible drug label.
- Ensure durability of accessible label formats until the prescription expiration date.
- Select a container that best supports the type of accessible label provided.
- Ensure all required information contained on the print prescription drug label is provided in the same sequence on the accessible label.
- Include in accessible labels the information on warning labels added to the container at the pharmacist's discretion.

A variety of methods and technologies exist to enable blind, visually impaired and elderly people to access information on prescription labels, including:

- Hard copy labels printed in large type or braille.
- Digital voice or text-to-speech recorders – “Talking bottles” that use a small electronic device attached to a drug container to read the label information aloud.
- Radio Frequency Identification Device (RFID) tags – Attaching RFID tags to drug containers that enable a dedicated device used by the patient to read the label aloud.
- Smart devices and computers equipped with electronic braille, large text and audio technology to access electronic text.

A [brochure](#) listing the best practices was issued in June 2016 by the National Council on Disability. The brochure is available at [http://www.ncd.gov/sites/default/files/ADLP\\_508.pdf](http://www.ncd.gov/sites/default/files/ADLP_508.pdf).

[Additional information](#) about the recommended best practices and a link to the working group’s [full report](https://www.access-board.gov/guidelines-and-standards/health-care/about-prescription-drug-container-labels) is available at <https://www.access-board.gov/guidelines-and-standards/health-care/about-prescription-drug-container-labels>.

[Print](#)

## Working Group Recommendations

### Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly

#### Access Board Working Group on Accessible Prescription Drug Container Labels

July 10, 2013

#### Table of Contents

- [Legislative Background](#)
  - [Working Group Participant Organizations](#)
  - [Why Are Best Practices Needed?](#)
  - [What Is a Prescription Drug Container Label?](#)
  - [Delivery Methods for Providing Accessible Prescription Drug Container Labels](#)
  - [Best Practices to Use for All Formats](#)
  - [Format-Specific Best Practices](#)
  - [Resources](#)
- 

#### Legislative Background:

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144, 126 Stat. 993). The law includes measures to promote drug safety and to improve FDA procedures for reviewing new medicines and medical devices.

A provision of the Act, **Section 904**, authorizes the Access Board to convene a stakeholder working group to develop best practices for making information on prescription drug container labels accessible to people who are blind or visually-impaired or who are elderly. (See 29 U.S.C. 792.) Under the law, representation within the working group must be divided equally between consumer and industry advocates. The Act exempts the working group from the Federal Advisory Committee Act.

The law calls for the working group to develop, no later than 1 year after the date of the enactment of this Act, best practices for pharmacies to ensure that blind and visually-impaired individuals have safe, consistent, reliable, and independent access to the information on prescription drug container labels.

According to Section 904, the best practices are not mandatory. They are not to be construed as accessibility guidelines or standards of the Access Board, nor do they confer any rights or impose any obligations on working group participants or other persons. The law makes it clear that nothing in Section 904 is to be construed to limit or condition any right, obligation, or remedy available under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) or any other federal or state law requiring effective communication, barrier removal, or nondiscrimination on the basis of disability.

The law also provides that the working group may make this best practices report publicly available through the internet websites of working group participant organizations, and through other means, in a manner that provides access to interested individuals, including individuals with disabilities. The National Council on Disability will conduct an informational and educational campaign in cooperation with the stakeholder working group to inform the public, including people with disabilities and pharmacists, of the best practices. The Government Accountability Office will undertake a review beginning 18 months after the date of this report to assess the extent to which pharmacies are following the best practices and to what extent barriers to information on prescription drug container labels remain.

## Working Group Participant Organizations

In October 2012, the Access Board formed an 18-member working group with representation from national organizations advocating for individuals who are blind, visually-impaired, and older adults, as well as industry groups representing retail, mail order, and independent community pharmacies.

The working group is comprised of representatives of the following organizations:

- AARP
- American Council of the Blind (ACB)
- American Foundation for the Blind (AFB)
- Blinded Veterans Association (BVA)
- Council of Citizens with Low Vision International (CCLVI)
- Express Scripts
- Metropolitan Washington Association of the Deaf Blind (MWADB)
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- National Council on Aging (NCOA)
- National Council on Independent Living (NCIL)
- National Federation of the Blind (NFB)
- National Council on Patient Information and Education (NCPIE)
- Rite-Aid
- Target
- US Pharmacopeia (USP)
- Walgreens
- Wal-Mart

The working group met in person in Washington, DC, on January 10 and 11, 2013, and subsequently via five teleconferences. The working group explored various alternatives, including braille, large print labels, and various auditory technologies such as "talking bottles" and radio frequency identification devices. The working group also considered whether there are technical, financial, manpower, or other factors unique to pharmacies with 20 or fewer retail locations which may pose significant challenges to the adoption of the best practices.

## Why Are Best Practices Needed?

Persons with visual impairments who cannot read print prescription drug container labels all too often report inadvertently taking the wrong medication, the wrong amount, at the wrong time, and under the wrong instructions, thereby endangering the health and safety of themselves and family members for whom they are caregivers. Without having ready access to their prescription drug container label information, persons with visual impairments are also at risk of taking expired medications, of not being able to obtain refills in a timely manner, and of being unable to detect pharmacy errors. The majority of persons who become blind or visually-impaired do so after age 60, a time when multiple medications are often prescribed and when persons may experience physical and cognitive conditions which heighten the necessity for safe, consistent, reliable, and independent access to prescription drug container label information.

In recent years, various organizations, including US Pharmacopeia (USP), the National Association of Boards of Pharmacy, and the National Council on Patient Information and Education, have recommended the adoption of patient-centered pharmacy practices to improve patient understanding and safe, effective use of

prescription medication. Inherently inclusive, patient-centered pharmacy practices promote accessibility, while a one-size-fits-all approach typically creates barriers.

In the context of this report, the term "best practice" refers to a set of working methods that the working group believes is most effective in providing access to prescription drug container label information to customers with blindness and visual impairments, including older adults.

The goal of the best practices for accessible prescription drug container labels is to offer guidance to pharmacies on how to provide accessible prescription drug container labels to patients with visual impairments to enable them to manage their medications independently and privately and have the confidence that they are taking their medications safely, securely, and as prescribed.

## What Is a Prescription Drug Container Label?

A prescription drug container label is a legal document that must be prepared by the pharmacist filling the prescription. The pharmacist must ensure the accuracy of the prescription drug container label, and include on the label all elements required by applicable state law.

In 2009, USP determined optimal prescription label content and format to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription drug container label instructions. USP created universal prescription drug container label standards for format, appearance, content, and language (see: **U.S. Pharmacopeial Convention** ). The best practices in this report build upon the USP universal patient-centered prescription drug container label standards.

## Delivery Methods for Providing Accessible Prescription Drug Container Labels

A variety of delivery methods are available for producing accessible prescription drug container labels in audible, braille, and large print formats. Delivery methods include:

- **Hard copy braille and large print:** A pharmacist filling prescriptions produces hard copy braille and large print labels upon request, and affixes the accessible labels to the prescription drug containers.
- **Dedicated electronic equipment:** Some equipment is designed specifically to provide accessible prescription drug container labels. Some dedicated electronic methods can be used with containers of various sizes, shapes, and materials. Examples of dedicated electronic methods include:
  - **Digital Voice or Text-to-Speech Recorder:** This is a small electronic device that a pharmacist affixes to a prescription drug container. When activated by pushing a button on the device, the patient hears the information printed on the prescription drug container label. One device is affixed to each prescription drug container. Some devices also have a USB drive.
  - **Radio Frequency Identification Device (RFID):** A pharmacist places an RFID tag on a prescription drug container. A patient who is blind or visually-impaired is equipped with a small, dedicated device that, when a container with an RFI Tag is placed over the device, audibly announces the text on the prescription drug container label. This technology may also provide prescription drug container label information in large print, and has a USB drive.
  - **Smart devices and computers:** Many patients with visual impairments use their own computers and smart devices equipped with electronic braille, large print, and audio technology to access electronic text. Visually impaired computer users, particularly those who are deaf-blind, may request access to prescription drug container labels using their computers and smart devices, either via internet applications (apps) or in combination with dedicated equipment equipped with a USB drive. Methods include pharmacists placing on the prescription drug container a QR code, RFI tag, or other small, electronic unit encoded with the prescription drug container label in electronic text, which visually impaired patients receive on smart devices or computers in electronic braille, large print, or audible

format. Note that using this delivery method does not involve pharmacists embossing a braille label; rather, pharmacists use an electronic delivery method that encodes the prescription drug container label text, which can be displayed via a computer screen, speakers, or an electronic braille display.

Some electronic prescription drug container label delivery methods may also have the capacity to include supplemental information about the prescription medications. In addition, some may have capability to translate prescription drug container label information into several languages.

The key to providing accessible prescription drug container labels is patient-centered communication between pharmacists and patients with blindness and visual impairment and patient representatives. Because the extent of visual impairment varies from person to person, some patients may need prescription drug container labels in an audible format, while others may need braille, and still others may need large print. Additionally, it is important to keep in mind that visually impaired patients who are not computer savvy may need hard copy braille or large print labels, or a dedicated electronic method that is easy to operate.

### **Best Practices to Use for All Formats**

The following best practices promote access to prescription drug container label information in all formats, including audible, braille, and large print labels.

- One of the best things pharmacists can do is to encourage patients and patient representatives to communicate their needs to pharmacists:
  - Advertise a local or, when possible, a toll-free telephone number to promote communication between patients and pharmacists;
  - If pharmacy websites and applications (apps) are made available to patients, ensure website and app accessibility; and
  - When a pharmacist observes a patient or patient representative having reading difficulty, offer education and counseling in a setting that maintains patient privacy.
- Follow universal patient-centered prescription drug container label standards.
- Make available options for accessible prescription drug container labels in audible, braille, and large print formats via methods using, for example, hard copy, dedicated devices, and computers or smart devices.
- Explain to the patient the available accessible prescription drug container label format options, and provide the prescription drug container label in the format option selected by the patient.
- Ensure that duplicate accessible labels preserve the integrity of the print prescription drug container label.
- Subject accessible prescription drug container labels to the same quality control processes used for print labels to ensure accuracy and patient safety.
- Maintain patient privacy in accordance with the Health Insurance Portability and Accountability Act (HIPAA) rules when preparing accessible prescription drug container labels, e.g., record audible labels in a location where patient information cannot be overheard by unauthorized persons.
- In advance, make arrangements to provide accessible prescription drug container labels. For example, maintain a sufficient inventory of supplies necessary to support timely provision of prescription drug container labels in accessible label formats.
- Provide prescription medication with an accessible prescription drug label within the time frame the same prescription would be provided to patients without visual impairments.
- Do not impose a surcharge or extra fee to an individual to cover the cost of providing an accessible drug container label and equipment dedicated for prescription drug container label access.
- Ensure the durability of accessible label format options until the expiration date specified on the prescription drug container label.
- Select a container that best supports the type of accessible label provided.
- For all accessible label formats, including audible formats, ensure that all required information contained on the print prescription drug container label is provided on the accessible label in the same sequence as the print label.

- Include in accessible prescription drug container labels the information on warning labels added to the container at the pharmacist's discretion.

### **Format-Specific Best Practices**

In addition to the best practices listed above, please note the following format-specific best practices.

#### *Audible Prescription Drug Labels*

For dedicated equipment, select devices that provide independent, easy to use, start/stop operation, with volume control, and ear bud access for privacy.

If using a voice recorder:

- speak in a clear voice;
- record information in a setting that minimizes background noise and maintains patient privacy.

Offer to show the patient how to operate the audible prescription drug container label.

#### *Braille Prescription Drug Container Labels*

Electronic delivery method: Acquire an electronic delivery method using RFI tags, QR codes, or other processes to provide electronic text of the prescription drug container label upon request. Consumers with electronic braille equipment may then access electronic text in braille format.

Note that, as required, the working group considered significant challenges that pharmacies may face in producing drug labels in accessible formats, such as hard copy braille. The working group recognizes that mail order and online pharmacies, because of their centralized structure, large volume, and mail delivery process, may be better equipped than local stores to provide hard copy braille prescription drug container labels. Many mail order and online pharmacies have established a unit with the necessary computer software and braille embossers to produce hard copy braille labels and a protocol to develop pharmacists' proficiency in printing accurate braille labels.

- If a local pharmacy store has a high demand for hard copy braille prescription drug container labels, acquire on-site braille embosser capacity and proficiency.
- If a local pharmacy store receives infrequent or occasional requests for hard copy braille prescription drug container labels, partner with a pharmacy that has braille prescription drug container labeling capacity to provide a hard copy braille prescription drug container label.

When embossing hard copy braille prescription drug container labels:

- Use contracted (Grade 2) braille.
- Emboss braille labels on transparent material in order to preserve the legibility of print container labels. Affix braille label to the prescription drug container with strong adhesive.
- Do not fold braille labels.

Printing Large Print Labels (hard copy):

- Print label in 18-point bold font.
- Use non-glossy paper or other material that is durable and a size that is easy to manipulate.
- Use print with highest possible contrast between text and background color (ideally black text on a white or pale yellow background). If printing on both sides, use material that does not allow print bleed-through from one side to the other.
- Use sentence case, with the initial capital letter followed by lower-case characters.
- Use non-condensed, san-serif font, such as Arial.
- Provide 1.5 line spacing.

- Use horizontal text only.
- Securely affix the large print label to the prescription drug container.
- When covering a large print label with protective tape, use non-glossy, transparent tape.

## Resources

### **USP Patient-Centered Prescription Label Standards**

UMS White Paper, The National Council for Prescription Drug Programs Work Group (WG), 2013

## Working Group Participant Organizations

- AARP
- American Council of the Blind (ACB)
- American Foundation for the Blind (AFB)
- Blinded Veterans Association (BVA)
- Council of Citizens with Low Vision International (CCLVI)
- Express Scripts
- Metropolitan Washington Association of the Deaf Blind (MWADB)
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- National Council on Aging (NCOA)
- National Council on Independent Living (NCIL)
- National Council on Patient Information and Education (NCPIE)
- National Federation of the Blind (NFB)
- Rite-Aid
- Target
- US Pharmacopeia (USP)
- Walgreens
- Wal-Mart

**Attachment ,**

*Draft Proposal to Amend 16 CCR § 1732.5*

**§ 1732.5. Renewal Requirements for Pharmacist.**

- (a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.
- (b) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.
- (c) All pharmacists with an email address shall subscribe to the board's email notification system and shall self-certify enrollment to the board in writing at the time of license renewal.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

DRAFT

# **Attachment 9**



**California State Board of Pharmacy**

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

**COMMUNICATION AND PUBLIC EDUCATION COMMITTEE  
MEETING MINUTES**

Date: May 25, 2016

Location: Department of Consumer Affairs  
1st Floor Hearing Room  
1625 N. Market Blvd.  
Sacramento, CA 95834

Committee Members Present: Debbie Veale, RPH, Chair  
Ramón Castellblanch, PhD, Vice Chair, Public Member  
Ricardo Sanchez, Public Member

Committee Members Not Present: Ryan Brooks, Public Member  
Lavanza (Cheryl) Butler, RPH

Staff Present: Virginia Herold, Executive Officer  
Laura Freedman, DCA Staff Counsel  
Debbie Damoth, Staff Services Manager

**1. Call to Order and Establishment of Quorum**

The meeting was called to order at 9:43 a.m. Roll call was taken and a quorum was established.

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

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

Note: After agenda item #3, Chairperson Veale asked for public comment for future meetings. There were no public comments.

**3. Update and Discussion on the Development of a Revised Patient Consultation Survey Questionnaire**

Chairperson Veale noted that at the July 2015 Board Meeting, the board reviewed the

results of a short questionnaire made available to licensees regarding patient consultation. She noted that at the October 2015 Board Meeting, President Gutierrez asked the committee to develop a broader survey.

In advance of this committee meeting, board staff contacted the following entities to determine if they were interested in working with the board to develop a broader survey for pharmacists. The UC Davis Graduate School of Management, Kaiser Family Foundation, and Sierra Health Foundation each declined to work with the board on such a survey. No responses were received from Philanthropy Dignity Health; California State University, Sacramento; and UC Santa Barbara.

Subsequently, board staff contacted the Office of Professional Examination Services (OPES), housed within Department of Consumer Affairs' (DCA) Division of Programs and Policy Review. OPES primarily provides professional psychometric expertise in examination development and validation services to DCA's regulatory entities through Intra-Agency Contract agreements.

Chairperson Veale indicated the committee's concern with the previous study completed in 2015 and discussed at the July 2015 board meeting was that it was not scientific or defensible should the study be used to develop policy or law. Ms. Veale continued OPES has experience developing and distributing surveys, including analyzing survey data. These projects include working with subject matter experts to develop the survey content; creating sampling plans; drafting survey communications such as introductory letters and follow up reminders; using Survey Monkey to distribute surveys; monitoring distribution; analyzing data and responses; and, writing reports documenting the survey process and results.

Chairperson Veale stated for the patient consultation survey project, OPES will meet with Board staff no later than June 30 to identify scope of work, expectations, project tasks, potential costs, and to create a timeframe for conducting this project.

Chairperson Veale introduced Division of Program & Policy Review Chief Tracy Montez, Ph.D., of Department of Consumer Affairs, who attended to address any questions the committee had.

Dr. Castellblanch stated the committee's interest is designing a survey to determine how a pharmacist is able to provide patient consultation and identify barriers to patient consultation. Dr. Montez acknowledged her understanding of the committee's intent, and also referenced her understanding that the board is concerned with privacy of the participants.

Ms. Veale informed Dr. Montez the survey needs to account for multiple practice site types (hospital, retail, etc.) as well as solicit input from licensees on how to increase patient consultation in the various settings. Dr. Montez confirmed the committee will be the subject matter experts for the survey. Ms. Veale asked if a survey could be ready by September 2016 when the committee meets next. Executive Officer Virginia Herold

indicated and Dr. Montez concurred that September 2016 is a good target date. The committee discussed options for keeping the survey anonymous versus offering an incentive for completion, such as continuing education (CE) credits. The committee also discussed the potential length of the survey.

Dr. Castellblanch expressed his interest in determining a fundamental problem: the reason(s) patient consultations aren't being done. He indicated it would be interesting to know if new board policies (e.g. corresponding responsibility, furnishing naloxone, etc.) might have any impact on patient consultations. Dr. Castellblanch indicated he was also interested in understanding how the survey would be disseminated.

Chairperson Veale asked for public comment.

Steve Gray, PharmD, J.D., stated that Kaiser and the Pharmacy Foundation of California are extremely interested in such a survey. He added that if patient consultation is the number one focus after the board's strategic planning session, Dr. Gray recommended keeping the survey to only patient consultation. Dr. Gray made several suggestions: define the term "consultation" to prevent confusion; that respondents be anonymous; that the survey separate hospital consultation from retail setting consultation; that the board work with unions that represent pharmacists to reach a greater number of pharmacists; and that the survey ask open-ended, short questions. Dr. Gray added that continuing education should not be awarded to respondents for participating in the survey.

Mr. Sanchez inquired if there were other states who have conducted patient consultation surveys. Ms. Herold indicated she was not aware of any surveys conducted by other states on this topic. Dr. Montez noted that OPES could include this type of research as part of the scope of the project. Ms. Herold indicated California is the leader in patient consultation.

Dr. Gray indicated that in his experience, the best surveys were validated with anonymous focus sessions.

#### **4. Discussion on Current Patient Consultation Practices and Actions the Board Can Take to Educate Consumers and Licensees on Appropriate Patient Consultations**

Chairperson Veale stated that at previous committee meetings, the importance of educating consumers and licensees on appropriate patient consultations has been discussed. Ms. Veale stated there may be benefit in waiting for the results of the upcoming patient consultation survey and board strategic planning sessions before moving forward.

Dr. Castellblanch inquired if board inspectors are looking at patient consultation as part of their inspections. Ms. Herold explained inspectors do look at patient consultation when the inspector observes these actions in a pharmacy – but many times there are no patients in the pharmacy when the inspectors are on site.

Dr. Castellblanch inquired about education provided about patient consultation. Ms. Herold stated that when the board receives a complaint regarding the lack of patient consultation,

and through the resolution of that complaint, the licensee receives education on appropriate consultation. Chairperson Veale referenced the board's newsletter *The Script* as a source of information as well.

Mr. Sanchez said that as a consumer, he has not had a problem receiving patient consultation at pharmacies he has visited.

Chairperson Veale asked for public comment.

Dr. Gray from Kaiser recommended segmenting public education and practitioner education. Dr. Gray stated with regard to the information provided to the patient during consultation, there should be a balance of information on the 'purpose' of the drug and any 'warnings' for the drug. Dr. Gray said that Kaiser uses retirees as secret shoppers to ensure consultation is occurring.

Ms. Herold suggested developing a video demonstrating what a good consultation looks like – and a bad consultation – as a tool for consumers and pharmacists. Chairperson Veale suggested a university competition to develop such a video.

Mr. Sanchez inquired as to how many consumer complaints a year the board received. Ms. Herold explained the board receives annually approximately 2,400 complaints and 400 reports known as Section 800 reports where there was a settlement of over \$3,000. Chairperson Veale explained the number of complaints is not a good indicator because if a complaint has been received by the board, the pharmacist did not resolve the issue for the consumer.

Dr. Castellblanch inquired about the availability of the Notice to Consumers (NTC) in other languages. Board staff indicated the NTC is available for download from the board's website in six languages in legal size paper, in addition to English. Dr. Castellblanch asked that, at minimum, a Spanish version be available in the full poster size.

## **5. Update on the Redesign of the Board's Website**

Chairperson Veale reported that in mid-May board staff began to migrate the existing site to the new format, and that the board anticipates it will be complete and operational in early June 2016. At the July 2016 board meeting, Webmaster Victor Perez will provide a presentation and overview on the updated website.

Chairperson Veale thanked Dr. Castellblanch for his assistance on this project and Dr. Castellblanch reciprocated. Dr. Castellblanch commended Webmaster Victor Perez on his work in completing this task.

## **6. Update and Discussion on Prescription Label Translations of Directions for Use**

#### a. Update on the Communication Plan

Chairperson Veale reported to the committee Assembly Bill (AB) 1073 was approved by the Governor on October 11, 2015, and that the provisions went into effect on January 1, 2016. The bill requires a pharmacist to use professional judgment to provide a patient with directions for use of a prescription, consistent with the prescriber's instructions.

Ms. Veale noted the bill also requires a prescriber to provide translated directions for use, if requested, and authorizes the dispenser to use the translations made available on the board's website to comply with the requirement. Dispensers are not *required* to provide translated directions for use beyond what the board has made available. However, the bill does *authorize* a dispenser to provide his or her own translated directions for use to comply with the requirement. Veterinarians are exempt from the requirement to provide translated directions for use.

Ms. Veale explained at the January 2016 Communication and Public Education Committee Meeting, the committee directed board staff to develop a communication plan and provide an update to the committee. The committee directed board staff to release a public service announcement about the change in law immediately.

Board staff released the public service announcement on February 10, 2016. The release was translated into Chinese, Korean, Vietnamese, Russian and Spanish. Overall, the release was sent to over 800 media outlets, as follows:

- 499 media outlets received the English and translated press releases;
- 272 media outlets received the Spanish translated press release;
- 33 media outlets received the Chinese translated press release;
- 17 media outlets received the Vietnamese translated press release;
- 12 media outlets received the Korean translated press release; and
- 3 media outlets received the Russian translated press release.

Chairperson Veale reported as part of the Communication Plan – Phase I, the information from the public service announcement was added to the board's website on the homepage. Additionally, board staff contacted the Department of Consumer Affairs' (DCA) Public Affairs Office for assistance in disseminating the message through DCA's website, Facebook and Twitter accounts. The board's Spring 2016 edition of the *The Script* also included an article on this topic.

Chairperson Veale noted that a copy of the board's web page, translated press releases, DCA's webpage search function showing "label translations," DCA's Facebook post and Tweet, and the board's newsletter article are provided in the meeting materials.

Ms. Veale reported as part of the Communication Plan – Phase II, board staff recommends the dissemination of information regarding the availability of written translations as part of a specific ***Did You Know?*** Campaign, to be implemented as follows:

- Flyer/Fact Sheet Development – Develop in concert with the DCA Office of Publications, Design and Editing. Identify fact sheet and tag line materials translated into the five languages and post these on the board’s website.
- Follow Up Press Release – Reiterate the message through a follow-up Press Release with Flyer/Fact Sheet directed to audiences of the five languages identified in the law.

Dr. Castellblanch expressed his appreciation for releasing press releases in multiple languages. He further inquired if there has been any consideration of checking with the Endowment to see if they are interested in working with the board and developing PSAs and/or videos. Ms. Herold indicated this had not considered.

Kimberly Chen of California Pan-Ethnic Health Network (CPEHN) indicated CPEHN is very interested in partnering with the board’s communication staff, as well as Assembly Member Ting’s office, to execute Phase II. Board staff Debbie Damoth will work with Ms. Chen and CPEHN on this effort.

Committee member Ricardo Sanchez stepped out of the meeting and returned at 10:51 am.

**b. Proposed Draft Regulation Language for Consideration**

Chairperson Veale reported the committee also discussed at the January 2016 committee meeting developing draft language for regulations requiring pharmacies to post information for consumers regarding the availability of written translations. Board staff drafted language for committee consideration to require the Point to Your Language notice include a translated direction for the consumer to ask about translations available. A copy of the proposed draft regulations for committee consideration was provided at the meeting materials. The committee discussed various options of updating the Point to Your Language notice as required by 16 CCR 1707.6(c).

**Motion:** Direct board staff to provide draft language for 16 CCR 1707.6(c) as discussed in the committee to reflect the addition of prescription labels being available in Spanish, Chinese, Korean, Vietnamese and Russian and provide prescription labels may be available for other languages referenced in 16 CCR 1707.6(c)

M/S: Sanchez/Castellblanch

Chairperson Veale called for comment from the board and public.

Kimberly Chen from CPEHN noted that since Cantonese and Mandarin are dialects of Chinese both will have the same written language.

Support: 3            Oppose: 0

## **7. Update on Development of FAQs Received From [ask.inspector@dca.ca.gov](mailto:ask.inspector@dca.ca.gov)**

Chairperson Veale reported that licensees are able to call and ask general questions of pharmacy inspectors. Inspectors answer calls on Tuesdays and Thursdays from 8:00 am to 4:30 pm. In addition, licensees may submit an email request to a pharmacist inspector at [ask.inspector@dca.ca.gov](mailto:ask.inspector@dca.ca.gov). Emails are responded to during business days. To ensure that all licensees receive the benefits of service, the board is developing an FAQ to be posted on the board's web site concerning the most frequent questions and issues.

Ms. Veale explained while the questions and answers are not intended as, nor should they be construed to be legal advice, the information is intended to provide guidance to the reader on relevant legal sections that should be considered when using professional judgment to determine an appropriate course of action. Should a licensee require legal advice or detailed research, the licensee is encouraged to contact an attorney or other source.

Board staff is in the process of collecting FAQs to add to the board's website as a reference for licensees. The board will continue to develop and increase the number of FAQs, as needed. An update on the draft FAQs was provided at the meeting.

Ms. Herold explained that many of the questions were difficult to create a response, as a written response has implications in what is said and what is not said too. Dr. Castellblanch mentioned he was impressed with the collection of FAQs.

There was no public comment.

## **8. Discussion and Consideration of Naloxone Related Matters**

### **a. Sample Naloxone Labels**

Chairperson Veale informed the committee pursuant to title 16 CCR section 1743.6 (c)(5), the board is required to provide on the board's website sample naloxone labels. Ms. Veale referred to the sample labels provided in the meeting materials. Ms. Herold indicated the labels were in pairs as they are part of a kit.

### **b. Communication to the California Healing Art Boards Regarding Naloxone**

Ms. Veale stated that at previous committee meetings, committee members have expressed an interest in reaching to out to California healing arts boards regarding naloxone access, regulation and protocol. Doing this would proactively inform physicians, nurses, physician assistants, and others about naloxone access, the existing protocol and the pharmacist's role in dispensing naloxone.

Ms. Herold stated she shared this information with the Medical Board of California, and has

talked to the Dental Board and their association. Ms. Herold also spoke on May 20, 2016, about the naloxone protocol at an opioid abuse event sponsored by the Sacramento County Medical Association.

Ms. Herold indicated the board's public information officer position is still vacant. Once the position is filled, writing articles for *The Script* for items such as naloxone will be part of the individual's duties. She added that board articles can be shared with other healing arts boards for their respective newsletters. Ms. Herold indicated the board needs to take the lead on this because the board knows that naloxone is not being distributed.

Dr. Castellblanch inquired as to why the fact sheet only addressed the injection type of naloxone. Ms. Herold explained that the San Francisco Department of Public Health is currently updating the fact sheet to include other forms of naloxone administration. Dr. Castellblanch inquired about the cost of the various forms of naloxone. Ms. Herold explained the nasal spray was about \$40 but the auto-injector is about \$800 for two administrations. Ms. Veale stated she was under the impression the nasal spray was about \$50-\$75. Dr. Castellblanch stated the prices are barriers to access.

Mr. Sanchez left the meeting at 11:17 am.

Ms. Veale stated it is important that the prescribers write the prescription so insurance can be billed. Ms. Veale indicated that if the patient is able to identify themselves and they have insurance, it is very likely that the price will be covered. She noted the issue of cost occurs when a prescription is for a "recipient" (not a patient) – so insurance can't be billed and the person is paying out of pocket.

Steve Gray of Kaiser stated they tried to determine through the associations which payors will pay when the prescriber on record is a pharmacist. He found that most claims are paid because an NPI number is referenced and it is not a controlled substance. They were also able to determine that Medi-Cal will cover naloxone; however, the nasal spray or nasal injection is not indicated for people who have destroyed their nasal passages from cocaine use.

Dr. Gray added that pharmacies are not providing naloxone because the protocol takes 20-60 minutes to initiate and complete the protocol with a patient.

Dr. Gray stated most insurance won't cover the cost unless the actual patient name is referenced. He said there is a misunderstanding that the label must have the name of the patient when, in fact, it does not need to have the name and can be anonymous – such as "recipient." Ms. Herold indicated the sample naloxone labels will be changed to reflect "recipient." Dr. Gray added there is confusion on what name goes on the label, what name goes on the insurance claim, etc.

Dr. Gray requested clarification if pharmacists are able to furnish the new product form

before the protocol is updated, specifically, the fact sheet. Ms. Herold indicated the protocol requires training by the pharmacist in all forms of naloxone and pharmacists may furnish all forms without waiting for the updated fact sheet.

The committee and Kaiser representatives discussed at length the challenges with a prescription for an unknown person.

Ms. Herold indicated the inability for insurance to be billed for naloxone for “recipient use” is a barrier to pharmacists providing naloxone. Ms. Herold asked if CPhA has been contacted. Dr. Gray indicated that would be a conversation worth having to resolve the issue. Ms. Lori Hensik with Kaiser indicated that the family member/friend will usually be the one administering the naloxone and should be the one receiving the consultation, and the insurance coverage issue poses a challenge.

Ms. Hensik also inquired about the storage of records for “anonymous” prescriptions, as well as the documentation of prescription in a medication record for “recipient.” Ms. Herold indicated she will consult with the board’s counsel to determine if a prescription designated for “anonymous” is sufficient for a medication record.

Dr. Gray inquired when the board inquires with board counsel about insurance billing, he requested that the board’s counsel also cross check federal labeling requirements for non-controlled substances. Dr. Gray believed there is an FDA rule and labeling requirement for non-controlled substance. Ms. Veale asked DCA Laura Freedman to research this for the committee.

Mr. Sanchez returned to the meeting at 11:40 am.

### **c. Need for Naloxone FAQs**

Chairperson Veale discussed the need and content for a naloxone FAQ and stated the board has some initial content to consider for FAQs. Ms. Veale expressed reservation in having the board write questions related to insurance coverage. She suggested indicating the pharmacist should check with insurance prior to billing. Dr. Castellblanch requested the board address the insurance and billing questions in the FAQs. Ms. Veale would like to have draft FAQs for the board to consider at the July 2016 board meeting.

Dr. Gray confirmed that FAQs in general are difficult because there may be a problem by what is *not* said. For example, Dr. Gray referenced questions #1 and #2 on the draft FAQs distributed at the committee meeting as a handout. He said that if the computer system documents the identity of the pharmacists, you don’t need to document this information in writing – and this isn’t addressed in the FAQs. He also noted that in the FAQs under section 1793.7 technician trainees are not referenced.

#### **d. Naloxone Fact Sheet for Patients**

Chairperson Veale reported pursuant to 16 CCR 1743.6 (c)(5), the board is required to approve a fact sheet for distribution to the patient by the pharmacist. The board approved the fact sheet entitled “Opioid Safety and How to Use Naloxone: A Guide for Patients and Caregivers” developed by the San Francisco Department of Public Health. A copy of the board-approved fact sheet was included in the meeting materials.

Ms. Veale noted that as Ms. Herold referenced earlier, the fact sheet is in the process of being updated by the San Francisco Department of Public Health in collaboration with California Department of Public Health. Board staff Debbie Damoth confirmed the estimated completion of the revised fact sheet is approximately July or August 2016 and will be brought to the committee when available. Ms. Veale requested if the revised fact sheet is available, it be included in the July 2016 board packet.

### **9. Update and Discussion on SB 493 Implementation**

#### **a. Immunization Protocol**

Chairperson Veale reported in July 2015, the board initiated a formal rulemaking to add section 1746.4 to Title 16 CCR to specify the requirements for a pharmacist to administer vaccinations. On January 19, 2016, following the completion of a 45-day comment period and two 15-day comment periods, the board adopted the final regulation text. The final rulemaking file was submitted to the Department of Consumer Affairs on January 29, 2016, for final review. A copy of the board approved regulation (pending OAL approval) language was provided in the meeting materials.

#### **i. Sample Administration Records for Immunizations**

Ms. Veale reported pursuant to the board adopted final text, the board is required to maintain on the board’s website an example of an appropriate vaccine administration record once the regulation is approved and effective.

Board staff identified three sample immunization formats, included in the meeting materials including: The California Immunization Record (yellow card) - California Department of Public Health; The California School Immunization Record - California Department of Public Health; and Immunization and Development Milestones for Your Child from Birth Through 6 Years Old - Centers for Disease Control and Prevention.

With the assistance of a Supervising Inspector, staff reviewed the sample immunization record formats and recommends using the California Department of Public Health’s yellow card. The yellow card is a widely recognized immunization record used in California and has space to write in immunizations given beyond

school age (e.g., HPV, Shingles, etc.). Staff felt the other two formats presented limitations.

**Motion:** Recommend to the board to post on the board's website The California Immunization Record (yellow card) developed by the California Department of Public Health as the board recommended vaccine record upon approval of pending adoption of regulation 16 CCR 1746.4.

M/S: Sanchez/Castellblanch

Chairperson Veale called for comment from the board and public. There was no public comment.

Support: 3          Oppose: 0

The committee took a break at 11:55 am and resumed at 12:10 pm.

**b. Self-Administered Hormonal Contraception Matters**

**i. Discussion and Consideration of Developing Referral Lists for Pharmacists to Give Patients When Self-Administered Hormonal Contraception is Not Furnished**

Chairperson Veale reported pursuant to 16 CCR 1746.1 (b)(9), the protocol for pharmacists furnishing self-administered hormonal contraception provides that if self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider; and that the pharmacist shall comply with all state mandatory reporting laws, including sexual abuse.

Both Ms. Herold and Ms. Veale stated they did not believe a referral list would be necessary. Ms. Lori Hensik of Kaiser agreed and stated sometimes providing a list causes unintended difficulties if the list is outdated or is not maintained.

**ii. Documents Available to Memorialize Prescriptions Furnished by a Pharmacist as a Drug Order**

Chairperson Veale reported pursuant to 16 CCR 1746.1 (b)(11), the protocol for pharmacists furnishing self-administered hormonal contraception provides each self-administered hormonal contraception furnished by a pharmacist pursuant to the protocol shall be documented in a patient medication record as required by 16 CCR 1717 and 1707.1. These records are required to be maintained for a period of at least three years from the date of dispense.

A sample document available to memorialize and document prescriptions furnished

by a pharmacist with a copy of a self-screening questionnaire was provided in the meeting materials.

Ms. Veale reviewed the sample document and recommended that the words “refer patient to” be removed, so as to be consistent with the committee’s discussion of the prior agenda item.

Ms. Herold indicated this sample document/form was received at the CPhA’s meeting. The intent of the form is to charge for screening and to allow for the transfer to another pharmacy, if allowed by law. Ms. Herold indicated the board’s counsel would have to review it. Ms. Veale concurred with Ms. Herold.

Dr. Steve Gray from Kaiser explained he was concerned this sample looked too similar to a telephone prescription. He explained this is a furnishing document and not a prescription. Dr. Gray provided history on the difference between furnishing, selling, and prescribing.

The committee reiterated its request that board counsel review the document.

### **c. Nicotine Replacement Therapy Matters**

#### **i. Discussion of The DCA Page: News from the Department of Consumer Affairs Blog Article – Pharmacists Can Help You Quit Smoking**

The DCA Page is the department’s webpage for the latest news. On March 29, 2016, The DCA Page featured an article about the nicotine replacement therapy regulation, included in the meeting materials. There was no board or public comment.

### **10. Discussion on the Development of FAQs for SB 493 Related Items**

Chairperson Veale reported Senate Bill 493 (c. 469, Hernandez) was enacted in 2013 and established a new license for an Advanced Practice Pharmacist (APP). The board is currently promulgating regulations to specify certification program requirements, as well as continuing education and other requirements. She noted the adopted regulations are currently being reviewed by the department.

At the April 2016 board meeting, the board requested that the Communication and Public Education Committee coordinate the development of a Frequently Asked Questions (FAQs) for SB 493 related items.

Ms. Veale stated she liked the idea of having FAQs for SB 493 related items. She stated it will be easily implemented as the board is currently working on FAQs for the board’s website and articles in *The Script*. The committee can forward any FAQ questions to board

staff as they wish. Ms. Herold reported Board President Gutierrez requested a compilation of FAQs and providers. Most questions received by the board now relate to insurance and billing.

Ms. Veale asked that FAQs related to SB 493 be held for discussion at the September 2016 Communication and Public Education Committee meeting.

## **11. Update and Discussion on CURES 2.0 and Communication to Licensees**

Chairperson Veale reported the Department of Justice (DOJ) recently released a CURES 2.0 registration tip sheet to help individuals register for or access the system. On April 6, 2016, the board issued a subscriber alert announcing the tip sheet as well as a reminder that all pharmacists with active California licenses need to be registered to access CURES 2.0 by July 1, 2016. Additionally, the DOJ has published on their website publications and training videos to assist in the registration process: <http://oag.ca.gov/cures/publications>. Ms. Veale noted that a copy of the board's subscriber alert, DOJ tip sheet, and a copy of the DOJ CURES 2.0 Publication and Training Video landing page was provided in the meeting materials.

Ms. Veale added that in February 2016, the board mailed out a reminder postcard to pharmacists to register for CURES 2.0 by July 1, 2016. She said that board staff is preparing a final letter to be mailed to registered pharmacists who are not registered with CURES 2.0. Any questions regarding these changes should be directed to [cures@doj.ca.gov](mailto:cures@doj.ca.gov).

Ms. Herold confirmed the final mailing to pharmacists not registered in CURES 2.0 will be a letter (not a postcard), as requested by the board. Ms. Herold stated that out of 46,000 licensed pharmacists the board believes approximately 14,000 pharmacists have not submitted applications to CURES.

Ms. Veale and Dr. Castellblanch inquired about the accessibility of DOJ staff. Ms. Herold reported DOJ has a better phone system in place now and they are seeking staffing augmentation. DOJ reported of the 6,200 paper applications were reviewed and DOJ resolved as many applications as they could before the remaining paper applications were abandoned. The number of applications DOJ resolved was not provided to us.

Dr. Castellblanch asked what will happen to the pharmacists not enrolled in CURES 2.0 after July 1, 2016. Ms. Herold reported the board will have to decide. Ms. Herold reported that there is a bill pending requiring prescribers to be registered and check on Schedule IIs and IIIs before writing a prescription.

Ms. Lori Hensik from Kaiser asked if the public is able to see who is registered in CURES. Ms. Herold stated she did not think that information is public.

## **12. Update and Discussion on Resources Available on the Board's Website**

Chairperson Veale reviewed the three resources available on the board's website: University of California, San Diego (UCSD) on Prescription Drug Abuse; Consumer Reports on Prescription Drug Abuse; and Drug Diversion Toolkit: Patient Counseling – A Pharmacist's Responsibility to Ensure Compliance by Centers for Medicare and Medicaid Services (CMS).

Ms. Herold explained at this point the board needs to determine the policy and procedure created by the committee for resources to be posted on the board's website to confirm the resource addresses a need and there is no actual or perceived conflict of interest.

The committee directed board staff to develop a draft policy for posting resources on the board's website and bring back to the committee. The committee directed staff to continue to reach out to Consumer Reports for approval to post their article on the board's website.

The committee directed the board to post on the board's website CMS' Drug Diversion Toolkit and the Centers for Disease Control's Opioid Guidelines.

There was no public comment.

## **13. Discussion and Consideration of the United States Access Board's Recommendations Related to Prescription Labels for Visually-Impaired and Elderly Patients**

Chairperson Veale reported as part of the U.S. Food and Drug Administration Safety and Innovation Act signed by President Obama on July 9, 2012, the Access Board was authorized to convene a stake holder working group to develop best practices for making information on prescription drug container labels accessible to people who are blind or visually impaired or who are elderly. Ms. Veale noted that a copy of the United States Access Board's Working Group Recommendations entitled *Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly* was provided in the meeting materials.

Ms. Herold inquired if the committee would like board staff to summarize and consolidate the guidelines, and post them on the board's website where prescription label samples are provided. She added that the board has not received complaints about prescription labels for visually impaired. Dr. Castellblanch requested the information be included in the consumer links as well. Board staff will work on the summary and posting to the board's website.

There was no public comment.

**14. Discussion on Federal Legislation: US Senate 524 – Comprehensive Addiction and Recovery Act of 2016**

Ms. Veale explained the committee will have the opportunity to discuss pending federal legislation US Senate 524 known as the Comprehensive Addiction and Recovery Act of 2016. As of March 10, 2016, the bill passed the US Senate with an amendment by Yea-Nay Vote: 94-1. A copy of US Senate 524 engrossed in Senate was provided in the meeting materials.

Dr. Castellblanch indicated it was stopped in the US House of Representatives.

There was no public comment.

**15. Proposal to Develop a Consolidated List of Drug Take Back Locations for the Board's Website**

Dr. Castellblanch reported he found the consolidated website assembled by the DEA for a list of drug take back locations for consumers. The committee directed board staff to work with Dr. Castellblanch on posting the link to the board's website.

Steve Gray from Kaiser indicated the board needs to ensure the list from the DEA is for consumers and not for a specific drug take-back day or for pharmacies to dispose of drugs. Dr. Gray noted that the DEA sites are for controlled substances and many county-run sites do not include disposal of controlled substances.

**16. Discussion on a Possible Regulatory Change to Require the Collection of Pharmacists' Email Addresses**

Chairperson Veale reported Business and Professions Code section 4003 (c) requires the board's executive officer maintain and update records containing the names, titles, qualifications and places of business of all persons subject to the Chapter 9. Further, 16 CCR 1704 requires all persons holding a license with the board to file a proper and current residence address with the board and to notify the board within 30 days of any and all changes in residence.

Ms. Veale noted that at the April 2016 board meeting, the board asked the Communication and Public Education Committee to discuss a possible requirement to collect pharmacists email addresses. Board staff did preliminary research and determined the fields in both the board's applicant and licensing tracking systems currently can accommodate the addition of this information. She noted that currently, the board has on record approximately 1,500 email addresses of the nearly 44,000 pharmacist licensees.

Ms. Veale referenced the information provided by staff in the meeting materials regarding the impact on workload to collect and maintain this information.

Ms. Veale also noted that currently, section 4013 of the Business and Professions Code requires all board-licensed facilities to subscribe to the board's email notification system.

The committee discussed the options of (1) requiring a pharmacist to maintain an email address with the board and (2) requiring pharmacists to sign up for email notification with the board's subscriber list. DCA Counsel Laura Freedman added that the board cannot mandate licensees communicate with the board electronically. She added that the board can say if a licensee has an email address, the licensee is required to provide it to the board.

Ms. Veale asked how the board might enforce the providing of the email addresses, if required. Ms. Herold added that inspectors can ask pharmacists during inspections to show what email address they have signed up for the board's email alert system.

Dr. Castellblanch stated he believes that email is a good way to communicate with licensees on issues such as naloxone, etc.

Ms. Freedman explained the email address is part of the address and believed the board can implement a requirement to provide this information via regulation.

Ms. Herold, Ms. Veale, and Dr. Castellblanch all agreed this matter needs to go to the board for discussion and final decision. Ms. Freedman confirmed that such a requirement can be implemented via regulation change, and be included with a pharmacist's license renewal.

**Motion:** Recommend that as a condition of license renewal, a pharmacist with an email address shall sign up for the board's email alert system, and self-certify on the renewal form that he or she has met this requirement.

M/S: Castellblanch/Sanchez

Chairperson Veale called for comment from the board and public.

Dr. Gray from Kaiser asked for clarification if the government is prohibited from mandating communication via email. Ms. Freedman clarified the self-certification question on the renewal would be worded as, "If the licensee has an email address, I certify my email address has been signed up for the board's email alert system." Dr. Gray inquired if this relieves the licensee of reporting a physical address. Ms. Freedman and Ms. Herold confirmed the licensee is still required to maintain a physical email address with the board. Ms. Veale confirmed one email address would be required.

Support: 3      Oppose: 0

## **17. Update on *The Script* Newsletter**

Chairperson Veale reported the Spring 2016 edition of *The Script* newsletter was issued

May 9, 2016. Board staff has begun writing articles for the Summer 2016 issue of *The Script*. There was no board or public comment.

#### **18. Update on Media Activity**

Chairperson Veale reported on the media activity for the board and referenced media activity provided in the Communication and Public Education Committee Chair Report. There was no board or public comment.

#### **19. Update on Public Outreach Activities Conducted by the Board**

Chairperson Veale reported on the public outreach activities conducted by the board and referenced materials provided in the Communication and Public Education Committee Chair Report. There was no board or public comment.

#### **20. Review and Discussion of News or Journal Articles**

Chairperson Veale reported on the news and journal articles collected as referenced in the meeting materials and provided by the Executive Officer to the committee members. Dr. Castellblanch stated he appreciated the articles Ms. Herold sends to the committee. There was no public comment.

#### **21. Future Meeting Dates**

Chairperson Veale reported the future meeting dates as September 8, 2016, and December 1, 2016. Ricardo Sanchez confirmed he is unable to attend the September 8<sup>th</sup> meeting.

Dr. Castellblanch revisited agenda item #14 - Discussion on Federal Legislation: US Senate 524 – Comprehensive Addiction and Recovery Act of 2016 and confirmed the bill passed the Senate on 3/10/16 and passed the House of Representatives on 5/13/16. Dr. Castellblanch noted that the two branches are now resolving differences.

Ms. Veale revisited agenda item #6 - Update and Discussion on Prescription Label Translations of Directions for Use, and requested that board staff have large NTC posters printed and available in Spanish. Ms. Veale asked board staff to bring to the next board meeting the large NTC posters in English and Spanish as well as the legal size posters translated in the other languages available on the board's website.

The meeting adjourned at 1:26 pm.