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

Victor Law, R.Ph., Chair
Debbie Veale, R.Ph., Vice Chair
Ryan Brooks, Public Member

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

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

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

3. **Discussion and Consideration of Recommendations for Patient-Focused Labeling Changes to California Law**

   a. Presentation and proposal from Chapman University School of Pharmacy

      At this meeting, the committee will have an opportunity to hear a presentation and proposal from Chapman University School of Pharmacy students recommending changes in patient-focused labeling requirements. A copy of the students' proposal is included in **Attachment 1.**

   b. Next Steps

      At this meeting, the committee will have the opportunity to discuss the recommendation made by Chapman University students as well as discuss any future steps the committee wishes to take based on the recommendation.

4. **Discussion and Consideration of Requirements Relating to Pharmacy Translations and Interpretations**

   At this meeting, the committee will have an opportunity to receive information and to discuss and consider recommendations to the board about laws and regulations related to prescription drug labels.

a. Presentation by Office for Civil Rights of U.S. Department of Health and Human Services on Final Rule Implementing Section 1557 of the Affordable Care Act (ACA) Regarding Nondiscrimination in Health Programs and Activities

The U.S. Department of Health and Human Services has issued a rule to implement Section 1557 of the Affordable Care Act, which forbids discrimination in health care on the basis of race, color, national origin, age, disability and sex. The rule took effect July 18, 2016.

The rule includes a requirement that health care providers that receive federal funding provide "meaningful access" to customers with limited English proficiency. The rule also requires providers to post taglines written in the top 15 languages spoken in the state by people with limited English proficiency. Taglines are short statements advising the public that interpreter and translation services are available free of charge.

At previous board and committee meetings, members have requested information about Section 1557 to determine whether the federal rule will have an impact on California laws and regulations, including requirements for prescription label translations. At this committee meeting, members will have an opportunity to hear a presentation about Section 1557 by a speaker from the HHS Office for Civil Rights.

Copies of a draft board newsletter article about the rule, a sample tagline (in English) and an APhA summary of key provisions of Section 1557 are in **Attachment 2**.

b. United States Access Board's Recommendations Related to Prescription Labels for Visually Impaired and Elderly Patients

At the May 2016 committee meeting, members discussed a set of recommended best practices for making information on prescription drug labels accessible to people who are blind, visually impaired or elderly. The recommendations were developed by a working group of stakeholders convened by the U.S. Access Board, a federal agency that promotes equality in access for people with disabilities.

The group developed more than a dozen specific recommendations, including:

- Follow universal patient-centered prescription drug container label standards.
- Make labels available in audible, braille and large-print formats.
- Ensure that duplicate labels preserve the integrity of the print prescription label.
- Do not impose an extra fee to cover the cost of providing an accessible label.

The group also reported a variety of technologies for providing accessible label information, including:

- Hard-copy labels printed in large type or braille.
- Digital voice or text-to-speech recorders.
- Radio Frequency Identification Device (RFID) tags.
- Smart devices and computers equipped with electronic braille, large text and audio technology.

At the committee's request, staff developed and posted a summary of the recommended best practices on the board's website. Staff also published the summary as an article – including website links to the working group's full report and a brochure version – in the summer 2016 issue of The Script. Copies of the brochure and *The Script* article are in **Attachment 3.**

This information is provided to the committee for discussion and consideration in recommending to the board possible changes in laws and regulations related to prescription drug labels.

c. NABP Request to Boards of Pharmacy Regarding Labeling Requirements for Emergency-Use Medications

NABP sent a letter asking state boards of pharmacy to review their requirements regarding the labeling of epinephrine auto-injectors and other similar emergency-administration medications by dispensing pharmacies. NABP states that EpiPens and similar emergency-use products represent a unique category of medications that must be given special consideration regarding their expiration dates.

The letter notes that many states require pharmacies to label dispensed prescription medications with a one-year expiration date or with the manufacturer-applied expiration date if less than one year form the date of dispensing. NABP requests that in situations where an EpiPen has not been removed from the original packaging, states allow a waiver for the EpiPen to be maintained and administered beyond the labeled one-year expiration date through the manufacturer-applied expiration date.

At this meeting, committee members will have an opportunity to discuss the NABP letter and consider what recommendations, if any, to make to the board. For the committee's reference, CCR section 1718.1 states:

> 1718.1. Manufacturer's Expiration Date.
> All prescription drugs not bearing a manufacturer's expiration date pursuant to Title 21, Code of Federal Regulations, section 211.137 are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed by any manufacturer, distributor, pharmacist, pharmacy or other persons authorized to dispense such drugs in California.

Business and Professions Code section 4119.3 establishes labeling requirements for epinephrine auto-injectors. BPC section 4076(a)(9) requires that prescription container labels include "the expiration date of the effectiveness of the drug dispensed."

Copies of the NABP letter and BPC sections 4119.3 and 4076 are in **Attachment 4.**

d. Necessary Modifications to Pharmacy Law or Regulations relating to Translation and Interpretation Services, if any

At the December 2016 board meeting, members discussed the possible impact of the Section 1557 implementation rule on California pharmacy law.

Staff reported that a cursory review indicated the Section 1557 rule would have a limited impact on California pharmacy laws and regulations. Staff noted that the federal requirement for taglines resembles the "Point to your language" requirement in CCR section 1707.6(c).

- The Section 1557 rule requires that taglines be provided in the top 15 languages spoken in the state by people with LEP. In California, those languages are Spanish, Chinese, Vietnamese, Tagalog, Korean, Armenian, Persian (Farsi), Russian, Japanese, Arabic, Panjabi, Mon-Kher/Cambodian, Hmong, Hindi and Thai. (Sources: U.S. Department of Health and Human Services, Office for Civil Rights; CA Department of Finance.)

- CCR section 1707.6(c) requires "point to your language" text to be printed in 12 specific languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog and Vietnamese.

At the December 2016 board meeting, President Gutierrez asked the Communication and Public Education Committee to review the federal rule and its impact on state regulations and to return with a recommendation to the board. Committee members also agreed to review recommended best practices for making prescription labels accessible to patients who are blind, visually impaired or elderly.

5. <u>Discussion and Consideration of Naloxone Matters</u>

a. SB 833 (Committee on Budget and Fiscal Review, Health, Chapter 30, Statutes of 2016)

At the September 2016 committee meeting, staff reported that SB 833 requires the California Department of Public Health to award funding to local health departments, local government agencies, community-based organizations or regional opioid prevention coalitions to support or establish programs that provide

naloxone to first responders and at-risk opioid users through programs that serve at-risk drug users. Committee members discussed the possibility that pharmacist organizations might be eligible for SB 833 funding to increase naloxone availability.

Update: Staff contacted CDPH to ask whether pharmacies might be eligible to apply for SB 833 grants. Holly Sisneros of the Prescription Drug Overdose Prevention Initiative at CDPH has informed staff that CDPH is currently working to implement SB 833. She added that the funds would most likely go to local health departments so that they can distribute naloxone to eligible agencies within their jurisdictions.

b. Federal Legislation: US S. 524 – Comprehensive Addiction and Recovery Act of 2016 (CARA) - Provisions Regarding Partial Fills for Schedule II

At the September 2016 committee meeting, members discussed a potential conflict between Section 702 (f)(2)(A)(ii) of CARA and California law. At the October 2016 board meeting, staff provided the following clarification from legal counsel:

> Pursuant to the Comprehensive Addiction and Recovery Act of 2016 (CARA), 21 USC §829(f) would be another situation where partial filling of a Schedule II controlled substance would be allowed provided the prescription is a valid prescription and the pharmacist exercises their corresponding responsibility when filling a controlled substance prescription:
>
> (1) If requested by the patient or practitioner with no fill after 30 days from date written (21 USC §829[f]).
>
> (2) For a terminally ill patient marked as "terminally ill," tendered within 60 days from date issued and no more dispensing after 60 days from date of issuance (CCR 1745[a][2] and [c], H&SC11159.2, 21CFR1306.13[b]).
>
> (3) For a Long Term Care Facility patient marked as "LTCF", tendered within 60 days from date issued and no more dispensing after 60 days from date of issuance (CCR 1745[a][1] and [c], 21 CFR 1306.13[b]).
>
> (4) When a pharmacy doesn't have enough, dispenses a partial with the balance within 72 hours (21 CFR 1306.13[a] and CCR 1745).

An article about this topic is planned for *The Script* scheduled for print in Summer 2017.

c. Availability of Naloxone at Pharmacies in Specific Communities, including Los Angeles County

In public comments regarding items not on the agenda at the January 2017 board meeting, Dr. Rebecca Trotzky reported to the board that few pharmacies near Los Angeles County-USC Medical Center carry naloxone and that most are not aware of laws allowing pharmacists to furnish naloxone. Dr. Trotzky, an ER doctor, said a survey by her medical students found that only 2 percent of independent pharmacies and about 30 percent of chain pharmacies carried naloxone in stock. She urged the board to provide more education and outreach to pharmacists about naloxone and the law.

Board President Gutierrez invited Dr. Trotzky to speak about this issue at the committee meeting today. Dr. Trotzky has informed staff that she is available to address the committee meeting by phone after 10 a.m. today.

d. Walgreens Request to Use In-House Fact Sheet for Patients Receiving Naloxone

Walgreens sent a letter to the board requesting approval to use a Walgreens-specific naloxone fact sheet for patients receiving opioid antagonists. The fact sheet would be provided to Walgreens patients whose primary language is English. For patients whose primary language is not English, Walgreens would provide materials printed in alternate languages that are on the board's website.

CCR section 1746.3(b)(6) requires pharmacists to provide naloxone recipients with "a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available in alternate languages for patients whose primary language is not English."

The board's website carries naloxone fact sheets in English, Spanish, traditional Chinese, Korean, Russian, Tagalog and Vietnamese.

Copies of the Walgreens letter, the Walgreens fact sheet and the board's online fact sheet in English are in **Attachment 5.**

At this meeting, the committee will have the opportunity to discuss the request from Walgreens and determine if the committee would like to make a recommendation to Walgreens or to the board.

e. Outreach Efforts to Licensees Regarding Naloxone Protocol and Training/CE Requirements

At the September 2016 committee meeting, Ms. Veale reported to members that many pharmacies are not dispensing naloxone. She suggested that the board send out periodic subscriber alerts to remind pharmacists that they can dispense naloxone and to direct them to information about naloxone on the board's website.

Staff has taken outreach steps to help improve awareness of laws and regulations related to dispensing naloxone:

- Subscriber alerts were sent in October 2016 and March 2017 reminding pharmacists about the protocol in CCR section 1746.3, which authorizes pharmacists to furnish naloxone without a prescription. Staff will continue to issue reminder alerts periodically.
- A detailed article about the protocol, including requirements for CE training before dispensing naloxone, was published in the Summer 2016 issue of *The Script*.
- Ms. Herold sent information letters about the naloxone protocol to executive officers of the healing arts boards in October 2016.
- An easy-to-read chart summarizing training and CE required by protocols for naloxone, self-administered hormonal contraception, nicotine replacement therapy, and initiating and administer vaccinations has been posted on the board's website.
- Information about naloxone on the website has been reorganized for easier access, including a single Naloxone webpage under "Important Information for Licensees." The webpage contains links to information and press releases about the protocol, fact sheets, screening questions and the text of CCR section 1746.3.
- Staff cohosted a training forum on drug abuse topics March 11, 2017, in La Jolla, including a session on providing naloxone pursuant to the state protocol. Pharmacists who attended the day-long event received an extra hour of CE credit to fulfill the requirements of the naloxone protocol.

Staff is exploring additional opportunities to educate pharmacists about naloxone, including subscriber alerts, newsletter articles and training events. At this meeting, the committee will be able to discuss future outreach ideas.

6. <u>Update and Discussion on the Development of FAQs for SB 493 Related Items</u>

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

<u>Update</u>: FAQs were drafted by staff, reviewed by counsel and posted on the board's website. A copy of the FAQs is in **Attachment 6.**

7. <u>Update and Discussion of a Board-Developed Public Service Billboard Message and Related Communication Materials</u>

At the September 2016 committee meeting, members reviewed proposed concepts for a bulletin board message developed by staff at Mr. Brooks' firm. The billboard is

intended to encourage parents to talk to their children about prescription drug abuse. The committee recommended that the board proceed with a proposal featuring drawings of pills around the message "Unattended Drugs are the Leading Killer of Kids."

At the October 2016 board meeting, members agreed with the committee's recommendation and voted to sponsor the billboard message. Mr. Brooks said his firm would work with the executive officer to finalize the billboard message, identify locations and perhaps generate additional media exposure.

Update: Staff has reached out to the Prescription Opioid Misuse and Overdose Prevention Workgroup, which is a joint effort among state agencies (including the Board of Pharmacy) to develop collaborative strategies to curb prescription drug overdose deaths and addiction in California. Staff is working to ensure that the board's billboard project is consistent with communication strategies being developed by the workgroup's Communication and Outreach Taskforce.

8. Update and Discussion on Development and Implementation of Communication Plan for Reaching Consumers and Licensees

At the September 2016 committee meeting, members received copies of a draft communication plan that included aspects for both consumers and licensees. Staff developed the draft in accordance with the board's Strategic Plan. The committee approved the plan with continued modifications and updates.

At this meeting, committee members will have an opportunity to discuss and give further direction to staff regarding the communication plan. A copy of the updated plan can be found in **Attachment 7**.

9. Discussion of Efforts by Drug Manufacturers to Stop Illegal Sales of Non-FDA Approved Products

The sale of drug products from unlicensed sources – foreign or domestic – is a major concern for patients, pharmacists, prescribers and drug manufacturers. According to the Food and Drug Administration, there is a growing network of rogue wholesale drug distributors selling potentially unsafe drugs in the U.S. market.

Representatives of Allergan met recently and discussed with board staff their concerns about the illegal importation of non-FDA approved products. They described Allergan's efforts to shut down Amazon Medica, a foreign and unauthorized entity reported to be illegally selling Allergan Aesthetics products, including counterfeit products that are not FDA approved for use or distribution in the United States.

This item is presented for the committee's information. Copies of information about Allergan's efforts against Amazon Medica are in **Attachment 8.**

10. Update on the Status and Implementation of the Approved Regulation Title 16, CCR section 1707.5, Regarding Patient-Centered Labels for Prescription Drug Containers

The Office of Administrative Law has approved proposed amendments to CCR section 1707.5, regarding patient-centered labels. The amended regulation takes effect July 1, 2017.

The change requires require pharmacists dispensing a generic drug to list the generic name and the statement "generic for _____" where the brand name is inserted, and the name of the manufacturer. An exemption is allowed when, in the professional judgment of the pharmacist, the brand name is no longer widely used – in which case the patient-centered portion of the label may list only the generic name, while the manufacturer's name may be included inside or outside the patient-centered area of the label.

Information about the amended regulation was emailed to subscribers on March 7, 2017, and an article will be published in the next issue of The Script.

11. Update on *The Script* Newsletter

Staff is preparing articles for the next issue, which is set for publication in April 2017.

12. Update on Media Activity

The board's executive officer (unless otherwise noted) participated in the following media interviews and requests for information:

- **Glendale News Press,** Sept. 6, 2016: Alene Tchekmedyian, disciplinary case against Kenneth Road Pharmacy in Glendale
- **The Hollywood Reporter,** Sept. 21, 2016: Peter Flax, pharmacy law re providing false information for prescriptions
- **Chicago Tribune,** Oct. 6, 2016: Ray Long, patient consultation requirements
- **Wall Street Journal,** Oct. 14, 2016: Arian Campo-Flores, synthetic opioid U-47700
- **Kurtis Productions,** Oct. 21, 2016: Chris Tamalunas, precedential decision re Pacifica Pharmacy
- **Los Angeles Times,** Oct. 21, 2016: Soumya Karlamanga, hormonal contraception regulation
- **KTLA,** Oct. 25, 2016: Irving Last, UCLA Medical Center pharmacy
- **USC School of Journalism,** Nov. 1, 2016: Katie Giacobbe, self-administered hormonal contraception
- **ABC 7 News,** Nov. 1, 2016: Justin Mendoza, generic prescription drug prices

- **Pharmacy Today,** Nov. 30, 2016: Rachel Balick, pending drug take-back regulations
- **Noozhound,** Jan. 18, 2017: Sam Goldman, L.M. Caldwell Pharmacist
- **Santa Barbara Independent,** Jan. 18, 2017: Kelsey Brugger, L.M. Caldwell Pharmacist
- **Chicago Tribune,** Feb. 2, 2017: Ray Long, pharmacist duty to consult patients
- **KPIX,** Feb. 6, 2017: Molly McCrea, Naloxone sales in California
- **North Bay Business Journal,** Feb. 13, 2017: Cynthia Sweeney, automated drug-dispensing systems
- **Veterinary Information Network News Service,** Feb. 14, 2017: Edie Lau, compounding law changes affecting veterinarians.
- **California Health Report,** March 6, 2017: Jessica Portner, update on label translations requirements in AB 1073.

13. Update on Public Outreach Activities by the Board

Major public outreach activities provided by the board's staff:

Past events:

- Feb. 24: Ms. Herold presented on Pharmacy Law to 350 pharmacists at a CPhA event.
- March 7: Ms. Herold presented on the Board of Pharmacy to 80 pharmacy students at Touro University.
- March 8: Supervising Inspector Janice Dang presented on "Surviving as a PIC" to fourth-year students at Western University School of Pharmacy.
- March 11: Supervising Inspector Antony Ngondara presented on "Preventing Drug Thefts and Diversion from Pharmacies" during an educational forum cohosted by the board, DEA and UC San Diego Skaggs School of Pharmacy.

Future events:

- Future events are scheduled based on request and availability. There are currently no scheduled future events.

14. Review and Discussion of News or Journal Articles

Below are summaries of articles of possible interest to board members. Copies of the articles are in **Attachment 9.**

When Old Medicine Goes Bad
NPR
Feb. 7, 2017
Most of us have reached for a painkiller, at one time or another, only to discover the date on the label shows it has expired. But what does an "expiration" date on medicine

really mean? Is it dangerous if you take it anyway? Less effective? It turns out that date stamped on the label actually means a lot.

Rx for confusion? Medical officials disagree about what should be on labels
Free Lance-Star
Feb. 4, 2017
Donald Bley, a retired doctor, would like physicians to list on a label why a drug is being prescribed – to note if it's for high blood pressure or diabetes pain, acid reflux or insomnia. With the extra detail on the label, patients taking several medicines would know exactly how and when to take each, as well as which capsule is for what condition.

Is an indication-based prescribing system in our future?
ISMP
November 2016
Incorporating the purpose of medications on orders and prescriptions would benefit patients, pharmacists and other health care team members. Here are six reasons to build indication-based prescribing into electronic prescribing systems.

Majority of Opioid Medications Not Safely Stored in Homes With Children, Survey Finds
Johns Hopkins Bloomberg School of Public Health
Feb. 20, 2017
Nearly 70 percent of prescription opioid medications kept in homes with children are not stored safely, a new study by researchers at the Johns Hopkins Bloomberg School of Public Health finds. In a national survey of 681 adults who used opioid pain relievers in the past year and had children ages 17 and younger living with them, only 31 percent reported safely storing them away from their children.

Sixteen National Health Care Provider Organizations Partner to Raise Awareness of Rogue Drug Sites
.pharmacy news, December 2016
NABP reports on worldwide efforts to counterfeit drugs.

15. <u>Future Meeting Dates in 2017</u>

- June 28
- Sept. 20
- Dec. 13

Attachment 1

CHAPMAN UNIVERSITY | SCHOOL OF PHARMACY

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To the California Board of Pharmacy;

We are students and faculty from the Chapman University School of Pharmacy (CUSP), and today we write to you about the recent modifications to Title 16 CCR 1776-1776.6. We believe that the current modifications are a monumental step forward to improving the public safety concerns related to disposal of medications. With that, we also urge you to reconsider including hazardous drugs, such as oral anticancer chemotherapy, to the list of medications that are accepted through the proposed Prescription Drug Take-Back programs.

The mechanisms of action of these agents make it harmful to any organism that comes into contact with it, especially the anticancer chemotherapeutic agents. Currently, there are standardized guidelines for the safe handling and disposal of these agents in the hospital setting, as outlined in USP <800>. However, there is a lack of standard guidelines in the U.S. for the ambulatory, community, and home settings. Approximately 25% of 400 novel chemotherapy agents in development are oral agents with multiple-day dosing regimens[1]. The increased availability of oral chemotherapy drugs has shifted drug administration from a supervised to a self-managed setting. Regimens using oral chemotherapy drugs provide the convenience for self-medication at home; however, they increase the risks of cross contamination of the patient's home environment, resulting in unintended exposure to family, caregivers, and visitors. In addition, patients have a lack of access to sites for safe disposal of oral anticancer chemotherapy and its empty containers, which may contain cytotoxic residues. These issues are exacerbated by the patient and caregiver's lack of awareness that these medications are hazardous, as well as the common misconception that oral anticancer chemotherapy are less toxic than parenteral anticancer agents[2].

If non-hazardous prescription drugs already pose an issue to the environment when improperly disposed of, the potential damage from hazardous medications is monumental. As medication experts, it is our responsibility to be proactive to protect our patients, caregivers, and the public from potential harms caused by medications. We, as part of the American Pharmacists Association – Academy of Student Pharmacists (APhA-ASP), are currently proposing through the October 2016 APhA-ASP Midyear Regional Meeting to advocate for regional and federal legislations that will enhance the compliance of relevant stakeholders in the proper disposal of hazardous oral anti-cancer chemotherapy drugs, such as encouraging the Boards of Pharmacy to mandate proper identification of hazardous drugs through prescription labeling. We hope the proposed action will serve to address the concerns expressed in the current bill relating to the safe handling of the hazardous medication through the Medication Take-Back Program.

Thank you for your consideration.

Sincerely,

Michael Phan, PharmD Candidate 2018, CUSP

Thien Huynh, PharmD Candidate 2018, CUSP

Ani Haroutunyan, PharmD Candidate 2018, CUSP

Esther Shin, PharmD Candidate 2018, CUSP

Siu Fun Wong, PharmD

Sun Yang, BPharm, MS, PhD

References:

1. *Patton J. Increased use of oral chemotherapy drugs spurs increased attention to patient compliance. J oncol Pract 2008;4:175–177.*
2. *DeCardenas R, Helfrich JS. Oral therapies and safety issues for oncology practices. Oncology Issues 2010;(March/April):40–42.*

APhA Academy of Student Pharmacists

Region 8 Midyear Regional Meeting

Proposing APhA-ASP Chapter:
Chapman University

Proposed Resolution Title:
Regulatory Actions for the Safe Dispensing and Disposal of Oral Anticancer Chemotherapy

Proposed wording:

APhA-ASP proposes and advocates for regional and federal legislations that will enhance the compliance of relevant stakeholders in the proper disposal of hazardous oral anti-cancer chemotherapy drugs, such as encouraging the Boards of Pharmacy to mandate proper identification of hazardous drugs through prescription labeling.

Background Statement:
The mechanisms of action of some therapeutic agents make it harmful to any organism that comes into contact with it, especially the anticancer chemotherapeutic agents. Currently, there are standardized guidelines for the safe handling and disposal of these agents in the hospital setting, as outlined in USP <800>. However, there is a lack of standard guidelines in the U.S. for the ambulatory, community, and home settings. Approximately 25% of 400 novel chemotherapy agents in development are oral agents with multiple-day dosing regimens [1]. The increased availability of oral chemotherapy drugs has shifted drug administration from a supervised to a self-managed setting. Regimens using oral chemotherapy drugs provide the convenience for self-medication at home; however, they increase the risks of cross contamination of the patient's home environment, resulting in unintended exposure to family, caregivers, and visitors. In addition, patients have a lack of access to sites for safe disposal of oral anticancer chemotherapy and its empty containers, which may contain cytotoxic residues. These issues are exacerbated by the patient and caregiver's lack of awareness that these medications are hazardous, as well as the common misconception that oral anticancer chemotherapy are less toxic than parenteral anticancer agents[2].

According to Wong et al, several existing practices may have contributed to the barriers identified. Only 1 out of 86 patients' medication containers included in the practice model reported was labeled as hazardous material [3]. In addition, patients rarely received instructions on the proper handling and disposal of the hazardous drugs and its containers from the dispensing pharmacy [3]. Unsafe disposal of unused drugs or containers can lead to contamination of the water system and the environment at large, creating potential public health adversity. In fact, Alameda county enacted the first medication disposal ordinance in 2012. In addition, the city officials of Santa Cruz have said that its groundwater and drinking water are being contaminated by improperly disposed drugs that pass through water treatment

centers. As a response, they have mandated the collection and disposal of unneeded medications and hazardous medical products. The city's Extended Producer's Responsibility Ordinance requires both pharmacies and pharmaceutical companies to address and meet these requirements by November 12, 2016. We propose to globally address these issues through the following criteria:

1) Mandate the inclusion of the hazardous symbol  as part of the label on prescription containers (B&P 4076). This will assure that all containers will be properly labeled upon furnishing the medication to the patient. The use of labeling will serve to refresh patients' memories to handle and safely dispose of their hazardous medications. It will also aid the disposal site personnel to accurately process these containers for waste management.

2) Enhance public access to proper disposal mechanisms. This can be achieved through collaborations with relevant stakeholders to improve availability by establishing programs and sites to promote proper disposal such as mail-back programs and take-back programs.

References:

1. Patton J. Increased use of oral chemotherapy drugs spurs increased attention to patient compliance. J Oncol Pract 2008;4:175–177.
2. DeCardenas R, Helfrich JS. Oral therapies and safety issues for oncology practices. Oncology Issues 2010;(March/April):40–42.
3. Wong SF, Bounthavong M, Nguyen CP, Chen T. Outcome Assessments and Cost Avoidance of an Oral Chemotherapy Management Clinic. JNCCN 2016;14:279-285.
4. Safe Storage and Disposal of Cancer Medications. Available at: http://www.cancer.net/navigating-cancer-care/managing-your-care/safe-storageand-disposal-cancer-medications. Accessed September 23, 2016.
5. Goodin S, Griffith N, Chen B, et al. Safe handling of oral chemotherapeutic agents in clinical practice: recommendations from an international pharmacy panel. J Oncol Pract 2011;7:7–12

Are there any adopted resolutions currently on the books related to this Proposed Resolution? Yes _x_ No___

If yes, please provide the number and title of the adopted resolution(s) as well as your rationale for the addition of this Proposed Resolution:

1987.2 Education and training of antineoplastic drugs

- This resolution focuses on safe handling of antineoplastic drugs among healthcare personnel
- Our proposed policy will focus more on training in the community setting, where patients receive their medications to take home. It also will focus on training patients properly on handling their medications.

1983.1 Safety and Antineoplastic Agents

- This resolution focuses on protecting personnel that handle antineoplastic agents, whereas this new proposal focuses on patients in the home setting.

2007.4 Proper Medication Disposal
- This resolution focuses on expired or unused medications
- This new proposed policy also includes empty vials that contain cytotoxic residues, as well as an emphasis on hazardous drugs

2012.3 Proper Medication Disposal and Drug Take-Back Programs
- The impact of the discussed class of drug is more detrimental to public than other kinds of medications.
- This new proposed policy focuses on proper education on labeling and handling, whereas other policies focus primarily on safe disposal.

Author of Proposed Resolution: Michael Phan, Thien Huynh, Ani Haroutunyan, Esther Shin
Author Phone Number: (949) 331-5285
Author Email Address: phan146@mail.chapman.edu

Attachment 2

NEW FEDERAL RULE REQUIRES 'MEANINGFUL ACCESS'

FOR CUSTOMERS WITH LIMITED ENGLISH PROFICIENCY

A new rule issued by the U.S. Department of Health and Human Services requires pharmacies to provide "meaningful access" to customers with limited English proficiency – including posting taglines written in at least 15 languages advising the public that interpreter and translation services are available free of charge.

The regulation implements Section 1557 of the Affordable Care Act, which forbids discrimination in health care on the basis of race, color, national origin, age, disability and sex. The rule went into effect on July 18.

A key section of the new regulation requires pharmacies to take reasonable steps to provide "meaningful access" for individuals whose primary language is not English and who have limited ability to read, write, speak or understand English. In such cases, pharmacies must offer an interpreter for oral communications and a translator for written paper or electronic communications.

The rule also spells out requirements for posting

- a comprehensive notice of nondiscrimination;
- a nondiscrimination statement, which is a single statement that the pharmacy does not discriminate on the basis of race, color, national origin, sex, age or disability in its health programs and activities; and
- taglines, which are short statements written in non-English languages indicating that language assistance services are available at no cost.

Within 90 days of the effective date of the rule, a pharmacy must post a notice of nondiscrimination and taglines in conspicuous public areas, on its website and on significant publications and communications targeted to beneficiaries, enrollees, applicants and the public.

Taglines must be written in **the top 15 languages** spoken in California by people with limited English proficiency. A sample tagline in Spanish:

- ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia linguística. Llame al 1-XXX-XXX-XXXX (TTY: 1-XXX-XXX-XXXX).

Also within 90 days of the effective date of the rule, pharmacies must post a nondiscrimination statement and taglines written in **the top two languages** spoken in California by people with

limited English proficiency in significant publications and communications that are small in size, such as postcards and tri-fold brochures.

HHS has posted samples of notices of nondiscrimination, nondiscrimination statements and taglines in English and 64 other languages on its website.

The implementation rule also spells out other requirements for providing meaningful access for individuals with limited English proficiency, including restrictions on who may serve as an interpreter. Pharmacies cannot require an individual to provide his or her own interpreter, nor use staff employees who are not qualified as interpreters. In addition, pharmacies cannot rely on an accompanying adult or minor child to interpret, unless the customer specifically asks that the adult act as an interpreter.

The new federal rule pre-empts California Code of Regulations section 1707. 6, which requires pharmacies to post "Point to Your Language" notices informing customers that free interpreter services are available in 12 specific languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Mandarin, Russian, Spanish, Tagalog and Vietnamese. The California State Board of Pharmacy is taking steps to bring state regulations into harmony with the federal regulation.

###

Appendix B to Part 92—Sample Tagline Informing Individuals With Limited English Proficiency of Language Assistance Services

ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1-xxx-xxx-xxxx (TTY: 1-xxx-xxx-xxxx).

New Federal Nondiscrimination Regulation Imposes Requirements on Pharmacies

On May 18, HHS and its Office of Civil Rights released the Nondiscrimination in Health Programs and Activities Final Rule. According to HHS, under the Rule, individuals are protected from discrimination in health coverage and care on the basis of race, color, national origin, age, disability and sex, including discrimination based on pregnancy, gender identity and sex stereotyping. In addition to implementing Section 1557 of the Affordable Care Act's prohibition on sex discrimination, the Final Rule also enhances language assistance for people with limited English proficiency and helps to ensure effective communication for individuals with disabilities. This regulation is applicable health care entities and providers receiving federal funds from HHS, such as health insurers, hospitals, physicians and pharmacies. Most of the provisions relevant to pharmacies take effect on July 18, 2016.

Compliance and Notice Requirements. The Final Rule requires entities to file an assurance of compliance (form HHS-690) as a condition of any application for Federal financial assistance[1] and to take continuous steps to notify the public regarding the following: (1) the entity does not discriminate; (2) the entity can provide free services and materials for those with limited English proficiency or a disability; (3) how to obtain aids and services; (4) contact method for the employee responsible for compliance; (5) the availability of a grievance procedure; and (6) OCR's contact information for discrimination complaints. Posting of such information must be in conspicuous physical locations, on entities' websites and in significant public communications. Translated resources made available by HHS for the purpose of satisfying notice requirements are available here.

Individuals with Limited English Proficiency (LEP). Covered entities must take reasonable steps to provide meaningful access for each LEP individual eligible to be served or likely encountered. The Proposed Rule listed relevant factors to consider when determining whether language obligations have been satisfied. The Final Rule only specifies one relevant factor - whether or not the entity had an effective and appropriate written language access plan. Although such a plan is not explicitly required by the Final Rule, APhA strongly encourages pharmacies to develop such plans to establish a framework to provide health care and services non-discriminatorily and the reasonable steps that will be taken to provide access to persons with LEP. HHS notes that substantial weight will be given to the nature and importance of the

[1] Nondiscrimination in Health Programs and Activities; Final Rule, 42 C.F.R. 92, §92.4 (2016) stating. "Federal financial assistance. (1) Federal financial assistance means any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal government provides or otherwise makes available assistance in the form of: (i) Funds; (ii) Services of Federal personnel; or (iii) Real and personal property or any interest in or use of such property, including: (A) Transfers or leases of such property for less than fair market value or for reduced consideration; and (B) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal government. (2) Federal financial assistance the Department provides or otherwise makes available includes Federal financial assistance that the Department plays a role in providing or administering, including all tax credits under Title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health-related insurance coverage for payment to or on behalf of an individual obtaining health related insurance coverage from that entity or extended by the Department directly to such individual for payment to any entity providing health-related insurance coverage."

program or activity and the particular communication in relation to whether language obligations have been satisfied.

The Final Rule reiterates that covered entities may not rely on family members, friends, and minor children to provide interpretation services. In addition, the Final Rule describes the skills needed for on-site staff able to provide interpretive services (i.e. qualified bilingual/multilingual staff standard). The Final Rule provides exceptions to these prohibitions, clarifies that the individual with LEP is not required to accept language assistance services[2] and encourages staff to record when language assistance services were offered and denied.

The Final Rule does not set thresholds for the number of languages assistance services that must be provided but does set a threshold for taglines — short statements written in non-English languages that indicate the availability of language assistance services free of charge. Covered entities must supply taglines in at least the top 15 languages spoken by limited English proficient populations statewide.

Individuals with disabilities. Covered entities must provide effective communications with individuals with disabilities and must adhere to federal law and standards of Title II of the Americans with Disabilities Act (ADA), which are more stringent standard. Under the Final Rule, covered entities must provide auxiliary aids and services to individuals with impaired sensory, manual or speaking skills, and certain facilities will need to conform for ADA 2010 accessible design standards. The rule does not adopt specific technology standards but does require covered entities to ensure that programs and activities provided in electronic or information technology are accessible to individuals with disabilities unless doing so would pose undue financial/administrative burden and would result in a fundamental alteration in the nature of the program or activity. If such conditions occur, the entity must provide information in another format that strives to ensure that individuals with disabilities have access to the services or benefits.

Sexual Orientation. The proposed rule does not resolve whether there is a prohibition of discrimination based on sexual orientation, but OCR will evaluate sexual orientation discrimination complaints to determine whether they involve discriminatory stereotyping of sexual attraction or behavior.

Exceptions to the discrimination rule. The proposed rule does not answer whether an exception exists for discrimination rooted in religious beliefs.

Enforcement. OCR will enforce section 1557 using the procedures detailed in Title VI of the Civil Rights Act. However, the procedures of the Age Act will be used in issues regarding

[2] Language assistance services may include, but are not limited to:
(1) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency;
(2) Written translation, performed by a qualified translator, of written content in paper or electronic form into languages other than English; and
(3) Taglines.

age discrimination. Covered entities must provide OCR with requested information in a timely manner or be at risk of being found in noncompliance. In such circumstances, OCR can apply enforcement tools, including suspension or termination of funding. Although OCR has discretion when evaluating efforts entities have taken to maintain and achieve compliance, good faith attempts are not a defense.

In addition to OCR's authority, individuals may sue directly under section 1557 in federal court, and compensatory damages are available in such actions.

Discrimination by insurers and in employee health benefit programs. The proposed rule also addresses discrimination by insurers and employee health benefit programs.

More information regarding the Final Rule is available here.

Summary of Key Requirements Affecting Pharmacies:

The compliance date of the below requirements is July 18, 2016 unless otherwise noted.

1. Designation of responsible employee (only if the covered entity has 15 or more employees)
   - Must designate at least one employee to coordinate its efforts to comply with and carryout out Section 1557 and this regulation's requirements, including investigation of any grievance or allegation that action would be prohibited by Section 1557 or this regulation)
   - **Tip:** Pharmacies that have a designated employee to satisfy standards under Section 504 or Title IX may use that individual to comply with Section 1557

2. Adoption of grievance procedures (only if the covered entity has 15 or more employees)
   - Must adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557 or this regulation)
   - **Tip:** Pharmacies that have a grievance procedure to satisfy standards under Section 504 may use that procedure to address disability claims under Section 1557 and all other Section 1557 claims, provided that the entity modifies the procedure to apply to race, color, national origin sex, and age discrimination
   - **Resource:** Example of a Section 504 grievance procedure that incorporates due process standards (http://www.hhs.gov/civil-rights/for-providers/clearance-medicare-providers/section-504-grievance-procedure/index.html)

3. File assurance of compliance form when applying for federal funding
   - Will be revised to include all civil rights law which covered entities must comply
   - **Resource:** Assurance of compliance form (HHS 690 Form): http://www.hhs.gov/sites/default/files/hhs-690.pdf

4. Training (encouraged, not required)

- Covered entities are encouraged, but not required, to train employees periodically on compliance with Section 1557. In the assumptions of the proposed rule, used to determine cost, it assumes that employers are most likely to train employees who interact with the public which is estimated to be 50% of employees. Pharmacists are included in the pool of staff anticipated to need training.
- **Useful resource:** To facilitate training that covered entities choose to provide, OCR will make available a training curriculum, and will engage in outreach and technical assistance to promote understanding of and compliance with the final rule (as of 5/25 this resource has not been made available)

5. Notices of nondiscrimination (a), taglines (b), and significant publications and communications (c & d) [*Pharmacies must comply within 90 days of the rule's July 18 effective date*]:
    - **a.** *Notice of nondiscrimination:* Must be placed in conspicuous physical locations where the entity interacts with the public (i.e. in store) and in a conspicuous location on the covered entity's website accessible from the home page of the covered entity's website – the notice posting must adhere to the following:
        (1) the covered entity does not discriminate on the basis of race, color, national origin, sex, age or disability in its health programs and activities;
        (2) the covered entity provides appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, free of charge and in a timely manner, when such aids and services are necessary to ensure an equal opportunity to participate to individuals with disabilities;
        (3) the covered entity provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency;
        (4) how to obtain aforementioned aids and services;
        (5) an identification of, and contact information for, the responsible employee (required if there are 15 or more employees);
        (6) the availability of a grievance procedure and how to file a grievance; and
        (7) how to file a discrimination complaint with OCR.
    - **b.** *Taglines*[3]*:* Must be in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States
        Tagline example: ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1-xxx-xxx-xxxx (TTY: 1-xxx-xxx-xxxx).

[3] Taglines mean short statements written in non-English languages that indicate the availability of language assistance services free of charge.

c. *Significant publications and significant communications* targeted to beneficiaries, enrollees, applicants, and members of the public (except those that are small-sized) posting must include:

Content: same as that of notices in physical locations/ website

Taglines: same as that of physical locations

d. *Significant publications and significant communications that are small-sized* (e.g.. postcards and tri-fold brochures) posting must include in a conspicuously visible font-size:

(1) Non-discrimination statement (the covered entity does not discriminate on the basis of race, color, national origin, sex, age or disability in its health programs and activities)

(2) Taglines: In at least the top two languages spoken by individuals with limited English proficiency of the relevant State or States.

Tip: A covered entity may combine the notice's content with the content of other notices if the combined notice clearly informs individuals of their civil rights under Section 1557 and this regulation.

Resource: Translated materials for covered entities (http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html): includes a sample notice of nondiscrimination, statement of nondiscrimination and taglines, all translated into various languages and developed for compliance with the regulation.

6. Take reasonable steps to provide meaningful access, free of charge and in a timely manner, for individuals with limited English proficiency to each individual with limited English proficiency eligible to be served or likely encountered in its health programs and activities
   - Must be provided free of change, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency
   - Specific requirements for interpreter and translation services (required if it is a reasonable step)
     - Offer a qualified interpreter[4] to an individual with limited English proficiency
     - Use a qualified translator[5] when translating written content in paper or electronic form

[4] Qualified interpreter for an individual with limited English proficiency means an interpreter who via a remote interpreting service or an on-site appearance:
(1) Adheres to generally accepted interpreter ethics principles, including client confidentiality;
(2) has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language; and
(3) is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

[5] Qualified translator means a translator who:
(1) Adheres to generally accepted translator ethics principles, including client confidentiality;Show citation box
(2) has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language; and
(3) is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

- Restrictions: Covered entity cannot:
    - Require a LEP individual to provide his/her own interpreter
    - Rely on an adult accompanying an individual with LEP to interpret or facilitate communication, exceptions are:
        i. Emergency involving imminent threat to safety of welfare of an individual or the public and no qualified interpreter is immediately available
        ii. Specific request from the LEP individual to have the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances
        iii. Rely on staff other than qualified bilingual/multilingual staff to communicate directly with LEP individuals
    - Additional requirements are listed for video remote interpreting services
- Language Access Plan: not required, but **APhA strongly encourages** covered entities to develop a language access plan to establish a framework to deliver health care and services non-discriminatorily and outline the reasonable steps that will be taken to provide access to persons with LEP

  Tip: Although individuals with LEP are not required to accept language assistance services, covered entities should document when such services are offered and the patients refuses them
  Resource: HHS Language Access Plan (2013)
  http://www.hhs.gov/sites/default/files/open/pres-actions/2013-hhs-language-access-plan.pdf (referenced in the Final Rule)

7. Take reasonable steps to provide meaningful access, free of charge and in a timely manner to provide effective communication for individuals with disability
    - A covered entity shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in health programs and activities

8. Must make accessible electronic and information technology programs or activities to individuals with disabilities unless there is undue financial and administrative burdens or a fundamental alteration in the nature of the health program or activity
    - Expectation to adapt: When undue financial and administrative burdens or a fundamental alteration exist, the covered entity must provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

9. Requirement to make reasonable modifications to policies, practices or procedures

- A covered entity shall make reasonable modifications to policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term "reasonable modifications" shall be interpreted in a manner consistent with the term as set forth in the ADA Title II regulation at 28 CFR 35.130(b)(7).

10. Covered entities that were required to adhere to the 2010 ADA Standards for Accessible Design prior to July 18, 2016 must comply with those standards for new construction or alteration prior to July 18, 2016
    - *If construction or alteration commenced on or after July 18, 2016:* Must comply with 2010 ADA Standards for Accessible Design.
    - *If a facility was not covered by the 2010 ADA Standards prior to July 18, 2016:* Must now comply with the 2010 Standards if the construction was commenced after December 18, 2017 (18 months after the effective date of the Final Rule).
    - *If a facility was constructed or altered in conformance with the 1991 Standards or the 2010 Standards:* Will be deemed to comply with the requirements of this section and other relevant sections noted in the Final Rule
    - *If a facility was constructed or altered in accordance with the Uniform Federal Accessibility Standards (UFAS)*: Will be deemed compliance with this section only if construction or alteration was commenced before July 18, 2016 and the facility or part of the facility was not covered by standards under the ADA
    - *Note:* According to the Final Rule "As nearly all covered entities under the final rule are already covered by the ADA standards, these changes impose a de minimis cost."

11. Evaluation of compliance – the Director shall consider:
    - Nature and importance of the health program or activity and the particular communication at issue, to LEP individual
    - Other relevant factors, including whether a covered entity has developed and implemented an effective written language access plan, the is appropriate to its particular circumstances, to be prepared to meet the obligation of this section

      Tip: A language access plan is not required, but APhA strongly encourages covered entities to develop a language access plan to establish a framework to provide health care and services non-discriminatorily and the reasonable steps that will be taken to provide access to persons with LEP
      Resource: HHS Language Access Plan (2013)
      http://www.hhs.gov/sites/default/files/open/pres-actions/2013-hhs-language-access-plan.pdf (referenced in the Final Rule)

Attachment 3

Best practices are a collaborative effort

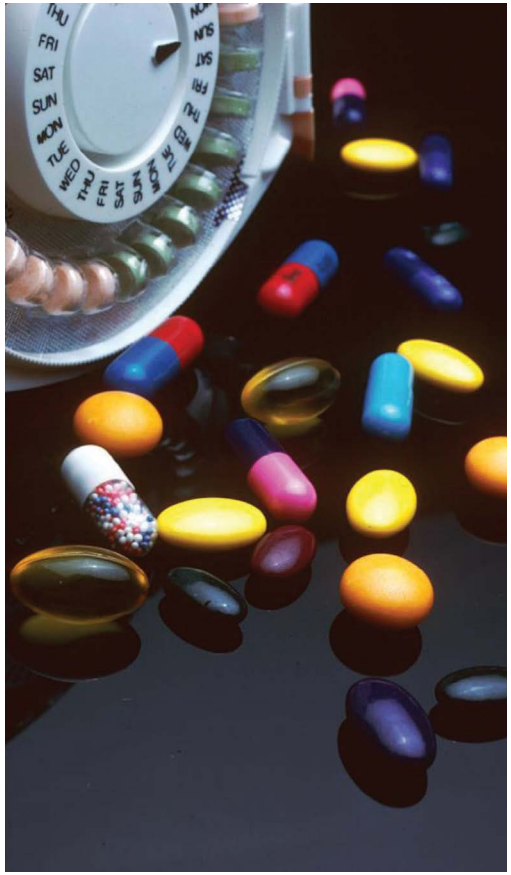
The U.S. Access Board's (www.access-board.gov) 18-member working group with representation of national disability organizations and industry groups representing retail, mail order, and independent community pharmacies, released best practices for how pharmacies can make their prescription drug labels accessible for blind, visually-impaired, or elderly customers.

This brochure contains a summary of delivery methods and best practices, and a link to the full report for more information.

National Council on Disability
1331 F Street, NW, Suite 850
Washington, DC 20004

Best Practices for Accessible Prescription Drug Labeling:

Pharmacies have a critical role to play to ensure the safety of blind, visually impaired, and elderly customers



"People with visual impairments who cannot read print prescription drug container labels all too often take the wrong medication, the wrong amount, at the wrong time, and under the wrong instructions… [They] 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."

—U.S. Access Board Working Group

Best Practices for All Formats

- Encourage patients and patient representatives to communicate their needs to pharmacists.
- Follow universal patient-centered prescription drug container label standards.
- Make available options for accessible prescription drug container labels in audible, braille, and large print.
- Explain the available accessible prescription drug container label format options, and provide it 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 when preparing accessible prescription drug labels.
- In advance, make arrangements to provide accessible prescription drug container labels by keeping a sufficient inventory of supplies.
- Provide prescriptions with an accessible prescription 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 container label and equipment dedicated for prescription drug container label access.
- 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 on the accessible label in the same sequence as the print label.
- Include in accessible prescription labels the information on warning labels added to the container at the pharmacist's discretion.

Best Practices Working Group Participant Organizations

AARP
American Council of the Blind
American Foundation for the Blind
Blinded Veterans Association
Council of Citizens with Low Vision International
Express Scripts
Metropolitan Washington Association of the Deaf Blind
National Association of Chain Drug Stores
National Community Pharmacists Association
National Council on Aging
National Council on Independent Living
National Federation of the Blind
National Council on Patient Information and Education
Rite-Aid
Target
US Pharmacopeia
Walgreens
Wal-Mart

Full Report

Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who Are Blind or Visually-Impaired or Who Are Elderly
http://go.usa.gov/cw3ZA

Contact Us

National Council on Disability
1331 F Street, NW, Suite 850
Washington, DC 20004
ncd@ncd.gov
www.ncd.gov

U.S. Access Board
1331 F Street, NW, Suite 1000
Washington, DC 20004
info@access-board.gov
www.access-board.gov

Federal Group Recommends Best Practices For Making Prescription Drug Labels Accessible To Blind, Visually Impaired, Elderly Patients

Federal best practices for prescription drug containers have been developed to make it easier for people who are blind, visually impaired or elderly to access label information.

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 stated 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.

Recommendations of the federal working group include:

- 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.

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

Attachment 4

NABP
National Association of Boards of Pharmacy
www.nabp.pharmacy

1600 Feehanville Drive
Mount Prospect, IL 60056
T) 847/391-4406
F) 847/375-1114

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: October 13, 2016

RE: Labeling Requirements for Emergency-Use Medications

As you are aware, there have been numerous reports related to the increasing price of epinephrine products and the impact on patient access; ie, EpiPen®. In an effort to further protect the public health and not place an undue financial burden on patients, NABP is respectfully urging state boards of pharmacy to review their current requirements regarding the labeling of epinephrine auto-injectors and other similar emergency-administration medications by dispensing pharmacies.

EpiPen auto-injectors, and other similar emergency-use medications, represent a unique category of medications for which special consideration must be given regarding the products' expiration dates. Many state laws or rules require pharmacies to label dispensed prescription medications with a one-year expiration date or with the manufacturer-applied expiration date if less than one year from the date of dispensing. In situations where an EpiPen has not been removed from the original packaging and has been stored under appropriate conditions, as determined by the pharmacist, NABP requests that states allow a waiver for the EpiPen to be maintained and administered beyond the labeled one-year expiration date through the manufacturer-applied expiration date.

NABP encourages state boards of pharmacy to adopt the above position or modify their position on labeling requirements for emergency-use medications. NABP also respectfully requests that if such allowances can be made that the information be shared with licensees and the public. NABP suggests including such information in the next state newsletter. Additionally, *NABP e-News* can serve as a vehicle to convey this information. NABP would be glad to work with states to provide such notice to their licensees and the public regarding pharmacy-labeled and manufacturer-applied expiration dates for these products.

cc: NABP Executive Committee

State of California

BUSINESS AND PROFESSIONS CODE

Section 4076

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

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

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

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

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

(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.

(Amended by Stats. 2015, Ch. 784, Sec. 1. (AB 1073) Effective January 1, 2016.)

State of California

BUSINESS AND PROFESSIONS CODE

Section 4119.3

4119.3. (a) Notwithstanding any other law, a pharmacy may dispense epinephrine auto-injectors to a prehospital emergency medical care person or lay rescuer for the purpose of rendering emergency care in accordance with Section 1797.197a of the Health and Safety Code, if both of the following requirements are met:

(1) A physician and surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed to a person described in subdivision (b) of Section 1797.197a of the Health and Safety Code. The physician and surgeon may issue the prescription only upon presentation of a current certificate demonstrating that the person is trained and qualified under Section 1797.197a of the Health and Safety Code to administer an epinephrine auto-injector to another person in an emergency situation. The prescription shall specify that the dispensed epinephrine auto-injector is for "First Aid Purposes Only" and that the named recipient is a "Section 1797.197a Responder." A new prescription shall be written for any additional epinephrine auto-injectors required.

(2) (A) The pharmacy shall label each epinephrine auto-injector dispensed with all of the following:

(i) The name of the person to whom the prescription was issued.

(ii) The designations "Section 1797.197a Responder" and "First Aid Purposes Only."

(iii) The dosage, use, and expiration date.

(B) Each dispensed prescription shall include the manufacturer's product information sheet for the epinephrine auto-injector.

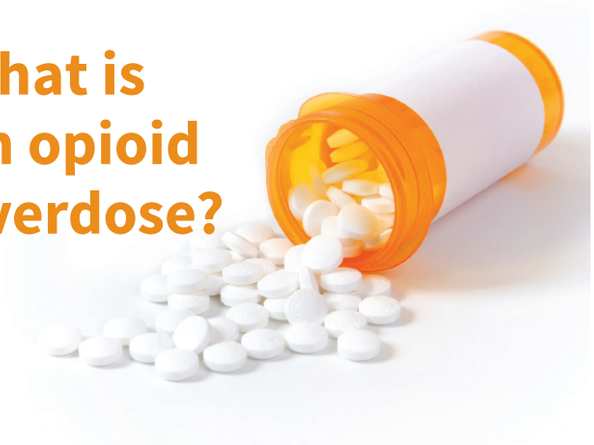
(b) The person described in subdivision (b) of Section 1797.197a of the Health and Safety Code receiving epinephrine auto-injectors pursuant to this section shall make and maintain a record for five years reflecting dates of receipt, use, and destruction of each auto-injector dispensed, the name of any person to whom epinephrine was administered using an auto-injector, and the circumstances and manner of destruction of any auto-injectors.

(c) The epinephrine auto-injectors dispensed pursuant to this section may be used only for the purpose, and under the circumstances, described in Section 1797.197a of the Health and Safety Code.

(Added by Stats. 2013, Ch. 725, Sec. 1. (SB 669) Effective January 1, 2014.)

Attachment

What is an opioid overdose?



Opioids can cause bad reactions that make your breathing slow or even stop. This can happen if your body can't handle the opioids that you take that day.

TO AVOID AN ACCIDENTAL OPIOID OVERDOSE:

- Try not to mix your opioids with alcohol, benzodiazepines (Xanax, Ativan, Klonopin, Valium), or medicines that make you sleepy.
- Be extra careful if you miss or change doses, feel ill, or start new medications.

Now that you have naloxone…

Tell someone where it is and how to use it.

Common opioids include:

GENERIC	BRAND NAME
Hydrocodone	Vicodin, Lorcet, Lortab, Norco, Zohydro
Oxycodone	Percocet, OxyContin, Roxicodone, Percodan
Morphine	MSContin, Kadian, Embeda, Avinza
Codeine	Tylenol with Codeine, TyCo, Tylenol #3
Fentanyl	Duragesic, Actiq
Hydromorphone	Dilaudid
Oxymorphone	Opana
Meperidine	Demerol
Methadone	Dolophine, Methadose
Buprenorphine	Suboxone, Subutex, Zubsolv, Bunavail, Butrans

* Heroin is also an opioid.

For patient education, videos and additional materials, please visit
www.prescribetoprevent.org

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

2016

Opioid safety and how to use naloxone

A GUIDE FOR PATIENTS AND CAREGIVERS

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

In case of overdose:

1 Check reponsiveness

Look for any of the following:

- No reponse even if you shake them or say their name
- Breathing slows or stops
- Lips and fingernails turn blue or gray
- Skin gets pale or clammy

2 Call 911 and give naloxone

If no reaction in 3 minutes, give second naloxone dose

3 Do rescue breathing and/or chest compressions

Follow 911 dispatcher instructions

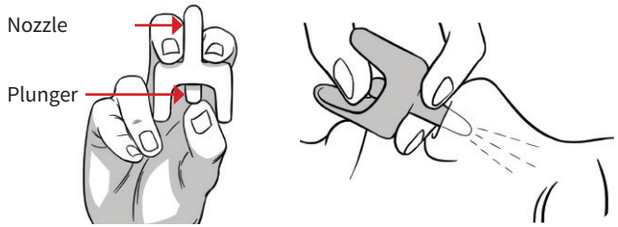
>> STAY WITH PERSON UNTIL HELP ARRIVES.

How to give naloxone:

There are 4 common naloxone products. Follow the instructions for the type you have.

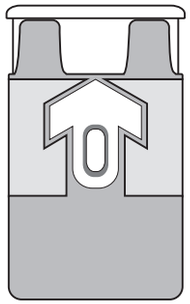
Nasal spray

This nasal spray needs no assembly and can be sprayed up one nostril by pushing the plunger.



Auto-injector

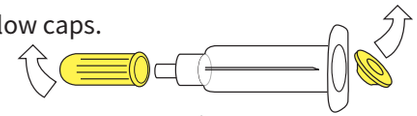
The naloxone auto-injector needs no assembly and can be injected into the outer thigh, even through clothing. It contains a speaker that provides step-by-step instructions.



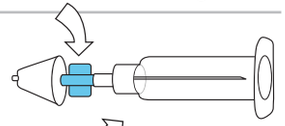
Nasal spray with assembly

This requires assembly. Follow the instructions below.

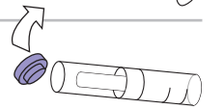
1 Take off yellow caps.

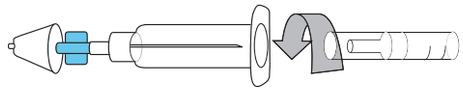


2 Screw on white cone.

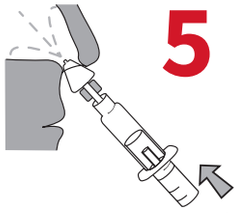


3 Take purple cap off capsule of naloxone.





4 Gently screw capsule of naloxone into barrel of syringe.



5 Insert white cone into nostril; **give a short, strong push** on end of capsule to spray naloxone into nose: **ONE HALF OF THE CAPSULE INTO EACH NOSTRIL.**

Push to spray.

6 If no reaction in 3 minutes, give second dose.

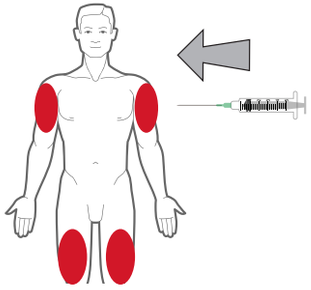
Injectable naloxone

This requires assembly. Follow the instructions below.

1 Remove cap from naloxone vial and uncover the needle.

2 Insert needle through rubber plug with vial upside down. Pull back on plunger and take up 1 ml.

3 Inject 1 ml of naloxone into an upper arm or thigh muscle.



4 If no reaction in 3 minutes, give second dose.

Lorri Walmsley, RPh
Senior Manager, Professional Affairs
Walgreen Company
5330 E. Washington St., D-105
Phoenix, AZ 85034
P 602-214-6618

January 3, 2017

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

Via Email: Virginia.Herold@dca.ca.gov

Dear Ms. Herold and the California State Board of Pharmacy,

Walgreen Co. intends to begin furnishing opioid antagonists at its locations in California in early 2017. Pursuant to California §1746.3(b) (6), I am writing to request approval from the California State Board of Pharmacy to utilize our Walgreen specific naloxone fact sheet for patients.

Walgreen Co. is currently providing opioid antagonists via pharmacist prescriptive authority or protocol in 34 other states and the District of Columbia. Our policy and procedure is to provide a patient medication leaflet along with a patient education fact sheet (enclosed) that auto-prints when the prescription is filled. This automated process for providing patient education materials has proven to be effective in the other locations where it has been implemented and has ensured that the patient has sufficient education materials once leaving the pharmacy.

We are proposing to use this same procedure for patients in California whose primary language is English. In order to fulfill the requirement for patients whose primary language is not English we intend to provide access through our intranet system to your website to print the materials in alternate languages.

I would welcome the opportunity to personally meet with you and all the members of the California State Board of Pharmacy in order to review this request. Also, I would send representation to a full board meeting to discuss further if that would be helpful. Your timely attention to this matter will be greatly appreciated.

Kindest Regards,

Lorri Walmsley

Lorri Walmsley, RPh
Senior Manager, Pharmacy Affairs

Enclosure: Naloxone Guide for Patients and Caregivers

Naloxone Guide for Patients and Caregivers

Walgreens at the corner of happy & healthy

The information provided below outlines how to recognize an opioid overdose and what do to if it ever occurs. It is important for you to share this with your family and friends. Create a plan of action so everyone knows the steps to follow in case of an emergency overdose situation. Notify family and friends where you plan to store naloxone so they can easily access the kit in case of an emergency.

What are opioids?

Opioids are generally prescribed to treat pain. When opioids are taken in high doses or abused, they can cause feelings of euphoria, relaxation, drowsiness, and warmth. If the individual takes too many opioids or combines them with other drugs or alcohol, this may cause problems such as difficulty breathing, loss of consciousness, cardiac arrest and even death.

What is naloxone?

Naloxone is an antidote for opioid overdose and reverses the effects of opioids. Naloxone only works if there are opioids present in the body and has no effect on other drugs or alcohol.

It usually takes 3-5 minutes for the medicine to work and lasts 30-90 minutes.

It is available for use during opioid emergency situations.

Common opioids include:

Buprenorphine	Suboxone, Subutex
Codeine	Tylenol #3
Fentanyl patch	Actiq, Duragesic
Hydrocodone	Vicodin, Norco
Hydromorphone	Dilaudid
Meperidine	Demerol
Methadone	Methadose
Morphine	MS Contin
Oxycodone	Oxycontin, Percocet
Oxymorphone	Opana

*Heroin is also an opioid.

Risk Factors for Overdose Anyone who uses prescription opioids or heroin are at risk for overdose. Other factors that may increase a person's risk include: switching between opioids, having a history of substance abuse or mental illness, mixing opioids with certain medications, taking opioids or heroin alone, recent emergency medical care after opioid intoxication, or having decreased tolerance but a high risk of relapse (i.e. recently completing a mandatory opioid detoxification or having abstained from use for a long period of time).

How to Avoid an Accidental Overdose:

- Do not adjust your own dose, skip doses, or take any extra doses.
- Do not abuse prescription opioids.
- Do not mix with other drugs and/or alcohol. *For Example*: anti-anxiety drugs like Xanax, Ambien, Ativan, Klonopin; anti-depressants; or cocaine.

STEPS to respond to an Overdose:

ACT IMMEDIATELY!

1. Recognize overdose
2. Call 9-1-1
3. Rescue breathing
4. Administer naloxone
5. Stay with person and continue rescue breathing until medical personnel arrive.

How to Identify an Opioid Overdose:

- Difficulty breathing, struggling to breathe, gurgling for breath, making deep snoring sounds
- Bluish lips and/or fingertips
- Pale, clammy skin
- Awake but unable to talk
- Small pupils
- Body very limp

STEP 1. Recognizing an Opioid Overdose

When an individual takes too many opioids the drug may block their ability to breathe, which may lead to coma or death.

1. Shout to see if the victim responds and gently shake their shoulder.
2. Rub your knuckles on their upper lip or up and down the front of their rib cage (**sternal rub**).
3. If patient is unresponsive, **CALL 9-1-1.**

STEP 2. Calling 9-1-1

When calling 9-1-1, it is important to share the following information:

1. Individual's breathing has stopped and they are unresponsive.
2. Exact location of the individual.
3. Whether or not naloxone has been given to the individual and if that helped.

STEP 3. Rescue Breathing

1. Place the individual on their back. Place one hand on their forehead and the other under their chin.
2. Tilt their chin up gently to open the airway.
3. Check to see if there is anything in their mouth blocking their airway, such as gum, toothpick, undissolved pills, syringe cap, fentanyl patch, etc. If so, remove it.
4. Pinch their nose with one hand and keep chin tilted up with the other hand. Create an airtight mouth-to-mouth seal and give 2 even, regular-sized breaths. Blow enough air into their lungs to make their chest rise. If the chest does not rise, make sure you pinch their nose and tilt their head back with each breath.
5. Give one breath every 5 seconds.

STEP 4. Administer Naloxone

- Follow the directions below to give either nasal spray naloxone or injectable naloxone.
- **Caution**: The naloxone medicine vial is glass so use hands to gently pry cap off.
- **Nasal naloxone note:** When twisting the glass medicine vial into bottom of plastic syringe, stop when you feel slight resistance. Naloxone will start to spray out the top of the white spray top. STOP!
- Remember to continue to give rescue breaths until emergency medical personnel arrive.
- Naloxone lasts for 30-90 minutes. Naloxone may wear off before the effects of the opioids are gone. The individual may experience overdose symptoms again if this happens.

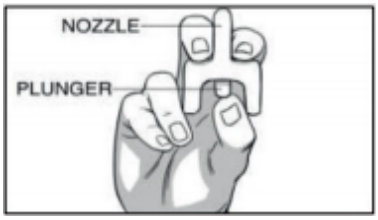
Narcan® Nasal spray

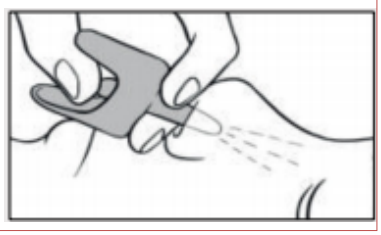
1. Remove Narcan nasal spray from the box. Peel back the tab with the circle to open the Narcan nasal spray.

2. Hold the Narcan nasal spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.

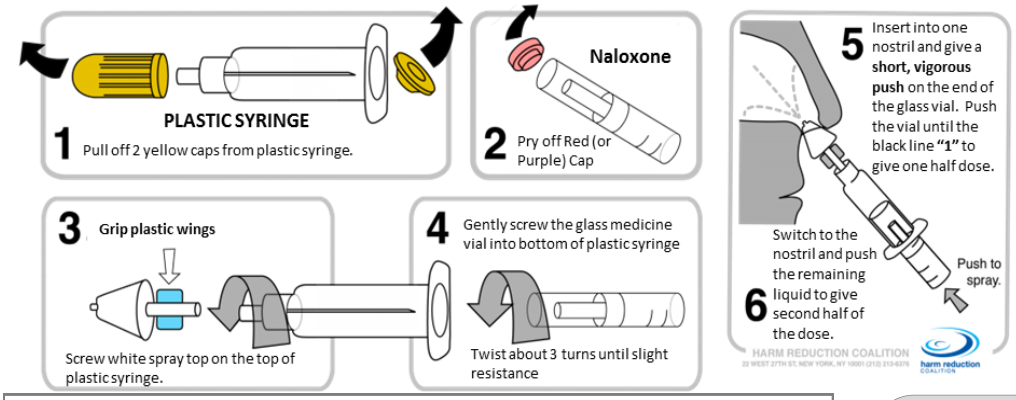
3. Gently insert the tip of the nozzle into either nostril. Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril, until your fingers on either side of the nozzle are against the bottom of the person's nose.

4. Press the plunger firmly to give the dose of Narcan nasal spray. Remove the Narcan nasal spray from the nostril after giving the dose.

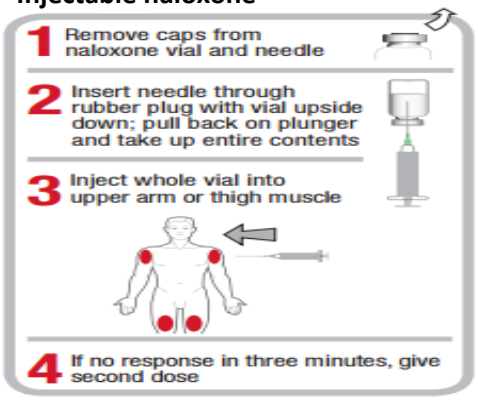




Nasal spray naloxone with atomizer



Injectable naloxone



Administering a second dose:

- If the naloxone did not work after you waited 2-5 minutes, you may give a second dose of medication.

⇒**Narcan Nasal Spray**: repeat step 2 every **2-3 minutes** until the person responds or emergency medical help is received.

⇒**Intranasal with atomizer**: if there is no change in **3-5 minutes**, remove the second naloxone medication from a new box and a new white spray top and repeat steps 1-4 to assemble. Then give the victim a second dose by giving one half of the dose in each nostril following steps 5-6.

⇒**Injectable naloxone**: if there is no change in **2-3 minutes**, repeat steps 1-4 to administer a second dose.

Recovery Position

If you have to leave the individual, even for a moment to call for help or to get naloxone, make sure to roll the individual over on their side with their top leg and arm crossed over their body. This position will help maintain an open airway. If they happen to vomit, this position will lessen the risk that they choke on their vomit.

Naloxone Storage Naloxone should be stored at room temperature and protected from light.

Important Resources:

Poison Control: 800-222-1222
Walgreens Pharmacy: 1-800-WALGREENS (800-925-4733)
www.prescribetoprevent.org
Information on local drug addiction treatment programs can be found by calling 877-SAMHSA-7 or by logging into: https://findtreatment.samhsa.gov/

Auto-injector:

The naloxone auto-injector, Evzio, is FDA approved for use in opioid emergencies. It comes with visual and voice instructions for injection into the thigh through clothing if necessary. The kit comes as a twin pack with 2 auto-injectors if a second dose is needed.

Signs of Withdrawal

If the naloxone is successful in overdose reversal the patient may experience withdrawal symptoms. Comfort the individual and keep them calm. An individual may experience withdrawal symptoms if the naloxone works to block the opioid in their system.

How to recognize Opioid Withdrawal:

- Dilated pupils
- Nausea, vomiting
- Agitation and anxiety
- Sweating

Walgreens
at the corner of happy & healthy

References: 1.) Massachusetts Department of Public Health. Opioid Overdose Education and Naloxone Distribution.
2.) Harm Reduction Coalition. Chicago Recovery Alliance. 3) San Francisco Department of Public Health. Opioid Safety and How to Use Naloxone.

Attachment 6

SB 493 FAQs

Self-Administered Hormonal Contraception Protocol Information

Q: Where can I find the information on the board's website about the self-administered hormonal contraception protocol?
A: This information can be found at:
http://www.pharmacy.ca.gov/licensees/hormonal_contraception.shtml

Q: Where can I find the actual self-administered hormonal contraception protocol?
A: The protocol can be found at 16 CCR §1746.1:
http://www.pharmacy.ca.gov/publications/hormonal_contraception_protocol_rphs.pdf

Q: What are the different methods considered as self-administered hormonal contraception for the purposes of this regulation?
A: Hormonal contraception products with the following routes of administration are considered self-administered:

- Oral;
- Transdermal;
- Vaginal;
- Depot Injection.

Q: Where can I find a copy of the self-screening tool required by the protocol?
A: The self-screening tool can be found at:
http://www.pharmacy.ca.gov/licensees/hormonal_contraception.shtml
Note: Patient self-screening tools are available translated into the following languages: Korean, Russian, Spanish, Tagalog, Traditional Chinese and Vietnamese. The translated versions can be found at: http://www.pharmacy.ca.gov/licensees/hormonal_contraception.shtml

Q: Does the pharmacy need to maintain a copy of the completed self-screening tool?
A: Yes, a copy of the most recently completed self-screening tool must be maintained for at least three years, from the date of dispense.

Q: What training is required prior to furnishing pursuant to this protocol?
A: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent, curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

SB 493 FAQs

Nicotine Replacement Therapy Protocol Information

Q: Where can I find the information on the board's website about nicotine replacement therapy protocol?
A: This information can be found at:
http://www.pharmacy.ca.gov/licensees/nicotine_info.shtml

Q: Where can I find the actual nicotine replacement therapy protocol?
A: The protocol can be found at 16 CCR §1746.2:
http://www.pharmacy.ca.gov/publications/nicotine_protocol.pdf

Q: What products are included in the nicotine replacement therapy protocol?
A: Prescription nicotine replacement products approved by the federal Food and Drug Administration and provided by a pharmacist for smoking cessation are covered under this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol.

Q: Where can I find the patient screening questions?
A: The patient screening questions can be found at
http://www.pharmacy.ca.gov/licensees/nicotine_info.shtml
Note: Patient screening questions are available translated into the following languages: Spanish, Traditional Chinese, Korean, Russian, Tagalog and Vietnamese. They can be found at:
http://www.pharmacy.ca.gov/licensees/nicotine_info.shtml

Q: What training is required for a pharmacist to provide nicotine replacement therapy under the protocol?
A: Prior to furnishing prescription nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of two hours of an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy.

Q: Is ongoing training required for the pharmacist to provide nicotine replacement therapy under the protocol?
A: Yes, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from an approved provider once every two years.

SB 493 FAQs

Vaccinations

Q: Where can I find the information on the board's website about vaccinations?
A: This information can be found at 16 CCR §1746.4:
http://www.pharmacy.ca.gov/about/vaccinations.shtml

Q: Where can I find the actual nicotine replacement therapy protocol?
A: The protocol can be found at:
http://www.pharmacy.ca.gov/laws_regs/1746_4_oa.pdf

Q: What training documentation must be maintained to provide immunizations under the protocol?
A: 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. **Note:** This documentation shall be kept on site and available for inspection.

Q: Is ongoing training required for the pharmacist to provide vaccinations under the protocol?
A: Pharmacists who practice or provide services pursuant to this protocol must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years. For information about the transition to CAIR2 please see the press release at the board's website: http://www.pharmacy.ca.gov/publications/cair.pdf

Q. What type of notifications is required after immunizations are provided by pharmacists under this protocol?
A: A pharmacist who participates in this protocol shall notify each patient's primary care provider of any vaccine 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 a 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. A pharmacist shall notify each pregnant patient's prenatal care provider, if known, of any vaccine administered to the patient within 14 days of the administration of any vaccine.

Q: Where can I find a copy of the sample appropriate vaccine administration record mentioned in the protocol?
A. A copy may be found at: http://www.pharmacy.ca.gov/about/vaccinations.shtml

SB 493 FAQs

Pending SB 493 Regulations

Q: What SB 493 regulations are pending?
A: Advanced Practice Pharmacist and Travel Medications regulations are pending.

Q: Where can I find the status of the pending SB 493 regulations?
A: The status of pending regulations can be found at:
http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml

Attachment 7

Communication and Public Education Communication Plan

The Board educates consumers, licensees, and stakeholders about the practice and regulation of the profession.

2017-2021

4.1 Develop and implement a communication plan for licensees and consumers to improve communication and keep these stakeholders better informed.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Develop plan and bring to committee for approval	Licensees and Consumers	List of tasks with corresponding: audiences, content/method, purpose , responsible parties and timing	To improve communication and keep stakeholders better informed	Staff, C&PE Committee	Completed September 2016
b. Provide direction and new assignments	Staff	Board, committee requests at meetings	To carry out board, committee requests to communicate with licensees, public	Board, C&PE Committee, Staff	Ongoing
c. Explore ways to engage more directly with licenses	Licensees	Solicit pharmacist input at board meetings, events	Foster dialogue, communication between licensees and board	Board, C&PE Committee, Staff	Ongoing

4.2 Identify and use additional resources for public and licensee outreach services to implement a communication plan.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Website	Licensees and Consumers	Post news, announcements online	Communicate immediate information to licensees, public	Staff	Ongoing
b. Newsletter	Licensees and Consumers	Publish news, announcements in formatted publication	Communicate to licensees, public	Staff	Quarterly
c. Subscriber alerts	Licensees and Consumers	Notices of recalls, regulations, news, important information	Communicate instantly to licensee, public	Staff	Ongoing
d. News archive	Licensees, Consumers	Website announcements, Script articles	Permanently archive web announcements in easy-to-find place	Staff	Completed January 2017
e. Topic pages	Licensees	Important information for licensees	Organize information by topic on easy-to-find webpages	Staff	Completed February 2017

4.3 Establish a process to collect email addresses and mobile numbers for text messaging, from all licensees for better ability to improve communications.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Research means to collect email addresses	Licensees	Mechanism to collect email addresses	To distribute information to licensees	Board staff C&PE Committee	TBD
b. Research means to collect mobile telephone numbers	Licensees	Mechanism to collect mobile telephone numbers	To distribute information to licensees	Board staff C&PE Committee	TBD

4.4 Educate licensees about the board's regulations by publishing summaries of all newly issued regulations and explain implementation tactics.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Inform licensees of new regulations	Licensees	Website Subscriber alert Newsletter	Disseminate information about new regulations	Board staff	TBD
b. Cohost training forum on drug abuse topics	Licensees	Training at live event	CE for licensees	Staff, DEA, UCSD School of Pharmacy	Completed March 2017
c. Produce CE courses	Licensees	Live sessions, webinar	Educate licensees on Pharmacy Law	Staff	2017

4.5 Inspect pharmacies at least once every four years to provide a forum for licensee-inspector communication and education in practice settings.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Inspect pharmacies at least once every four years	Licensee – pharmacies	Inspection	Forum for licensee-inspector interaction	Inspectors Board staff	TBD

4.6 Communicate the availability of new or specified pharmacy services and locations so that the public is aware of pharmacies that can meet their needs.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Naloxone availability at pharmacies	Consumers	Website	Inform the public	Board staff	TBD

4.7 Revise consumer-facing materials (e.g., posters, point-to-your-language notices, television messages) to achieve better consumer understanding of their rights and optimal use of medications.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Notice to Consumers	Consumers	Update regulation language	Inform consumers of rights	Board staff C&PE Committee	TBD
b. Point-to-your-language notice	Consumer	Update regulation language	Inform consumers of rights	Board staff C&PE Committee	TBD

Attachment 8

WHERE IN THE WORLD IS **AMAZON**MEDICA?

Amazon Medica, an online drugs distributor, is **illegally and fraudulently selling into the U.S. non-FDA approved** injectable pharmaceuticals for treating arthritic joint pain, chronic migraines, bladder dysfunction, upper limb spasticity, cervical dystonia, primary axillary hyperhidrosis, blepharospasm and strabismus, and for cosmetic use.

Amazon Medica claims as "Our Brands": Allergan; Merz Aesthetics; Q-Med (Galderma); Sanofi (Aventis, Genzyme); Ferring Pharmaceuticals; Fidia Farmaceutici; and Zimmer Biomet.

+ Claims to be **GREAT BRITAIN'S #1 pharmaceutical wholesaler** with affiliated UK pharmacy
+ Office listed in **LOS ANGELES** – **NO OFFICE EXISTS**
+ Name servers registered in **AMSTERDAM**
+ Site server registered in **SINGAPORE**
+ Domain registered by proxy company in **AUCKLAND, NZ**
+ Owner of website based in **KUALA LUMPUR**
  - Same owner founded **MagicGroup Asia** & **MagicLabs**
  - MagicGroup Asia & MagicLabs **specialize in digital advertising**

Product Protection Update

Allergan

Amazon Medica: Illegal seller of Allergan Aesthetics products

The situation

Amazon Medica is a foreign and unauthorized criminal entity that is illegally selling Allergan Aesthetics products, including BOTOX® Cosmetic (onabotulinumtoxinA) and JUVÉDERM® XC. Not only is the authenticity of the products Amazon Medica sells in question, but the "JUVEDERM ULTRA 2, JUVEDERM ULTRA 3, and JUVEDERM ULTRA 4" products it promotes and sells are not FDA approved for use and distribution in the United States. Any and all sales of Allergan Aesthetics products through Amazon Medica—counterfeit, compromised, or otherwise—is illegal. **This is a violation of federal law and, more importantly, puts patients' safety at risk.**

What Allergan is doing

Allergan is doing everything in its power to educate providers and patients, and to shut down Amazon Medica (see inside).

Please see specific actions that Allergan has taken against Amazon Medica on the following page.

BOTOX® Cosmetic (onabotulinumtoxinA) Important Information

Indications

Glabellar Lines

BOTOX® Cosmetic (onabotulinumtoxinA) for injection is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

Lateral Canthal Lines

BOTOX® Cosmetic is indicated for the temporary improvement in the appearance of moderate to severe lateral canthal lines associated with orbicularis oculi activity in adult patients.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX® Cosmetic and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses, including spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and upper limb spasticity and at lower doses.

Please see additional Important Safety Information on following pages.

Amazon Medica: Illegal seller of Allergan Aesthetics products

What Allergan is doing (continued)

Actions that Allergan has taken:

- Notified Amazon Medica and its known employees that their activity violates federal law and endangers patients
- Working with organizations and companies to impede Amazon Medica's ability to do business
- Successfully removed Amazon Medica's promotional video from *YouTube*®

Risks for you, your practice, and your patients

- Federal law prohibits non-FDA–approved drug importation
  - These products may be counterfeit or compromised, and can pose a health risk to your patients. The identity, purity, and source of these products are unknown

What you can do

- **Continue to let us know about any intelligence** you receive on Amazon Medica. Please send information to your Allergan representative
- **Rest assured** that Allergan is doing everything in its power to protect patients and providers by shutting down Amazon Medica in the same manner that Gallant Pharma, Medical Device King/Pharmalogical, and other foreign and unlicensed suppliers have been shut down
  - Read more about Gallant Pharma, Medical Device King, and the legal consequences of violating FDA regulations:
    - **Physician Guilty of Illegal Importation of Non-FDA-Approved Products:** www.fda.gov/ICECI/CriminalInvestigations/ucm397123.htm
    - **Pharmaceuticals President Sentenced to 60 Months in Prison:** Justice.gov/usao-edny/pr/president-pharmaceutical-companies-sentenced-60-months-prison-long-running-scheme-sell
    - **Convicted—$3.4M in Restitution and 3 Years Imprisonment for Gallant Head:** Justice.gov/usao-edva/pr/co-leader-illegal-drug-company-gallant-pharma-sentenced-3-years

Together, we can help protect our patients and the industry from illegal suppliers.

IMPORTANT SAFETY INFORMATION (continued)
CONTRAINDICATIONS
BOTOX® Cosmetic (onabotulinumtoxinA) is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation.

WARNINGS AND PRECAUTIONS
Lack of Interchangeability between Botulinum Toxin Products

The potency units of BOTOX® Cosmetic are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of BOTOX® Cosmetic cannot be compared to nor converted into units of any other botulinum toxin products assessed with any other specific assay method.

Please see additional Important Safety Information on following page.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Spread of Toxin Effect
Please refer to Boxed Warning for Distant Spread of Toxin Effect.

No definitive serious adverse event reports of distant spread of toxin effect associated with dermatologic use of BOTOX® Cosmetic (onabotulinumtoxinA) at the labeled dose of 20 Units (for glabellar lines), 24 Units (for lateral canthal lines), 44 Units (for simultaneous treatment of lateral canthal lines and glabellar lines) have been reported.

Serious Adverse Reactions With Unapproved Use
Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX® to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX®. The safety and effectiveness of BOTOX® for unapproved uses have not been established.

Hypersensitivity Reactions
Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such reactions occur, further injection of BOTOX® Cosmetic should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent and, consequently, the causal agent cannot be reliably determined.

Cardiovascular System
There have been reports following administration of BOTOX® of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease. Use caution when administering to patients with pre-existing cardiovascular disease.

Pre-existing Neuromuscular Disorders
Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from onabotulinumtoxinA (see *Warnings and Precautions*).

Dysphagia and Breathing Difficulties
Treatment with BOTOX® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Pre-existing Conditions at the Injection Site
Caution should be used when BOTOX® Cosmetic treatment is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle(s).

Human Albumin and Transmission of Viral Diseases
This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

ADVERSE REACTIONS
The most frequently reported adverse event following injection of BOTOX® Cosmetic for glabellar lines was eyelid ptosis (3%).

The most frequently reported adverse event following injection of BOTOX® Cosmetic for lateral canthal lines was eyelid edema (1%).

DRUG INTERACTIONS
Co-administration of BOTOX® Cosmetic and aminoglycosides or other agents interfering with neuromuscular transmission (eg, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX® Cosmetic may potentiate systemic anticholinergic effects.

The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX® Cosmetic.

USE IN SPECIFIC POPULATIONS
BOTOX® Cosmetic is not recommended for use in children or pregnant women. It is not known whether BOTOX® Cosmetic is excreted in human milk. Caution should be exercised when BOTOX® Cosmetic is administered to a nursing woman.

Please see accompanying full Prescribing Information including Boxed Warning and Medication Guide.

BotoxCosmetic.com 1-800-BOTOXMD BCT101925 09/16 163109

Attachment 9

shots

TREATMENTS

When Old Medicine Goes Bad

Listen · 2:07 Queue Download Transcript

February 6, 2017 · 4:38 AM ET
Heard on Morning Edition

PATTI NEIGHMOND

Heat and steam from your shower or shave can rob medicine of its potency long before the drug's expiration date.

Angela Cappetta/Getty Images

Most of us have reached for a painkiller, at one time or another, only to discover the date on the label shows it has expired. But what does an "expiration" date on medicine

really mean? Is it dangerous if you take it anyway? Less effective?

It turns out that date stamped on the label actually means a lot. It's based on scientific evidence gathered by the manufacturer showing how long the drug's potency lasts. Companies expose their medications to different environments, different temperatures and humidity levels to see just how long it takes for the medication to degrade to the point that its effectiveness is compromised.

The general rule, says pharmacist Mike Fossler, with the American College of Clinical Pharmacology, is that once a drug is degraded by 10 percent it has reached "the end of its useful life." If you take it months or even years past the expiration date, it's unlikely to do you any harm, he says; it just might not do you much good.

That may not be a big deal if you're treating a headache, but if you're fighting a bacterial infection with antibiotics like amoxicillin or ciprofloxacin, for example, using less than fully potent drugs could fail to treat the infection and lead to more serious illness.

Pharmacist Mohamed Jalloh, a spokesman for the American Pharmacists Association, says there's an even bigger reason not to rely on old drugs: antibiotic resistance. When you inadvertently "underdose" yourself by taking antibiotics that aren't full strength, he says, you run the risk that the bacteria you're battling will figure out not only how to defeat this weakened drug, but other antibiotics, too.

At least 23,000 people each year in the U.S. die from infections that have become resistant to antibiotics, according to the Centers for Disease Control and Prevention.

"If your medicine has expired, don't use it," concurs Ilisa Bernstein, deputy director of the office of compliance in the Food and Drug Administration's Center for Drug Evaluation and Research.

That goes for over-the-counter drugs, as well as prescription meds. Check the expiration date before even buying those pain relievers or allergy tablets, some pharmacists advise — the same way you check your milk. Buy the one with the date that's furthest away.

"Once the expiration date has passed," Bernstein says, "there is no guarantee that the medicine will be safe and effective."

Of course, even new drugs can quickly lose potency if they're not stored properly. Get those pills out of the bathroom "medicine cabinet" now, pharmacists say. The steam from your shower or shave kills pills fast.

"Medicines like the kind of environment that people like — a little dry and not too hot or cold," Fossler says. And, of course, don't take medication to the beach or leave it in a hot car. Like humidity, heat degrades a medicine's active ingredients.

Some medications are more vulnerable than others, so check the label. Insulin, certain immunotherapy drugs, and some children's pain relievers and cold remedies require refrigeration and protection from light.

And compared to capsules and tablets, "liquids are not as highly preserved," says Barbara Kochanowski, a scientist with the Consumer Healthcare Products Association. Liquid drugs can more easily become contaminated with bacteria and fungus.

Anytime you see a change in the color, odor or consistency of a drug — such as a cream turning into a runny solution — consider it a red flag, Kochanowski says, and consult your pharmacist. It's probably time to toss that medication.

Some drugstores, hospitals with pharmacies, drugmakers and drug-treatment centers have been authorized by the federal government, in recent years, to serve as "drug-take-back" sites for some drugs that are expired, or no longer needed. You can check the FDA and Drug Enforcement Agency websites for their latest guidance on the safest ways to dispose of various drugs.

medications expiration date antibiotic resistance prescription drugs infectious disease

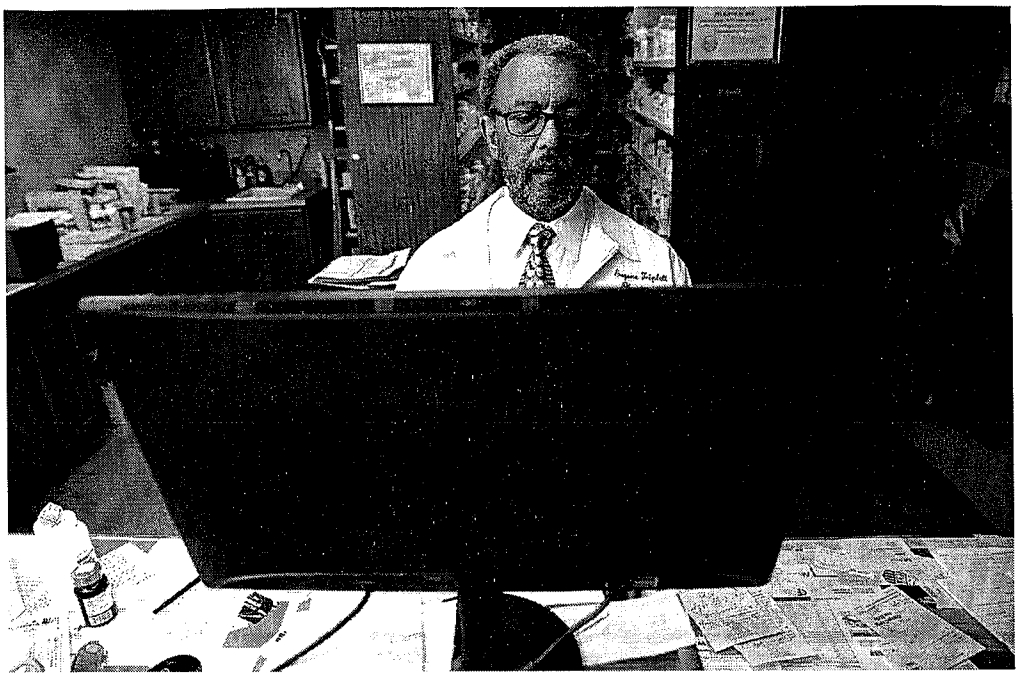
http://www.fredericksburg.com/features/health_living/rx-for-confusion-medical-officials-disagree-about-what-should-be/article_c56b3bcb-cb28-5356-ac6d-b8339f2f5435.html

EDITOR'S PICK | FEATURED

Rx FOR CONFUSION?

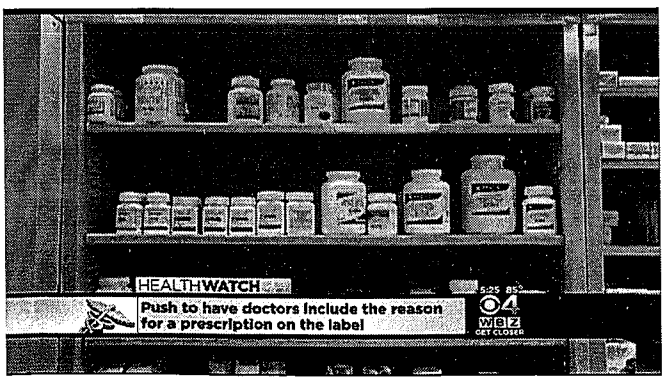
Rx for confusion? Medical officials disagree about what should be on labels

By CATHY DYSON THE FREE LANCE–STAR Feb 4, 2017



Suzanne Carr Rossi / The Free Lance–Star

Eugene Triplett, president of the Rappahannock Pharmacists Association, agrees it would be helpful for prescription labels to include the condition being treated.



Autoplay: On | Off

Donald Bley said he feels like a prophet in the wilderness, shouting about the need for more instructions on prescription labels.

The retired doctor, who spent more than 30 years in family practice and community health, would like fellow physicians to list on a label why a drug is being prescribed, to note if it's for high blood pressure or diabetes pain, acid reflux or insomnia.

With the extra detail on the label—and not just on the information sheet that comes with the drug—patients taking several medicines would know exactly how and when to take each, as well as which capsule is for what condition.

More information might be especially helpful for elderly patients who might get as many as four or more new prescriptions at one time. Even though doctors counsel the patients on the use of each drug, older people may forget the details.

"I can assure you I will not remember precisely how to take each drug before I reach the parking lot," said the 70-year-old, who lives in Spotsylvania County. "And I'm a doctor!"

Bley asked Del. Mark Cole to put forth a resolution in the Virginia General Assembly this year, and House Bill 1424 would have mandated that every prescription written in the state list the purpose for which the drug is prescribed.

It didn't go far.

The bill died in session, after two state health care groups quickly jumped on the bandwagon against it, saying the proposal would do more harm than good.

"The added administrative burden ... would be tremendous," responded the legal counsel for the Medical Society of Virginia. "We are concerned it would slow down the ability of physicians to timely see and treat their patients and hamper the ability to make necessary prescriptions."

The Virginia Hospital and Healthcare Association stressed that physicians and pharmacists already discuss medications with patients, and that those taking drugs can always ask more questions of those who write or fill prescriptions. That's the way to address the need for more information, the association's general counsel wrote, not to "create an unworkable burden on prescribers and pharmacies."

How difficult would it be to add a few words to a label? Would it really help patients?

The answer seems to depend on who you ask.

HEARTBEAT OR HEARTBURN?

In 2008, Bley wrote a guest column in The Free Lance–Star, asking other doctors to give patients more information on follow-up care when they leave hospitals. He spent four years in Culpeper as a hospitalist, a physician who deals exclusively with hospitalized patients.

"Consider that the patient is your elderly, widowed mother," he wrote. "Wouldn't you want her to have the best discharge instructions possible?"

He said the same goes for the medicine mom may take. In one of the scenarios presented in his prescription-label campaign, he described an elderly woman released from the hospital with nine new prescriptions.

When it came time for refills, she couldn't afford them all so she skipped a few. Because she didn't know which drug regulated her heartbeat and which helped with heartburn, she inadvertently stopped taking the more vital medication.

As a result, she ended up in the emergency room with a wildly irregular pulse.

"If she had been able to read on the label, 'Take one twice daily to stabilize heart rhythm' and 'Take one at bedtime for heartburn,' would she have made a better choice?" he asked.

In such a case, the patient would not be the only one feeling the pain. The hospital would have faced a financial penalty from Medicare for having the same patient readmitted for the same condition within 30 days.

'DOCTORS ARE BURDENED'

Pharmacists put on the label only what the doctor dictates. There are times when Eugene Triplett, owner of Wilderness Center Pharmacy in Locust Grove, has called a doctor and asked for more information about how a drug should be taken. If the doctor gives permission, Triplett puts the details on the prescription label.

The condition the drug is meant to treat is noted in about one out of 10 prescriptions, and that's usually when the medicine is prescribed for pain, said Triplett, president of the Rappahannock Pharmacists Association for 10 years.

"Yeah, it would be helpful" if doctors spelled out the condition, Triplett said, then added in the next breath that "it's not gonna happen. Doctors are burdened now. Their time is taken up with all the bureaucratic insurance, and it would be one more thing they would have to do."

He and Tina Kelly Bowling, who directs pharmacy services at the Moss Free Clinic in Fredericksburg and also works at a retail pharmacy, said one drug can be used to treat several, and differing, conditions.

Triplett fills a lot of prescriptions for drugs initially designed for people with epilepsy. But his customers don't take the drug to treat seizures; they take it for tingling or pain in the feet from diabetes.

That's what's known as "off-label use," when drugs are prescribed because of the side effect they produce. Likewise, Bowling said some early antidepressants didn't work well at treating depression, but did make people sleepy, so they're still prescribed, in low doses, for insomnia. And, a medicine typically used for high blood pressure can help with migraine headaches.

Both have seen people get confused about their medicine, as has Dr. Lisa Sarber at her practice of internal medicine in Spotsylvania.

"I'm amazed at the number of patients who have no idea what medications they take or why they are taking what they are taking," Sarber said. "I don't usually write the condition for which the prescription was written for, although I can see why this would be helpful."

'INFORMATION IS POWER'

Douglas Schulte, vice president of physician practice operations at Mary Washington Healthcare, agreed that "medication administration can be quite confusing. The improper use of medications is a serious cause of illness for patients."

While it would be nice to put more information on prescription labels, Schulte said there simply isn't room on the label—and he said it isn't practical for doctors to devote additional time to the task.

William Reese, a doctor with Reese Medical Associates in Spotsylvania, was more blunt about it.

"We are so over-regulated as it is that we spend more time on paperwork than on patient care," he wrote in an email. "Adding an additional burden on prescription writing is not necessary."

Schulte believes better patient care results when physicians and pharmacists alike take the time to educate patients on medicine and its side effects.

Patients have a responsibility, too, added Triplett the pharmacist.

"Just think about it, 50 years ago, they didn't even put the drug and what it was used for on the label, people just trusted the doctor," Triplett said. "Information is power, and in this day and time, patients have to take control of their own health care."

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THE SURVEY SAYS ...

In researching this story, Reporter Cathy Dyson asked acquaintances to look at their prescriptions and share what was on the label in terms of dosage or condition.

None of the 35 labels listed "take as directed." All gave a specific dosage, such as "take one pill daily by mouth."

Four of the 35 labels specified what the medicine was supposed to treat. Two said to take as needed for pain and two said the same for coughing.

Cathy Dyson

November 2016 • Volume 15 Issue 11

ISMP

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Is an indication-based prescribing system in our future?

In the July 28, 2016, issue of *The New England Journal of Medicine*, Schiff et al.[1] provide a compelling argument in favor of incorporating indications into the medication ordering process. A longtime proponent (along with ISMP and other organizations) of including the purpose of medications on orders and prescriptions, Schiff et al. note that, since most prescriptions and medication orders are now electronic, the format for implementing indication-based prescribing is within our grasp. The authors suggest that electronic prescribing systems are currently handicapped because they do not include the indication, alluding to the fact that, although legibility issues have been resolved with electronic prescribing, the risk of errors is still present due to the complexities with drug choices and regimens, and the risk of selecting the wrong medication among several look-alike drug names from a drop-down list. The authors suggest it's time to enter the age of reason in medicine and believe that indication-based prescribing is the missing link with electronic prescribing. As such, they are currently building and testing a prototype, funded by the Agency for Healthcare Research and Quality (AHRQ), that will enable electronic indication-based prescribing to be achieved.

Potential Benefits of Indication-Based Prescribing

(1) Helps prevent errors by narrowing medication choices

One in every 1,000 medication orders in a hospital or prescriptions in a community/ambulatory pharmacy has been associated with selecting the wrong drug while prescribing, transcribing, dispensing, or administering medications.[2-5] One of the primary causes of these errors is drug name similarity.[6] In fact, **ISMP's List of Confused Drug Names** (www.ismp.org/sc?id=2832) comprises close to 400 different drug name pairs, which include only those that have been published in the *ISMP Medication Safety Alert!* acute care and community/ambulatory newsletters. Recent examples of published mix-ups between look-alike drug names, some of which have not yet been added to **ISMP's List of Confused Drug Names**, include:

- risperi**DONE** and r**OPINIR**ole
- hydr**OXY**zine and hydr**ALAZINE**
- **RAPAFLO** (silodosin) and **RAPAMUNE** (sirolimus)
- acetaminophen and aceta**ZOLAMIDE**
- penicill**AMINE** and penicillin

Many of these errors happened during order entry when selecting a drug from a computer drop-down menu or pick list.

For years, ISMP has recommended including the medication's purpose with prescriptions and hospital orders to prevent errors. Knowing the medication's purpose helps healthcare

continued on page 2—**Indication >**

SAFETY briefs

HIGH-ALERT

Confused drug names. ISMP recently received a report of confusion between two sound-alike drug names **TRESIBA** (insulin degludec) and **TARCEVA** (erlotinib). Tarceva, a kinase inhibitor for the treatment of metastatic non-small cell lung cancer and pancreatic cancer, was mistakenly documented on the patient's home medication and discharge lists instead of Tresiba. A nurse caught the error when reviewing the medication list with

continued on page 2—**SAFETY briefs >**

In deepest sympathy...

We were saddened to learn of the cancer-related death on October 22nd of one of the most respected medication safety researchers of our time, **Betsy Allan Flynn.** Dr. Flynn worked closely with Dr. Kenneth Barker at Auburn University (AU). Together they furthered methods for prospective monitoring of medication systems in hospitals and community pharmacies. They developed AU MEDS, which was later commercialized and adopted by a number of hospitals to help proactively identify flaws in their medication safety systems. Dr. Flynn was a co-investigator on over $5 million of research, and conducted studies in over 250 sites in the US, France, the United Kingdom, and Italy. She published or presented more than 125 papers. She is a former recipient of the ISMP Cheers Award, among many other honors and recognitions. She also served on the Institute of Medicine's Committee on Identifying and Preventing Medication Errors and the US Pharmacopeia Safe Medication Use Expert Committee.

> Indication—continued from page 1

practitioners avoid confusion between medications with look-alike names, as most are used for different purposes. It's also crucial to know the drug's indication when conducting an independent double check to prevent or detect drug selection errors, dosing errors, or wrong patient errors. If a check is needed, a second practitioner must match the drug's indication to the patient's diagnoses to verify that the medication is being used appropriately for the patient's condition, and that it is dosed properly for its intended use. Some medications have multiple uses, each with a different dosing schedule, such as oral methotrexate for oncologic or nononcologic indications and mefloquine and **MALARONE** (atovaquone/proguanil) for prophylaxis or treatment of malaria. Thus, providing information about the indication also helps prevent dose, dosage form, or dose frequency errors.

Schiff et al.[1] agree and suggest that, by providing an indication, medication choices, dosage forms, and dosing regimens are narrowed, so the risk of choosing the wrong drug, form, or dosing schedule is lessened. Pharmacists, nurses, and patients/families will be able to more easily recognize and intercept prescribing or dispensing errors.

(2) Helps empower and educate patients, increasing patient adherence

Knowing the indication helps patients and their caregivers keep their medications straight, and most patients prefer prescription labels that list the medication's indication.[7] Yet, according to Schiff et al.,[1] patients often do not understand why they are taking prescribed medications. Without this knowledge, patient adherence to the medication is decreased.[8]

Not knowing the purpose of prescribed medications has also led to patient misunderstandings, prescriber distrust, and a refusal to take the medication, particularly when drugs are used off-label. For example, ISMP has published several reports in which patients with head and neck pain were angry with their physicians after learning from a pharmacist or a drug information leaflet that amitriptyline, which had been prescribed by their physicians, was an antidepressant. Neither the patients nor the pharmacists were aware that the drug had been prescribed for an off-label use to treat neuropathic pain.

Additionally, not knowing the purpose of medications can contribute to diagnostic errors. Oto et al.[9] described two patients who had been prescribed car**BAM**azepine for neuropathic pain without clearly understanding the medication's intended use. After developing blackouts, the patients and their treating physicians, who had not prescribed car**BAM**azepine, inferred from the drug therapy that the patients had epilepsy. Both patients underwent unnecessary diagnostic tests and treatment.

(3) Improves communication with the healthcare team and patients/families

The entire healthcare team must have knowledge of the intended indication of prescribed medications to understand what is being treated, the desired outcome, and what to teach the patient.[1] For example, pharmacists should never be expected to dispense a medication without knowing its intended use for that specific patient, which typically is the case in community/ambulatory pharmacies. Would other health professionals feel that he or she is providing safe and quality care while working without this crucial information? For decades, pharmacists have advocated for including the indication on prescriptions, but prescribers were worried about confidentiality—a legitimate concern.

continued on page 3—Indication >

> SAFETY briefs cont'd from page 1

the patient at discharge. Including the purpose of the medication on medication lists as well as prescriptions can enable practitioners to match the drug's indication to the patient's condition.

OTC's with similar names but totally different ingredients. **CLARISPRAY** is fluticasone propionate, a corticosteroid nasal spray, which is generically equivalent to **FLONASE ALLERGY RELIEF**. In the upper right-hand corner of the ClariSpray package label (**Figure 1**, left), Bayer, the distributor of the product, notes that it is "from the makers of **CLARITIN**." Claritin is loratadine, an antihistamine. With this product association, similar package colors and graphics, and since each name starts with "CLARI-," it's possible that some patients may think that ClariSpray is a spray form of loratadine.

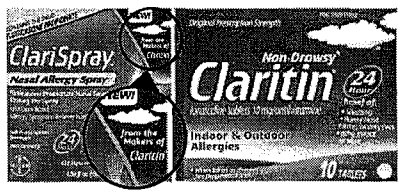

Figure 1. ClariSpray (L) is labeled "from the Makers of Claritin," but it doesn't contain loratadine (R).

Similarly, **MUCINEX ALLERGY** is fexofenadine, an antihistamine, and generically equivalent to **ALLEGRA ALLERGY**. However, despite carrying the Mucinex name, it doesn't actually contain guai**FEN**esin, an expectorant, which is the only ingredient in the original Mucinex product and included in most other Mucinex formulations.

No cases of mix-ups have been reported yet, but one reporter did indicate that the use of the Mucinex name for a non-guai**FEN**esin product has contributed to quite a bit of confusion in her long-term care facility. Please keep in mind the possibility of confusion and mix-ups if you have these products in your pharmacy. Consumers and pharmacists need to be aware of the differences between these products. If you encounter any errors with

continued on page 3—SAFETY briefs >

> **Indication**—continued from page 2

However, better communication with the healthcare team is still compatible with protecting patient information, and protections provided under the Health Insurance Portability and Accountability Act (HIPAA) allow for this communication between professionals who are providing care to the patient.

ISMP has previously published that, per the US Department of Health and Human Services (HHS), listing a medication's purpose or the patient's diagnosis on a prescription, for example, does not violate HIPAA.[10] Although a patient's diagnosis or purpose for using a medication would qualify as protected health information (PHI), communicating this information on a prescription does not require separate, special authorization because the information is used for the purpose of treating the patient. A violation would occur only if the prescription was then used for a purpose not defined by HIPAA, such as copying it for a marketing company. We've also heard concerns that listing a purpose on prescriptions may not meet the qualifications of providing only the minimum amount of information necessary to treat the patient. However, the "minimum necessary" rule does not apply when PHI is disclosed between providers treating the same patient.

For sensitive indications, such as those related to mental health or human immunodeficiency virus (HIV) infection, the authors note that systems could be designed to permit prescribers or patients to opt out of having the indication included on prescription container labels.[1] However, ISMP believes it might still be possible to include descriptions such as "for mood" or "for infection" on prescriptions and labels to communicate the drug's general purpose. In the end, inclusion of indications on the prescription and on the prescription container label may require different implementation strategies to advance indication-base prescribing as a standard of practice.

(4) Helps with medication reconciliation

As described by the authors,[1] an indication-based prescribing system could support the reorganization of the patient's medication list into a more logical grouping around indications, which makes the task of medication reconciliation infinitely less difficult and aids in the re-prescribing of medications during transitions of care. Knowing the reason why medications were prescribed for the patient, and grouping the drugs by indication, makes it easier to spot duplicates and permits an accurate evaluation of whether adjustments or discontinuations are in order.

(5) Helps prescribers choose the best medications for their patients

Prescribers need and want help choosing the best medications for their patients, while allowing them to make the final decision and maintain their autonomy.[1] With drug choices and regimens becoming increasingly complex, support for prescribing decisions would be an extremely important resource when using electronic systems. A system is envisioned in which prescribers could enter an indication, or click on a problem in the patient's problem list, and be presented with the best medications to choose from based on data in the patient's electronic health record. Such data includes allergies, current and prior medications (to avoid repeating a drug that previously failed), insurance coverage, and formulary requirements. The idea is that such an indication-based prescribing system could increase efficiency, support the selection and appropriate use of medications, improve documentation of the problem list, allow integration of the problem list with the prescribed medications, facilitate reimbursement coding, and streamline the prior authorization process.

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these products, please report them to ISMP at: www.ismp.org/merp.

HIGH-ALERT

More outpatient oral cancer drugs should be in blister packs. Certain oral cancer drugs would benefit greatly from safer packaging, such as child-resistant blister packs. We've asked the US Food and Drug Administration (FDA) to give this more consideration. Our medication safety colleagues at *Prescrire*, a French publication, recently wrote about a 30-month-old child who swallowed 8 tablets of mercaptopurine 50 mg (400 mg). The drug was actually prescribed for his 7-year-old sister with acute lymphoblastic leukemia. Although the child initially suffered liver cell damage, this resolved within 12 days, and there were no permanent sequelae. It was learned that the tablets were dispensed in a prescription bottle with a child-proof cap. It is unknown how the drug was actually accessed by the child. However, improperly replaced caps are a well-known problem with bottles.

Incidents like this one are a reminder that child-resistant blister packaging that meets the requirements of the Poison Prevention Packaging Act can help reduce the risk of poisoning. Still, it is critically important to remind patients to keep all medications and vitamins up and away and out of a child's reach and sight. Dispensing chemotherapeutic agents, and other hazardous drugs in blister packs, can also better protect pharmacy employees from exposure to hazardous drugs and prevent any potential cross-contamination that might occur if the drugs are counted on a counting tray that is not cleaned before use for a subsequent prescription. Also, blister packs designed as calendar packs can improve adherence in addition to preventing errors, including fatal oral methotrexate errors as a result of inadvertent daily instead of weekly dosing.

Revision to drug name pairs with tall man letters. As a result of ISMP and ISMP Canada harmonizing certain drug

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(6) Aids in measuring drug effectiveness and learning from off-label use

Schiff et al.[1] remind readers that a drug's effectiveness cannot be measured meaningfully without knowing its reason for use. Thus, an indication-based prescribing system would permit clearer assessments of drug effectiveness, could be used to support drug outcomes research, and could possibly provoke labeling changes or prescribing improvements, including with off-label drug use.

Addressing the Challenges

Because indication-based prescribing represents such a compelling opportunity to improve patient safety and quality, AHRQ has funded a 3-year project spearheaded by Schiff et al.[1] to create and test a prototype system while identifying and addressing the challenges inherent with its development and use. Rather than burdening prescribers with adding indications to prescriptions, the team is working with human factors and information technology experts and policy leaders to build an electronic prescribing system that will allow prescribers to start with an indication or the patient's problem list and then guide them toward the best medication choices.

Development of this prototype is not without its challenges. According to the team,[1] the key to designing the system is making sure it fits into and enhances the typical prescribing workflow and leverages other information technology systems. To date, some of the challenges associated with this process include:

- Defining the best terminology to use for the indications
- Differentiating billing codes for reimbursement versus drug indications
- Deciding how to manage empirical treatment when no definitive diagnosis exists
- Determining how to manage drugs given for multiple different indications
- Complexities in creating "smart" drug recommendations based on indications that incorporate patient allergies, contraindications, avoidance of current medications or past medications that have failed, and insurance or formulary restrictions
- Complexities in transmitting indication information between prescribing systems, pharmacy systems, and electronic health records
- Limited real estate for placing indications on prescription container labels
- The potential for inhibiting legitimate off-label use if the indications do not include these uses

Conclusion

We agree with Schiff et al.[1] that indications are a missing link connecting patients to their prescribed drugs, and that electronic prescribing systems must incorporate drug indications. We look forward to learning more about the development and testing of the prototype indication-based prescribing system.

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name pairs that utilize tall man letters, a change was made to two name pairs on the US **ISMP List of Look-Alike Drug Names with Recommended Tall Man Letters** (www.ismp.org/Tools/tallmanletters.pdf). The name pairs with revised tall man letters (followed by the other look-alike drug name in the pair in parentheses) are dil**TIAZ**em (diaze**PAM**) and s**AX**agliptin (**SIT**agliptin). We regret any confusion that this may have caused.

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Majority of Opioid Medications Not Safely Stored in Homes With Children, Survey Finds

REPORTED RATES OF SAFE STORAGE ESPECIALLY LOW IN HOMES WITH OLDER CHILDREN AND TEENS

Nearly 70 percent of prescription opioid medications kept in homes with children are not stored safely, a new study by researchers at the Johns Hopkins Bloomberg School of Public Health finds.

In a national survey of 681 adults who used opioid pain relievers in the past year and had children ages 17 and younger living with them, only 31 percent reported safely storing them away from their children. Among those homes with children 7 to 17 years old, just 12 percent reported safe storage.

The researchers defined safe storage as keeping the medication in a locked or latched place for homes with younger children and a locked place for homes with older children.

The findings appear in the March edition of the journal *Pediatrics*.

"Our work shines a light on the pervasiveness of unsafely stored opioids in American homes with children," says study lead author Eileen McDonald, MS, a faculty member in the Johns Hopkins Center for Injury Research and Policy. "Unsafely stored opioids can contribute to accidental ingestions among younger children and pilfering by older children, especially high school students. We know that teens who use these drugs recreationally frequently get them from homes where they are easily accessible, increasing their risk for addiction and overdose."

Overdose fatalities almost doubled among those 17 and younger between 1999 and 2015. In the last five years, more than 600,000 children of the same age were treated in U.S. hospital emergency departments for all types of poisoning. The 2014 National Survey on Drug Use and Health identified opioids as the second most common illicit drug-use category among 12- to 17-year-olds after marijuana.

The study also explored attitudes thought to be linked to medication storage habits. Nearly three-quarters, or 73 percent, agreed that children can overdose on opioids more easily than adults. Yet the survey found that just 13 percent of respondents "worry" about their children accessing their opioid medications, with parents of

older children reporting that they were significantly less likely to worry about children accessing medication than parents of younger children.

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The researchers say the findings support the need to not only educate families about the importance of storing pills safely but also to develop new technology, such as 'smart' packaging that only allows the prescribed person to open the bottle, to prevent older children from accessing the pills.

"Unfortunately, the current child-resistant packaging that was transformative in reducing medication poisoning in young children will not keep older children and teens safe," says Andrea Gielen, ScD, ScM, study senior author and director of the Johns Hopkins Center for Injury Research and Policy. "We need new packaging, such as tamper-resistant personalized pill dispensers, to make it easier for parents to keep these potentially dangerous medications inaccessible to older children. In the meantime, parents should keep their medications locked away and dispose of any leftover pills promptly and safely."

"Our findings should encourage pediatricians to ask patients about the presence of opioids in the home," McDonald says. "This paper also demonstrates the need to educate parents and children about opioid-related risks and how easily kids can access opioids that aren't under lock and key."

For their study, the researchers drew from a nationally representative GfK Group KnowledgePanel sample of nearly 5,000 adults to identify people who had used prescription opioids in the past year and lived in a home with children. The online survey was administered between Feb. 24 and March 16, 2015.

"*Pediatrics*" was written by Eileen M. McDonald, MS; Alene Kennedy-Hendricks, PhD; Emma E. McGinty, PhD, MS; Wendy C. Shields, MPH; Colleen L. Barry, MPP and Andrea Gielen, ScD, ScM.

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Committed to Safe Online Pharmacy Around the World

Sixteen National Health Care Provider Organizations Partner to Raise Awareness of Rogue Drug Sites

The Alliance for Safe Online Pharmacies (ASOP Global) is collaborating with 16 national health care provider organizations to encourage doctors, pharmacists, and other health care providers to educate patients about buying medication safely online. Along with the American Medical Association (AMA) and the American Pharmacists Association, NABP is among the partners in this initiative. "Helping patients understand their medical conditions and treatment options is just part of what we do," AMA President Andrew W. Gurman, MD, said in a December 15, 2016 news release. "In addition, we should talk with patients about all of their medications, including how to purchase them from a safe source – especially if they are considering buying them online."

More information about ASOP Global's health care providers campaign is available at *www.BuySafeRx.pharmacy*. ASOP Global is a nonprofit organization dedicated to protecting consumers around the world, ensuring safe access to medications, and combating illegal online drug sellers. ASOP Global and the Federation of State Medical Boards also worked with the United States Food and Drug Administration, University of California San Diego, and LegitScript to develop Internet Drug Sellers: What Providers Need to Know, a free online continuing education program for pharmacists and physicians.

NABP Informs EU Stakeholders About .Pharmacy as a Tool to Combat Counterfeit Drugs Globally

NABP representatives traveled to Brussels, Belgium, in mid-November 2016 to meet with regulators and stakeholders as part of the Association's continued efforts to raise awareness of the .Pharmacy Top-Level Domain Program and its role in combating counterfeit drugs. NABP met with representatives of the European Healthcare Distribution Association, the Pharmaceutical Group of the European Union, and the US trade mission to the EU. NABP and EU regulators also discussed the EU member

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states' implementation of the common logo, a mandatory, hyperlinked seal of approval demonstrating the validity of licensed internet pharmacies operating in the EU, and how the .pharmacy initiative might support and complement this program.

MHRA Gives 24 Reasons to Avoid Dangers of Fake Medicines Sold Online

The Medicines & Healthcare products Regulatory Agency (MHRA) of the United Kingdom created a FakeMeds advent calendar providing information in a festive format to educate consumers on the dangers of counterfeit medicines and the rogue internet drug outlets that sell them. Each day the advent calendar reveals a different fact to help consumers buy medicine safely online. The 10 square, for instance, quips, "Jingle bells, scammers sell fake meds on the net," and provides a counterfeit hotline number. This light-hearted tool is part of MHRA's ongoing campaign to raise awareness of a global public health threat. "The FakeMeds advent calendar is a seasonal way of drawing attention to the different aspects of falsified medicines," MHRA Senior Policy Manager Lynda Scammell says in a December 14, 2016 news release. "Anything like this that gets the message across in an engaging way is vital to help raise awareness."

WHO Modifies Fake Medicine Terminology to Prioritize Health and Safety Over IP

The term "counterfeit" implies a breach of intellectual property (IP) rights, which some say is not the primary issue when it comes to fake medicine. Due to this controversy, the World Health Organization (WHO) has been using the term "substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products" to describe this global public health threat. In a report issued on November 23, 2016, an informal working group convened by WHO recommended dropping the word "counterfeit" and using simply "substandard and falsified" to describe these medical products. According to the report, falsified medical products are considered to be "medical products that deliberately/fraudulently misrepresent their identity, composition or source."

Online Medication Sales Flourish in India Despite Ban

The sale of medicine over the internet is not allowed in India, but that rule has not stopped online drug sellers, according to a December 1, 2016 *Times of India* article. Sellers are taking advantage of recent financial turmoil in India to sell medicine at a discount online, the *Times* reports. The All India Organisation of Chemists has raised concerns about the unregulated sale of medicine over the internet, saying that it would lead to the misuse of dangerous and habit-forming medicines. While the practice is currently illegal, regulators in India are considering legislation that would allow the sale of medicine online.

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