



## COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

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

Report of the Communication and Public Education Committee Meeting held October 6, 2015.

**a. Requests for Waivers of Requirements for Patient-Centered Labels as Provided in California Business and Professions Code Section 4076.5(d) from: Coram CVS/Specialty Infusion Services**

The statutory requirements for patient-centered labels contain a provision that allows the board to provide a waiver from the requirements in certain circumstances.

Below are the provisions that provide the waiver from section 4076.5(d):

- (d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.
- (e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:
- (A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
  - (B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
  - (C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.
  - (D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.
- (2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

The board has heard several requests from several entities over the years, but has never approved a waiver.

The board received a waiver request from Coram CVS/Specialty Infusion Services.

At the October 2015 Communication and Public Education Committee, Ms. Lauren Berton, Director of Pharmacy Regulatory Affairs, CVS Health, which includes Coram CVS Specialty Infusion Services, and Patricia Igarashi, Pharmacist and Branch Manager in Hayward, California presented Coram CVS Specialty Infusion Services' request for waiver grant an exemption to Business and Professions Code section 4076.5 (e) (2) and California Code of Regulation section 1707.5.

A copy of Coram CVS/Specialty Infusion Services' request for waiver and presentation is included in **Attachment 1**.

The committee inquired further about the processes used by Coram CVS/Specialty Infusion Services and the exemption sought. Executive Officer Virginia Herold asked Ms. Berton if the labels used by Coram CVS Specialty Infusion Services are compliant with California pharmacy law. Ms. Berton stated that the labels currently used are not compliant with pharmacy law. Additionally, Mr. Brooks requested Coram brings a sample TPN bag to the full board meeting.

**Committee Recommendation (Motion):** Recommend to the board that Coram be granted a two year conditional waiver and Coram be required to self-report complaints to the board.

[**Note:** BioRx LLC. submitted a request for waiver to be considered at the Communication and Public Education Committee on October 6, 2015. However, BioRx LLC. did not send a representative to the meeting. The committee requested BioRx, LLC. attend the next committee to discuss their waiver request.]

**b. Survey Questionnaire with Regard to Patent Consultation Released in July 2015 for Revision for Future Use**

At the July Board Meeting, the board reviewed the results of a short questionnaire made available to the public via Survey Monkey regarding patient consultation. Over 1,000 individuals responded to this survey. A copy of initial survey and results are included in **Attachment 2**.

During the discussion on the results of the survey, there were questions raised about the quality of the questions themselves. The board asked that the committee take a look at the questionnaire and see if it could be improved.

At the October 2015 Communication and Public Education Committee, Chairperson Veale suggested the survey was a good place to start but preferred improving the survey and inquired to the resources within the Department of Consumer Affairs. Executive Officer Virginia Herold stated that the survey was strictly a temperature gauge to receive some answers on basic questions from the field for the board to discuss.

The committee discussed the content and results of the survey.

Mrs. Veale expressed concern that the board is not addressing issues such as consultation in the pharmacy. She stated the committee needs to know *why* consultation is not regularly performed, and whether the issue involves additional education, training, or staffing problems. Ms. Veale indicated the next step is doing something about the lack of consultations, but she is not comfortable moving forward solely based on this survey.

Ms. Herold suggested bringing the conversation to the full board. Ms. Veale indicated the committee must decide whether this survey was well done or is a more robust survey required.

**Committee Recommendation (Motion):** 1) Bring before the full board for discussion the results from the current limited survey, 2) Discuss if the committee should prepare a broader survey, and 3) Request legal options available to invoke change.

**c. Request to Augment Information on the Board's Website Regarding the State's Emergency Contraception Protocol**

For a number of years, California has had a protocol that allows pharmacists to provide emergency contraception to patients who request it. The protocol was developed by a group of sponsors for the enabling legislation, vetted and approved by the board and the Medical Board. A copy of Statutes and information regarding Emergency Contraception are included in **Attachment 3**.

Recently, the board received a request from Professor Sally Rafie, PharmD, BCPS, from UCSD's School of Pharmacy. In her request, Dr. Rafie provided information about components she believes would provide better information to pharmacists who provide emergency contraception and educational items for the public who may seek emergency contraception.

Additionally, Dr. Rafie requested the board's assistance in sharing a new emergency contraception reference for pharmacists and patients. She stated that she is aware of confusion about the regulations surrounding emergency contraception access with the numerous changes in the last few years.

At the October 2015 Communication and Public Education Committee Dr. Rafie joined the committee meeting via telephone call. The committee found Dr. Rafie's information included in the meeting materials to be very informative and her ideas of placement to expose these protocol facts to both the pharmacists and the public very clear and helpful. Chair Veale asked Ms. Herold if Dr. Rafie's materials were suitable for placement on the board's Web site and in *The Script*. Ms. Herold replied that she has sent the information to the Board's legal counsel and is waiting for an answer.

The committee also felt the first page of Dr. Rafie’s handout was helpful; however, the committee was concerned that the second page displayed actual products that may be misconstrued as board endorsement or advertising.

Ms. Herold also requested Dr. Rafie send the board a letter from the Reproductive Health Technologies Project or from another group that has been a proponent of the protocol over the years, stating that distributing this information would be a beneficial step for the cause, and thereby further validate placing the information on the board’s web site.

**Committee Recommendation (Motion):** Recommend to the board placing the information on the board’s Web site provided the product brand names, pictures, and prices are deleted, and request a follow up with legal counsel on appropriateness.

**d. October is “Talk About Prescriptions Month”**

Every October, the National Council on Patient Information and Education (NCPIE) promotes consumer education themes. This year, the theme is again “Talk About Your Medications Month.” The goal is to “focus attention on the value that better medicine communication can play in promoting better medicine use and better health outcomes.”

In their press release, NCPIE states:

The ultimate objective of any communication between patients and their healthcare providers is to improve the patient's health and medical care. Good communication is at the heart of good medicine. In fact, data have shown that patients reporting good communication with their health providers are more likely to be satisfied with their care, follow advice and adhere to the prescribed treatment. Of course, communication is a two-way street. Consumers need to be aware of the questions to ask, and healthcare providers in turn must be able to share medical information in a meaningful way that their patients are able to understand and act on. To that end, Talk About Your Medicines Month empowers both.

The board may want to promote patient consultation as part of the board’s contribution to this educational campaign, and for patient education.

At the October 2015 Communication and Public Education Committee, Ms. Herold stated that there would be a press release written by and issued this month from the addition of the board’s new Public Information Officer, Ed Selznick. A copy of the board’s press release will be available as a handout at the next board meeting.

A copy of the NCPIE Press Release and more information is included in **Attachment 4**.

**e. Redesign of the Board's Website**

Board Webmaster Victor Perez continues his work on redesigning the board's Web site to make it more user-friendly. A snapshot of the new design was provided at the July Board Meeting. Mr. Perez plans to complete the redesign by the end of the year.

At the October 2015 Communication and Public Education Committee it was announced that Mr. Perez will continue to work on the Web site with a goal of finishing the work by the end of 2015. At Mr. Brook's suggestion, the Chair and Vice Chair will review the Web site prior to release. The board may have another press release announcing the update.

**f. .Pharmacy Domain and Options for the Board to Distribute Public Information**

As discussed at prior meetings, the National Association of Boards of Pharmacy has established a .pharmacy (pronounced as "dot pharmacy") top level domain suffix system that will identify websites that comply with NABP's standards. This is like the "Good Housekeeping Seal" of approval. According to the NABP, of the 10,000 websites it has investigated, 97 percent do not conform to standard requirements for pharmacies. One component of the .pharmacy system is the offering to state boards of pharmacy the opportunity to establish .pharmacy websites for their use. The Board of Pharmacy's .pharmacy website is [www.CAboard.pharmacy](http://www.CAboard.pharmacy), which currently links to our [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) website.

At the October 2015 Communication and Public Education Committee Ms. Herold stated the California State Board of Pharmacy now has a suffix that leads directly into the board's Web site by typing in [www.caboard.pharmacy](http://www.caboard.pharmacy) and that half-the U.S. State Boards of Pharmacy, plus many legitimate national and international entities, are part of the .pharmacy community. A copy of the Internet Drug Outlet Identification Program Progress Report by NABP is included in **Attachment 5**.

Ms. Herold then presented a 60 second PSA developed by the NABP regarding the .pharmacy domain that has aired thousands of times on television and radio. The PSA may be viewed at <https://www.youtube.com/watch?v=OnHwDfH1MdU>.

Mr. Brooks suggested that the board should begin discussing possible legislation that can be introduced where any pharmacy or drug company selling into California is required to have the .pharmacy suffix. Mr. Brooks continued this would allow a consumer who does not see the .pharmacy designation to steer clear of what is quite possibly a counterfeit drugs operation. Dr. Castellblanch expressed concern for possible issues with federal commerce law. Mr. Brooks agreed and requested legal counsel to research potential conflicts and advise the committee.

**Committee Recommendation (Motion):** Discuss at the committee level possible legislation to require .pharmacy Web site address for all pharmacies and companies shipping into California as well as consult with Legal counsel.

**g. Status of Final Report on the Activities of the Prescription Drug Abuse Subcommittee**

Over the last two years, the board convened a Prescription Drug Abuse Subcommittee to deal with issues relating to prescription drug abuse. Seven subcommittee meetings were held. Minutes of these subcommittee meetings can be found on the board's Web site.

Recently, Chairperson of the subcommittee, Ramón Castellblanch offered to write a report summarizing the major work of this subcommittee.

Dr. Castellblanch submitted a comprehensive outline of a report that he will be writing soon from work with the Prescription Drug Abuse Sub-Committee.

One particular area to be highlighted in Dr. Castellblanch's report is the board's proactive work regarding the "Red Flags", creating regulations requiring pharmacists to take continuing education on "Red Flags" as well as developing a Board brochure on the topic of "Red Flags." Dr. Castellblanch will submit a completed and final report before the next Communication and Public Education Meeting. Mr. Brooks commended Dr. Castellblanch's report.

The minutes from the October 6, 2015, can be found in **Attachment 6**.

# **Attachment 1**



April 21, 2015

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

Re: Coram CVS/specialty infusion services Exemption Request from 16 California Code of Regulations Section 1707.5 Patient Centered Labels for Prescription Drug Containers as authorized by Section 4076.5

Dear Executive Officer Herold:

I am writing to you in my capacity as Director of Regulatory Affairs for CVS Health and its family of pharmacies located across the United States. I am seeking exemption from Title 16 California Code of Regulations Section 1707.5 Patient Centered Labels for Prescription Drug Containers as authorized by section 4076.5. This exemption is being sought for all resident Coram CVS/specialty infusion pharmacies licensed in California. I am requesting this exemption based on the unique service Coram CVS/specialty infusion services provides and the unique challenges of labeling a Total Parenteral Nutrition ("TPN") solution dispensed by these pharmacies. Administration of TPN solutions dispensed by Coram CVS/specialty infusion pharmacies are initiated at the patient's home by a home care nurse for the first two visits and then conducted by self administration or by caregivers thereafter. Patients and caregivers receive collaborative patient education at the time of admission into the service, with routine follow up. Also, there are multiple ingredients included in the TPN solution, making it difficult to provide a label that meets the space and font requirements of Section 1707.5. There is not a sample label provided on the Board's website which demonstrates compliance to the label requirements for this practice setting. Please find outlined below demonstration of the pharmacies compliance with exemption criteria listed in 4076.5(e)(1)(A-D). A list of licensed facilities included in this requested exemption is provided in Attachment A.

(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.

Each facility is JCAHO-accredited for Home Care Accreditation Program.

Attachment B is each facility's JCAHO Accreditation Certificates obtained March 1, 2014 and valid for up to 36 months.

(B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.

Patient Education begins at admission to Coram services and is ongoing based upon patient assessment and compliance with the Plan of Care. This education is collaborative with nursing, pharmacy, caregiver and patient.





Current Policy I304-028 – Patient Education, describes the patient education process to ensure patients/caregivers receive training and education in a manner that meets their language, reading and comprehension needs starting at admission with routine evaluation, which demonstrates compliance to this requirement for exemption.

- (C) The patient receives weekly or more frequent follow-up contacts by a nurse or pharmacist.

Prior to shipping the medication, the pharmacist, nurse or admission support personnel calls the patient to confirm date/time of the delivery. If an admission support personnel initiates the call, the pharmacist then speaks with the patient. The Pharmacist also receives the weekly laboratory monitoring for review and discussion with the patient.

Please see attachment C, an example of a therapy specific weekly contact form, which demonstrates compliance to this requirement for exemption.

- (D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.

Development of the plan of care by Coram nursing or a contracted home health agency with ongoing patient monitoring is initiated at time of admission and continued until therapy is completed.

Current Policy I306-070 – Clinical Admission and Care Plan Development, describes the patient admission process once an order is received from a physician or health care provider with prescriptive authority. The Care Plan is a collaborative effort developed during the admission process with the patient/caregiver, nursing and pharmacy staff. This Care Plan details specific goals and desired outcomes to be attained during the patient's course of therapy and is reviewed and updated as needed during the course of therapy.

Attachment D is a sample of the current label for Coram CVS/specialty infusion pharmacies label.

I appreciate the California Board of Pharmacy's consideration for exemption for 1707.5 Patient-Centered Labels for Prescription Drug Containers for all resident Coram CVS/specialty infusion pharmacies licensed in California. Should you have any additional questions or require additional information, please do not hesitate to contact me at 401.770.1819.

Sincerely,

A handwritten signature in black ink that reads "Karen DiStefano".

Karen DiStefano, RPh  
Director, Pharmacy Regulatory Affairs  
CVS Health  
Karen.distefano@cvscaremark.com

# Example

12310 World Trade Drive Suite 188  
San Diego, CA 92128-3793  
**CORAM** .DEA# BC4458368 FAX: (858) 518-2482  
C/O. PHARMACY. PHARMACY  
(858) 576-6969 / (888) 548-7887

Coram Alternate Site Services, Inc.

Patient: [REDACTED] RX#: [REDACTED]

Patient ID: [REDACTED] Prescriber: [REDACTED]

TOTAL VOLUME: 1800 ml (EXCLUDES ANY OVERFILL)

			Final Conc:
TRAVASOL 10%	900 ML		5 %
DEXTROSE 70%	428.57 ML		16.67 %
STERILE WATER FOR INJECTION		334 ML	

ADDITIVES ARE LISTED PER BAG:

CALCIUM GLUCONATE	18	MEQ
MAGNESIUM SULFATE	30	MEQ
POTASSIUM ACETATE	20	MEQ
POTASSIUM CHLORIDE	70	MEQ
SODIUM ACETATE	115	MEQ
SODIUM PHOSPHATE	15	MM
MULTI TRACE-5 CONCENTRATE	1	ML

ADMINISTRATION DIRECTIONS:

INFUSE 1800 ML OVER 9 HOURS INTRAVENOUSLY via CURLIN pump in TPN mode infuse bag three times WEEKLY. Pump will TAPER UP 1 HOUR AND TAPER DOWN 1 HOUR. Bag volume: 1850 ml; Volume to be infused: 1800 ml; Inf rate: 225ml/hr; Up Ramp: 1 hr; Down Ramp: 1 hr; Total Inf Time: 8hrs; KVO: 0ml/hr; Look iv: 2 ADD TO TPN BAG JUST PRIOR TO INFUSION:  
MVI 13 10 ml

\*\*\*Bag Contains Overfill\*\*\*

Allow drug to reach ROOM TEMPERATURE before administration.

Compounded by Coram Pharmacy

ORIGINAL FILL: 02-27-2015

STORAGE: REFRIGERATED

DATE PREPARED: 02-27-2015

Days Supply: 7

Quantity: 3

DISCARD AFTER: 03-26-2015

RPh: LUNDBERG

**CORAM**  
C/O. PHARMACY. PHARMACY

Coram LLC: California Licensed Pharmacies  
(as of 04-06-2015)

LEGAL NAME	d/b/a	Pharmacy Permit	ADDRESS	CITY	ST	ZIP	TIN
Coram Alternate Site Services, Inc.	Coram CVS/specialty Infusion Services	PHY51893 and LSC100115	3101 Sillect Avenue, Suite 109	Bakersfield	CA	93308-6348	76-0215922
Coram Healthcare Corporation of Southern California	Coram CVS/specialty Infusion Services	PHY51891 and LSC100116	5571 Ekwill Street, Suite A-B	Goleta	CA	93111-2346	58-2006708
Coram Healthcare Corporation of Northern California	Coram CVS/specialty Infusion Services	PHY51866 and LSC100005	3160 Corporate Place	Hayward	CA	94545-3916	58-1972773
Coram Healthcare Corporation of Southern California	Coram CVS/specialty Infusion Services	PHY51890 and LSC100595	2710 Media Center Drive, Building #6, Suite 150	Los Angeles	CA	90065-1748	58-2006708
Coram Healthcare Corporation of Southern California	Coram CVS/specialty Infusion Services	PHY51889 and LSC100385	4355 East Lowell Street, Suite C	Ontario	CA	91761-2225	58-2006708
Coram Healthcare Corporation of Northern California	Coram CVS/specialty Infusion Services	PHY51894 and LSC100394	9332 Tech Center Drive, Suite 100	Sacramento	CA	95826-2598	58-1972773
Coram Alternate Site Services, Inc.	Coram CVS/specialty Infusion Services	PHY 51896 and LSC100594	12310 World Trade Drive, Suite 100	San Diego	CA	92128-3793	76-0215922
Coram Healthcare Corporation of Southern California	Coram CVS/specialty Infusion Services	PHY51897 and LSC100111	3002 Dow Avenue, Suite 104	Tustin	CA	92780-7247	58-2006708

# Coram Healthcare Corporation of Northern California

Sacramento, CA

has been Accredited by



## The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the  
Home Care Accreditation Program

March 1, 2014

Accreditation is customarily valid for up to 36 months.

  
Rebecca J. Patchin, MD  
Chair, Board of Commissioners

Organization ID #559903  
Print/Reprint Date: 04/09/2014

  
Mark R. Chassin, MD, FACP, MPP, MPH  
President

The Joint Commission is an independent, not-for-profit national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at [www.jointcommission.org](http://www.jointcommission.org).



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# Coram Alternate Site Services, Inc.

Bakersfield, CA

has been Accredited by



## The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the  
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March 1, 2014

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Chair, Board of Commissioners

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# Coram Healthcare Corporation of Northern California

Hayward, CA

has been Accredited by



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Home Care Accreditation Program

March 1, 2014

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Rebecca J. Patchin, MD  
Chair, Board of Commissioners

Organization ID #559903  
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Mark R. Chassin, MD, FACP, MPP, MPH  
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# Coram Alternate Site Services, Inc.

San Diego, CA

has been Accredited by



## The Joint Commission

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Home Care Accreditation Program

March 1, 2014

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Rebecca J. Patchin, MD  
Chair, Board of Commissioners

Organization ID #559903  
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# Coram Healthcare Corporation of Southern California

Los Angeles, CA

has been Accredited by



## The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the  
Home Care Accreditation Program

March 1, 2014

Accreditation is customarily valid for up to 36 months.

  
Rebecca J. Patchin, MD  
Chair, Board of Commissioners

Organization ID #559903  
Print/Reprint Date: 04/09/2014

  
Mark R. Chassin, MD, FACP, MPP, MPH  
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# Coram Healthcare Corporation of Southern California

Ontario, CA

has been Accredited by



## The Joint Commission

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Home Care Accreditation Program

March 1, 2014

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Rebecca J. Patchin, MD  
Chair, Board of Commissioners

Organization ID #559903  
Print/Reprint Date: 04/09/2014

  
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# Coram Healthcare Corporation of Southern California

Goleta, CA

has been Accredited by



## The Joint Commission

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Home Care Accreditation Program

March 1, 2014

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Rebecca J. Patchin, MD  
Chair, Board of Commissioners

Organization ID #559903  
Print/Reprint Date: 04/09/2014

  
Mark R. Chassin, MD, FACP, MPP, MPH  
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# Coram Healthcare Corporation of Southern California

Tustin, CA

has been Accredited by



## The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the  
Home Care Accreditation Program

March 1, 2014

Accreditation is customarily valid for up to 36 months.

  
Rebecca J. Patchin, MD  
Chair, Board of Commissioners

Organization ID #559903  
Print/Reprint Date: 04/09/2014

  
Mark R. Chassin, MD, FACP, MPP, MPH  
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**Coram CVS/specialty Infusion Services  
Waiver Request for Title 16, Section 1707.5  
Patient Centered Labels for Prescription Drug Containers**

**California Communication and Public Education Meeting  
Tuesday, October 6, 2015  
Sacramento, CA**

**Lauren Berton, PharmD  
Director, Pharmacy Regulatory Affairs**

# Objectives

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- Provide overview of services provided by Coram CVS/specialty Infusion Services
- Sample Label Review
- Demonstration of compliance with exemption criteria listed in 4076.5(e)(1)(A-D) to allow for exemption to be granted to 1707.5 Patient Centered Labels for Prescription Drug Containers

# Coram CVS/specialty Infusion Services

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- Eight pharmacy locations servicing California patients
  - Bakersfield, Goleta, Hayward, Los Angeles, Ontario, Sacramento, San Diego and Tustin
- Provide high quality, personalized care and support using a multidisciplinary team including Pharmacists and Nurses to patients with acute or chronic conditions by providing infusion services in the patient's home or ambulatory infusion sites.
- Therapies provided include:
  - nutrition (both parenteral and enteral)
  - anti-infective
  - immunoglobulin
  - pain and palliative care
  - transplant and immune therapy

# Sample Label

12310 World Trade Drive Suite 188  
 San Diego, CA 92128-3793  
**CORAM.** DEAN BC4458368 FAX: (858) 610-2402  
 (858) 576-5959 / (888) 546-7997

Coram Alternate Site Services, Inc.

Patient: [REDACTED] RX#: [REDACTED]

Patient ID: [REDACTED] Prescriber: [REDACTED]

TOTAL VOLUME: 1800 ml (EXCLUDES ANY OVERFILL)  
 TRAVASOL 10% 800 ML Final Conc: 5 %  
 DEXTROSE 70% 420.57 ML 16.67 %  
 STERILE WATER FOR INJECTION 334 ML

**ADDITIVES ARE LISTED PER BAG:**

CALCIUM GLUCONATE	10	MEQ
MAGNESIUM SULFATE	30	MEQ
POTASSIUM ACETATE	20	MEQ
POTASSIUM CHLORIDE	70	MEQ
SODIUM ACETATE	115	MEQ
SODIUM PHOSPHATE	15	MM
MULTI TRACE-5 CONCENTRATE	1	ML

**ADMINISTRATION DIRECTIONS:**

INFUSE 1800 ML OVER 8 HOURS INTRAVENOUSLY via CORALIN pump in TPN mode infuse bag three times WEEKLY. Pump will TAPER UP 1 HOUR AND TAPER DOWN 1 HOUR. Bag volume: 1850 ml; Volume to be infused: 1800 ml; Inf rate: 225ml/hr; Up Ramp: 1 hr; Down Ramp: 1 hr; Total Inf Time: 8hrs; KVO: 0ml/hr; Look iv: 2 ADD TO TPN BAG JUST PRIOR TO INFUSION:  
 KVI 13 10 ml

\*\*\*Bag Contains Overfill\*\*\*  
 Allow drug to reach ROOM TEMPERATURE before administration.  
 Compounded by Coram Pharmacy  
 ORIGINAL FILL: 02-27-2015 STORAGE: REFRIGERATED  
 DATE PREPARED: 02-27-2015 Days Supply: 7 Quantity: 3  
 DISCARD AFTER: 03-20-2015 Rph: LUNDBERG



Sample labels provided on the Board's website which demonstrate compliance to the label requirements in 1707.5 are not applicable to this practice setting

1625 N. Market Blvd.  
Sacramento, CA 95834  
(555) 555-9810

Refill Phone:  
(555) 555-9810  
www.pharmacy.ca.gov

CAUTION: Please see Medication Guide for information about this drug that may affect other than the patient for whom it was prescribed.

Rx# 06197 1234567 Prescriber: Roger Brown MD

**JOHNSON, JUDITH**

NOR-QD 0.35MG TAB Mfg: WL

TAKE 1 TABLET ORALLY DAILY

PREVENTS PREGNANCY

Qty: 84 Date Filled: 09/19/10 GMR Discard: \_\_\_\_\_

LIGHT YELLOW, ROUND, TABLET, 'WATSON 235'.

Refill After: 11/17/10 Refills: 6 Please call 48 hrs in advance for refills.

**DAVE'S DISCOUNT DRUGS** 12345 MAIN ST, ANYWHERE, US  
(800) 987-6543

NO REFS  
Expires: 11/05/11 Qty: 90

RX: 411509 Date: 05 Nov 10  
Dr: R DEAN JENNINGS

**SMITH, JOHN**

**PREDNISONE 10MG TAB/QLTST**

Take 6 tablets by mouth daily for 6 days then take 5 tablets daily for 5 days then take 4 tablets by mouth daily for 4 days then take 3 tablets by mouth daily for 3 days then take 1 tablet by mouth daily for 1 day then take 1/2 tablet the last day.

**PURPOSE:** To reduce inflammation

This medicine may lower your ability to fight off infections. Avoid contact with people who have contagious diseases.

Take with food or milk

If You Have Diabetes, This Medicine May Change Your Blood Or Urine Sugar. If This Occurs, Call Your Doctor.

It is very important that you take or use this exactly as directed. Do not skip doses or discontinue unless directed by your doctor.

THE TABLET IN THE CONTAINER ABOVE IS A PINK/WHITE tablet rounded scored white (NDC 100)

## 4076.5 Standardized, Patient-Centered Prescription Labels; Requirements

---

- Business and Professions Code 4076.5(e)(1) allows the board to grant an exemption to the requirements of regulations promulgated for a standardized, patient-centered prescription drug label dispensed to a patient if certain exemption criteria is met. The regulations exemption request we are seeking is for Title 16, Section 1707.5 Patient Centered Labels for Prescription Drug Containers
- Business and Professions Code 4076.5(e)(2) clarifies that the “for the purposes of paragraph one, home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.”



## Compliance to Exemption Criteria listed in 4076.5(e)(1)(A-D)

---

- 4076.5(e)(1)(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy
  - Included in the exemption request are the JCAHO Home Care Accreditation Program certificates for each of the eight pharmacies
  - Dated March 1, 2014 and valid for 36 months
- 4076.5(e)(1)(B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist
  - Patient education begins at admission to Coram services and is ongoing. The education is collaborative with nursing, pharmacy, caregiver and patient.

## Compliance to Exemption Criteria listed in 4076.5(e)(1)(A-D)

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- 4076.5(e)(1)(C) The patient receives weekly or more frequent follow up contacts by a nurse or pharmacist.
  - Nurses visit patient weekly for PICC line sterile cleaning
  - Prior to shipping the medication, a pharmacist, nurse or support personnel call the patient to confirm delivery. If a support personnel initiates the call, a pharmacist then speaks with the patient
  - Pharmacists also receive weekly laboratory monitoring for review and discussion with the patient
- 4076.5(e)(1)(D) Care is provided under a formal plan of care based upon a physician and surgeon's orders
  - Development of the plan of care by Coram nursing or contracted home health agency with ongoing patient monitoring is initiated at time of admission and continued until therapy is completed.

# **Attachment 2**

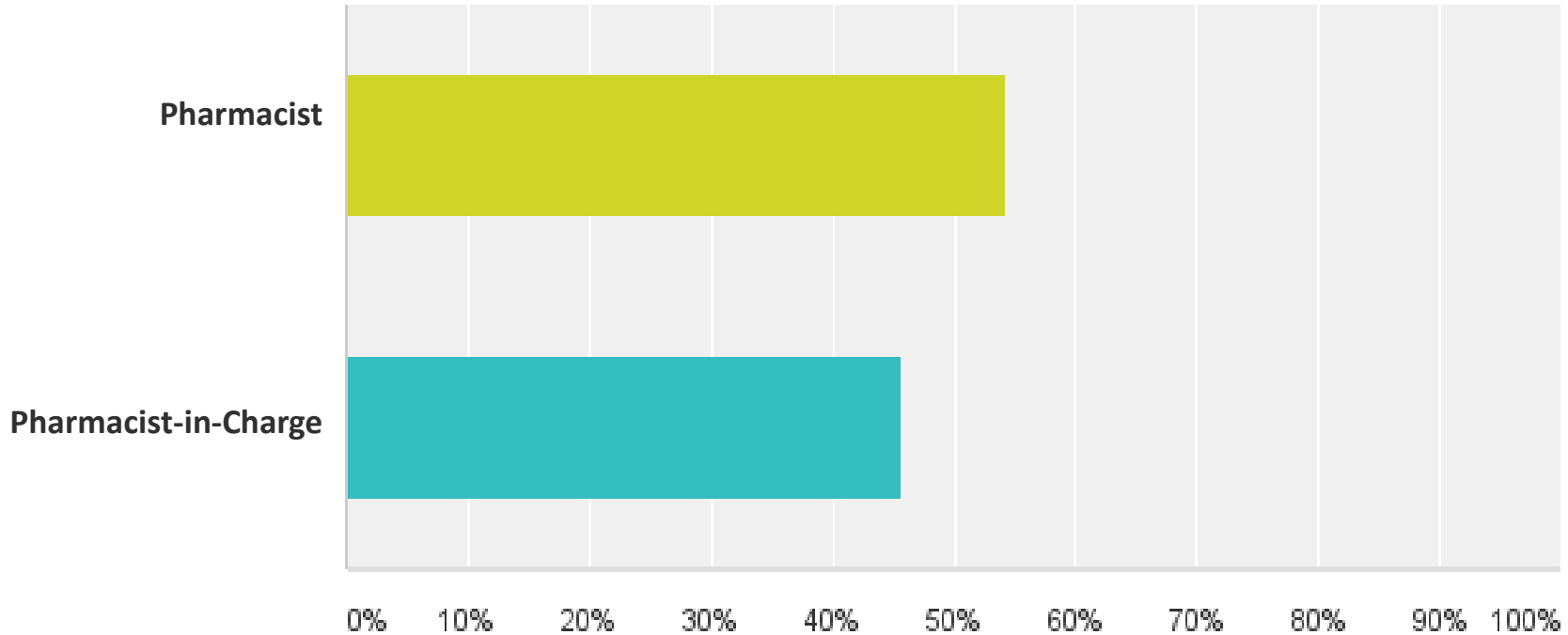
# Survey for Pharmacists

# 1,006 total responses

Survey Date: July 20-24, 2015

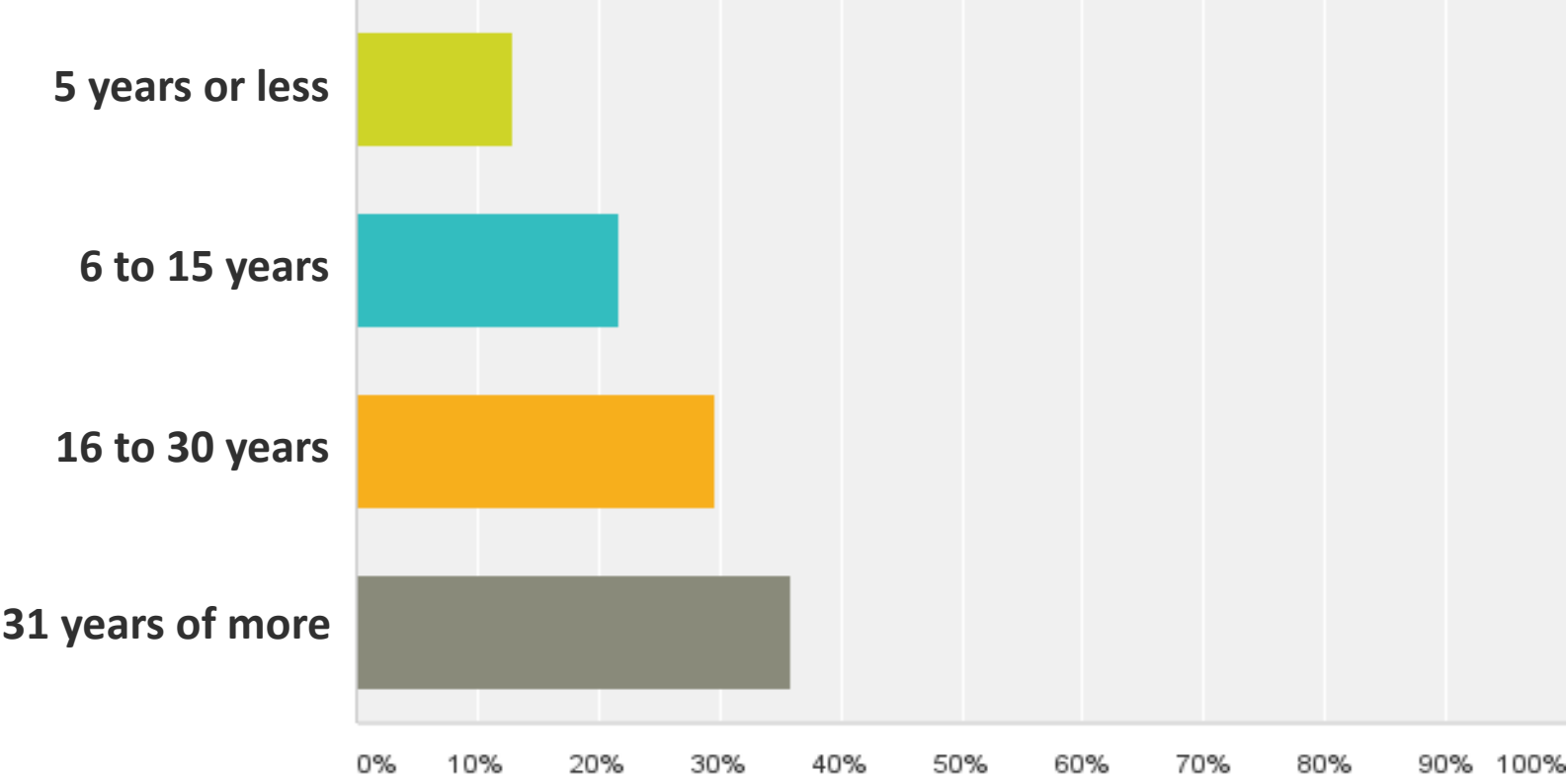
# Question 1: I am a licensed California\_\_\_\_\_.

Answered: 998 Skipped: 8



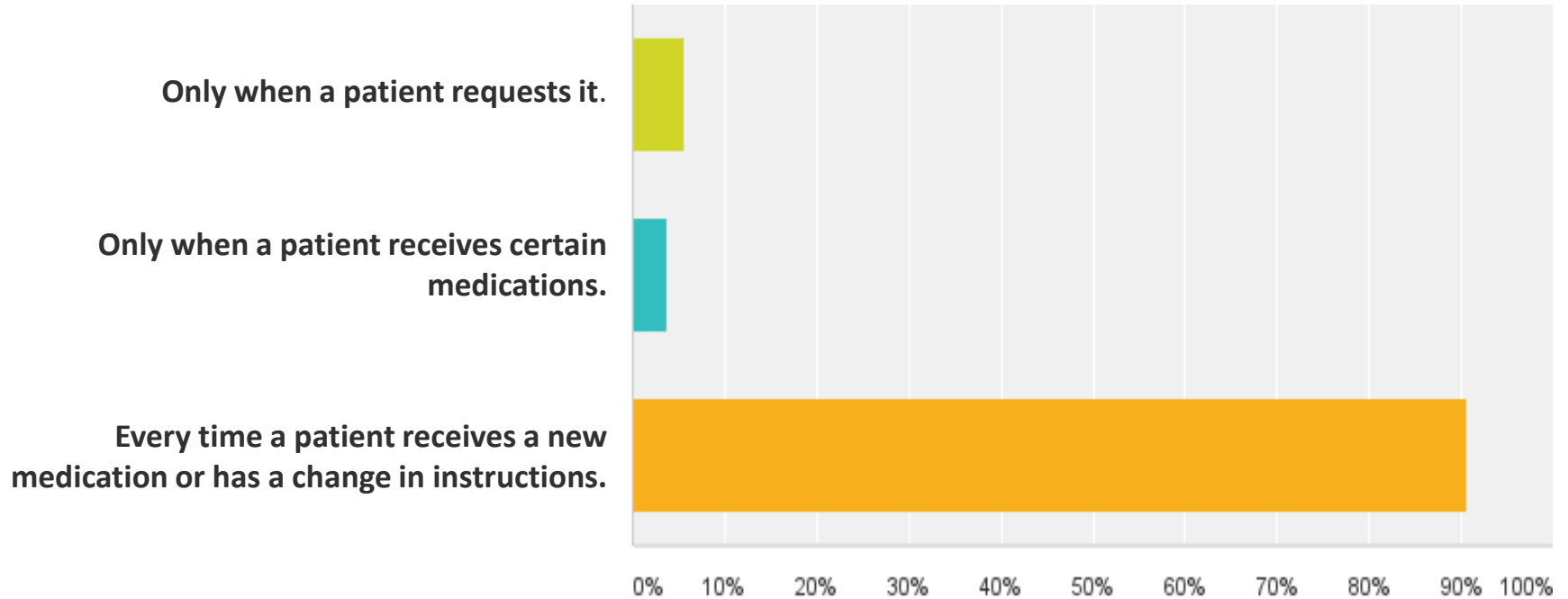
# Question 2: How long have you been a pharmacist?

Answered: 1,004  
Skipped: 2



## Question 3: I consult....

Answered: 897 Skipped: 109

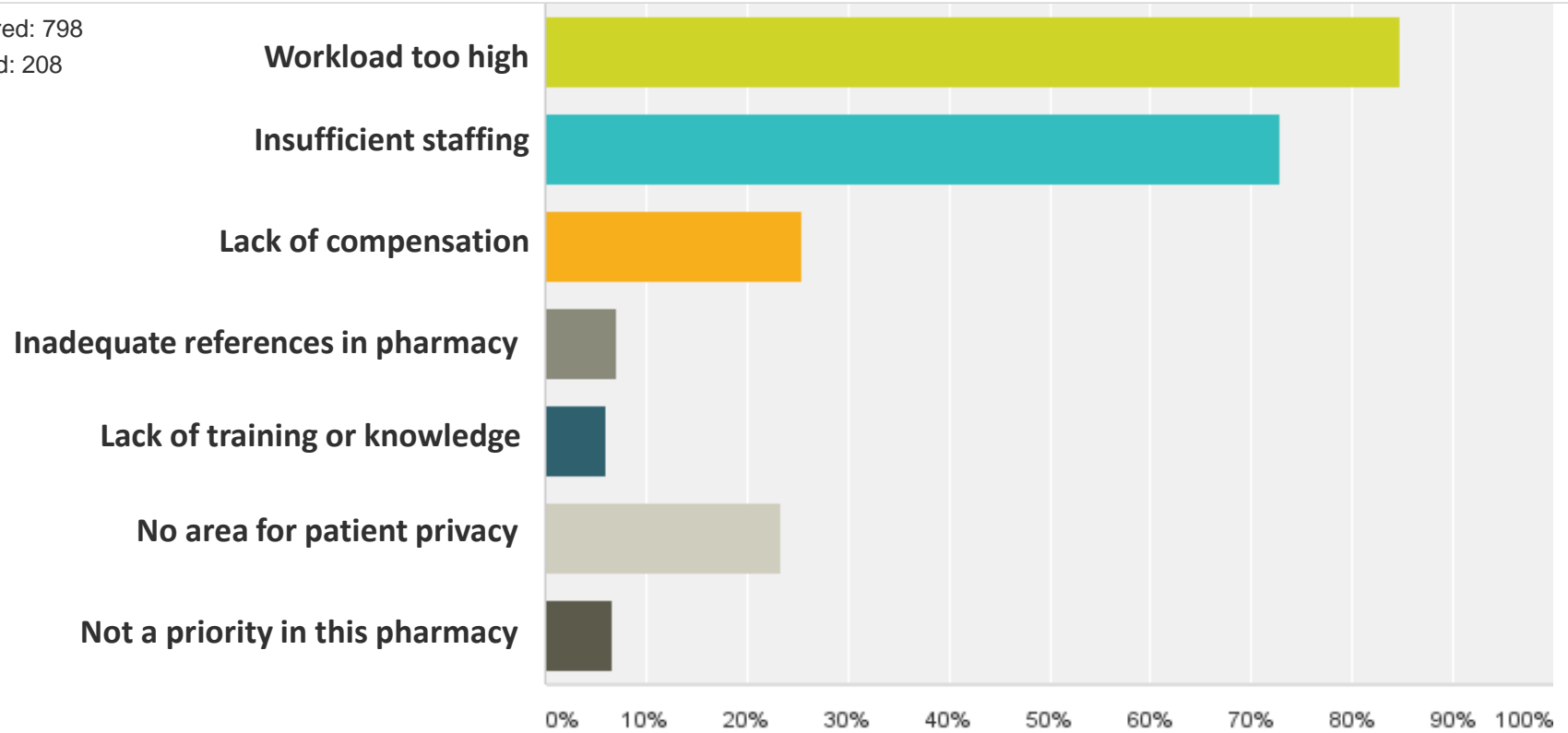




## Question 4: What barriers exist to a pharmacist initiating consultation (mark all that apply):

Answered: 798

Skipped: 208



Answers to the question: What barriers exist to a pharmacist initiating a consultation?	
None, I make it a priority to consult.	53
Patients in are in hurry and will not wait for consultation.	37
Doesn't apply to my practice setting.	30
The pharmacist is too busy / pressure from employer to fill prescriptions quickly even if that means not consulting.	24
No reimbursement for consultation.	12
Language or other communication barriers.	12
Lack of privacy to provide consultation.	9
The clerk or technician is the one working with the patient initially and they do not tell the patient they need to wait to talk to the pharmacist.	8
Ratio of technicians to pharmacists is too low.	6
Lack of training or experienced staff.	2

# **Attachment 3**

## CA State Board of Pharmacy Regulations:

- (a) A pharmacist furnishing emergency contraception pursuant to Section 4052.3(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.
- (b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).
  - (1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.
  - (2) Purpose: To provide timely access to emergency contraceptive medication and ensure that the patient receives adequate information to successfully complete therapy.
  - (3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and communicate the following:

Are you allergic to any medications?

Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) after unprotected intercourse.

EC use will not interfere with an established or implanted pregnancy.

If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. For other options for EC, consult with your health care provider.

Please follow up with your health care provider after the use of EC.

- (4) The pharmacist shall provide a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations. Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section 4052.3(e).
- (5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.
- (6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.
- (7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.
- (8) EC Product Selection: The pharmacist will provide emergency contraception medication from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.
- (9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.
- (10) Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

(11) Medications Used for Emergency Contraception

***Dedicated Approved Products for Emergency Contraception***

*Ethinyl Estradiol Brand Dose*

<i>per dose (mcg) One Tablet Regimens Plan B™ One-Step</i>	1 tablet	0	1.5mg levonorgestrel
ella™	1 tablet	0	30mg ulipristal
Levonorgestrel	1 tablet	0	1.5mg levonorgestrel

*Two Tablet Regimens*

Next Choice™	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	0	Each tablet is 0.75 mg levonorgestrel
Levonorgestrel	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	0	Each tablet is 0.75 mg levonorgestrel

***Oral Contraceptive Pills***

<i>Brand</i>	<i>Tablets per Dose (two doses 12 hours apart*)</i>	<i>Ethinyl Estradiol per dose (mcg)</i>	<i>Levonorgestrel per dose (mg)*</i>
Alesse	5 pink tablets	100	0.50
Aviane	5 orange tablets	100	0.50
Levlen	4 light-orange tablets	120	0.60
Levlite	5 pink tablets	100	0.50
Levora	4 white tablets	120	0.60
Lo/Ovral	4 white tablets	120	0.50
Low-Ogestrel	4 white tablets	120	0.60
Nordette	4 light-orange tablets	120	0.60
Ogestrel	2 white tablets	100	0.50
Ovral	2 white tablets	100	0.50
Tri-Levlen	4 yellow tablets	100	0.50
Triphasil	4 yellow tablets	120	0.50
Trivora	4 pink tablets	120	0.50
Ovrette	20 yellow tablets	0	0.75

\*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

<i>Non-Prescription Drugs</i>	<i>Dose</i>	<i>Timing of Administration</i>
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first EC dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.

## EMERGENCY CONTRACEPTION: A GUIDE FOR PHARMACIES AND RETAILERS (JUNE 2015)

### What is emergency contraception (also known as “the morning-after pill”)?

- Emergency contraception (EC) prevents pregnancy; EC will not disrupt an existing pregnancy.
- EC pills that contain the progestin hormone, levonorgestrel (LNG), are sold under several names, including Plan B One-Step®, Take Action®, My Way®, Next Choice One-Dose®, and others. Most levonorgestrel EC products are available over-the-counter (OTC) without age restrictions. (See reverse side for specific product details.)
- EC pills that contain ulipristal acetate are available under the brand name ella® and are prescription only.
- All EC works best when taken as soon as possible after unprotected sex but may be effective up to 5 days after.
- EC is safe for women of all ages to use.

### What are the restrictions for purchasing EC over-the-counter? Do customers need to show ID?

- For the one-pill LNG EC products containing one 1.5 mg levonorgestrel pill (brand Plan B One Step® and generics), there are NO age or point-of-sale restrictions. Previously, OTC purchases were subject to age restrictions, but these have been removed by the U.S. Food and Drug Administration (FDA) and most brands have updated their labels to reflect the new regulations.
  - Any woman or man of any age can purchase these EC products without needing to show ID.
  - There is no limit on the number of packages that a person can purchase.
  - Although some of the generic one-pill product labels state that the product is intended for women aged 17 and older, this is not a restriction on sale (no ID required); it is guidance for the consumer only.
- For the two-pill LNG EC products containing two 0.75 mg levonorgestrel pills, there are still age restrictions and these must be kept behind the pharmacy counter. A pharmacy staff member must check ID to ensure the person purchasing the product is age 17 or older, but a pharmacist consultation is not required.

### Where can EC be found within pharmacies and stores?

- Pharmacies and retailers can sell one-pill LNG EC products directly from store shelves as long as the products have updated OTC packaging.
  - Most retailers stock it in the family planning aisle so it can be found easily.
  - There is no need for these EC products to be kept behind the pharmacy counter.
- Two-pill LNG EC products must still be stocked behind the pharmacy counter. The customer can purchase the product without a prescription if they are at least 17 years old. Patients aged 16 or younger will need a prescription. Some states may have protocols that allow the pharmacist to provide a prescription directly to patients.
  - You may consider removing these products from your stock unless they are cheaper than the one-pill products. The one-pill product is easier for patients to take and there's no chance of not taking the second pill at the right time.
- Ulipristal acetate (ella®) is available by prescription only so it must be kept behind the pharmacy counter. Some states may have protocols that allow the pharmacist to provide a prescription directly to patients.

### Why is it important to stock one-pill LNG EC on the shelf?

- EC is a woman's last chance to prevent an unintended pregnancy after birth control failure, sexual assault, or unprotected sex.
- EC works best when it's taken as soon as possible. Convenient and timely access is critically important.
- Keeping EC behind the counter is an unnecessary and harmful barrier; FDA has approved these EC products to be sold on store shelves without any restrictions.
- Customers may feel embarrassed about purchasing EC; placing it directly on the shelf without locked security boxes protects people's privacy and confidentiality.
- Pharmacies and stores have an important role to play in helping women prevent unintended pregnancy by maintaining a stock of easily accessible EC on the shelf at all times.

### Can men purchase LNG EC?





- Yes, men can purchase over-the-counter LNG EC. There are no sex/gender restrictions on the sale of any over-the-counter products. However, prescriptions for EC can only be issued to the patient who will be taking it.

### What can I do if my store doesn't stock one-pill LNG EC on the shelf?

- If you are the person who makes stocking decisions, you can make space for EC in the family planning aisle.
- If your store doesn't sell EC on the shelf, it may be because the regulations around EC have changed frequently in the past few years, and it can be confusing. Share these guidelines with your management and encourage them to stock EC on the shelf.
- If you cannot fulfill a customer's request for EC, please refer them to Not-2-Late's EC locator: [www.not-2-late.com](http://www.not-2-late.com).

## FDA-APPROVED EMERGENCY CONTRACEPTIVE PILLS AS OF JUNE 2015

Under current regulations, the products listed below should be made available in the following ways:

PRODUCT	INFORMATION
<p><b>Teva EC products (Plan B One-Step®, Take Action™, and Aftera™)</b></p> 	<ul style="list-style-type: none"> <li>• <b>May be stocked on OTC shelves in stores.</b></li> <li>• Available for purchase over-the-counter for all ages –ID check is <u>not</u> required.</li> <li>• Take as soon as possible; may be effective up to 5 days after unprotected sex.</li> <li>• 1 tablet (1.5mg levonorgestrel)</li> <li>•</li> </ul>
<p><b>Other Generic One-Pill Levonorgestrel EC Products</b></p> 	<ul style="list-style-type: none"> <li>• <b>May be stocked on OTC shelves in stores.</b></li> <li>• Label indicates that the product is intended for use by women ages 17 and older, but ID check is <u>not</u> required.</li> <li>• Take as soon as possible; may be effective up to 5 days after unprotected sex.</li> <li>• 1 tablet (1.5mg levonorgestrel)</li> <li>•</li> </ul> <p>Additional generic one-pill LNG EC products not listed here may become available soon.</p>
<p><b>Generic Two-Pill Levonorgestrel EC Product</b></p> 	<ul style="list-style-type: none"> <li>• <b>Must be stocked behind the pharmacy counter.</b></li> <li>• Prescription required for those 16 years and younger. Available for purchase over-the-counter for those 17 and older.</li> <li>• Only EC product that is currently “dual labeled” for prescription and OTC usage.</li> <li>• Take both pills together as soon as possible; may be effective up to 5 days after unprotected sex.</li> <li>• 2 tablets (each 0.75mg levonorgestrel)</li> <li>•</li> </ul>
<p><b>ella®</b></p> 	<ul style="list-style-type: none"> <li>• <b>Must be stocked in the pharmacy as a prescription-only drug.</b></li> <li>• Available for purchase by prescription at the pharmacy</li> <li>• Only EC product labeled for prescription use only.</li> <li>• Take as soon as possible; effective up to 5 days after unprotected sex.</li> <li>• 1 tablet (30mg ulipristal acetate)</li> </ul>

If you have questions or want to share comments about how EC is sold at your store, contact us: [asec@americansocietyforec.org](mailto:asec@americansocietyforec.org).

Learn more about EC at [www.not-2-late.com](http://www.not-2-late.com) and [www.rhtp.org](http://www.rhtp.org).



## **Pharmacy Access to Emergency Contraception in California: Opportunities for Enhancing Pharmacist and Public Education**

### **Situation:**

Many opportunities related to availability of emergency contraception (EC) and misinformation given to consumers and prescribers identified anecdotally and by research studies. Selected key findings:

- EC is available in 80% of pharmacies [Wilkinson et al. 2012; Samson et al. 2013; Rafie et al. 2013].
- Pharmacy staff members regularly give misinformation about age restrictions for EC to consumers (43%) and physicians (39%) alike [Wilkinson et al. 2012]. Callers are often put on hold or passed between multiple pharmacy staff members to get answers to their questions about EC [Wilkinson et al. 2012; Nelson et al. 2009].
- Young men are denied EC at pharmacies that require the presence of a female or her identification card [Bell et al. 2015; Wilkinson et al. 2014].
- Use of EC among sexually active teens has increased from 15% in 2006-2010 to 22% in 2011-2013 ( $p < 0.05$ ) [NCHS Data Brief #209].

### **Background:**

California has a protocol for pharmacists to provide direct pharmacy access to emergency contraception. The protocol was recently expanded to include all emergency contraceptive pills, including the newest ulipristal acetate (Ella).

### **Assessment:**

Pharmacists may believe there's no need for pharmacy access to EC now that there are over-the-counter products available. However, pharmacy access is critical for insurance coverage and to ensure patients receive the most effective method. All prescribed contraceptives are covered without patient cost sharing by plans compliant with the Affordable Care Act requirements. The over-the-counter EC products range from ~\$40-\$55. Further, many consumers are facing barriers to the over-the-counter product such as age, ID, and gender requirements [see Situation section above]. All the over-the-counter EC products contain levonorgestrel. Pharmacists may determine that ulipristal acetate (Ella) is more effective for a particular patient based on how many hours since unprotected intercourse or her body weight [Cleland et al. 2014]. Pharmacy access remains critical for some women who need to access this product.

Many pharmacists may be unaware that ulipristal acetate (Ella) was added to the California protocol. Prescriber awareness and prescribing of ulipristal acetate (Ella) remains low as well at 52% and 14% respectively [Batur et al. 2015].

# Pharmacy Access to Emergency Contraception in California: Opportunities for Enhancing Pharmacist and Public Education

## **Recommendations:**

### **Pharmacist Education:**

- Include an article in the next issue of The Script newsletter regarding this pharmacist authority and recent updates to the protocol.
- Add the following resources on the Board website where the protocol is posted:
  - EC guide for pharmacies and retailers (by the American Society of Emergency Contraception, Reproductive Health Technologies Project, and the American College of Clinical Pharmacy Women's Health Practice and Research Network) on the Board website with the protocol: [http://americansocietyforec.org/uploads/3/2/7/0/3270267/pharmacy\\_ec\\_access\\_overview.pdf](http://americansocietyforec.org/uploads/3/2/7/0/3270267/pharmacy_ec_access_overview.pdf)
  - Locator tools that pharmacists can list their pharmacies in:
    - Princeton's Not2Late EC locator: <http://ec.princeton.edu/providers.html>
    - Bedsider EC locator: [http://bedsider.org/clinic\\_submissions/new?has\\_ec=true](http://bedsider.org/clinic_submissions/new?has_ec=true)
  - Patient education materials that can be printed or ordered: <http://providers.bedsider.org/order-materials/> and <http://www.reproductiveaccess.org/resources/>

### **Public/Consumer Education:**

- There is currently nothing on the Board website aimed at the public related to EC and pharmacy access to EC. Under the Consumers tab on the Board website, create space for information on EC. Include the following resources:
  - Not2Late & Bedsider EC locator tools: <http://not-2-late.com> and [http://bedsider.org/where\\_to\\_get\\_it](http://bedsider.org/where_to_get_it)
  - Bedsider website for information about all EC methods: [http://bedsider.org/methods/emergency\\_contraception](http://bedsider.org/methods/emergency_contraception)
  - Bedsider patient education (single page): [http://www.contraceptionjournal.org/cms/attachment/2020606468/2040327265/gr1\\_lrg.jpg](http://www.contraceptionjournal.org/cms/attachment/2020606468/2040327265/gr1_lrg.jpg) or Reproductive Health Access Project patient education (single page): <http://www.reproductiveaccess.org/wp-content/uploads/2014/12/emergency-contraception.pdf>

# **Attachment 4**



2015

October is NCPIE's 30th  
**“TALK ABOUT  
YOUR MEDICINES”** Month

*Safe use.  
Safe storage.  
Safe disposal.*

learn more at: [talkaboutrx.org](http://talkaboutrx.org)



**2015**

**Talk About Your  
Medicines Month**

## **Have a conversation about: *Safe Medicine Use***

***Can you answer these questions about the  
medicines you take?***

1. What specifically is the medicine for?
2. How and when do I take it, and for how long?
3. What side effects should I expect, and what should I do about them?
4. Should I take this medicine on an empty stomach or with food?
5. Is it best to take it in the morning or evening?
6. Will it work safely with any other medicines I'm taking?

[talkaboutRx.org](http://talkaboutRx.org)



**2015**

**Talk About Your  
Medicines Month**

## **Have a conversation about: *Safe Medicine Storage***

Approximately 60,000 young children are brought to the emergency room each year because they got into medicines that were left within reach.

***Are the medicines in your  
home stored safely?***

[talkaboutRx.org](http://talkaboutRx.org)

**FOR IMMEDIATE RELEASE**  
January 28, 2015

Contact: Ray Bullman  
(301) 340-3940  
[bullman@ncpie.info](mailto:bullman@ncpie.info)

## **New Educational Campaign Seeks to Increase Patient and Healthcare Provider Communication about Prescription Medicines**

*Talk Before You Take Campaign Launches in Response to New Research Showing Communication Gaps*

Rockville, MD (January 28, 2015) – New public research shows that there are gaps in communication between healthcare providers and patients about the benefits and potential risks of prescription medicines. Nearly half of Americans are taking prescription medicines, and over 20 percent of Americans take at least three. Yet research shows that approximately 62 percent of patients are not aware of any safety warnings about their medicines, and 10 percent of patients unaware of the possibility of a severe reaction or side effect to any of the medicines they are taking actually experience a serious drug reaction.

Improving communication about prescription medicines can help ensure that patients avoid adverse drug reactions, improve adherence, and live healthier lives. Today the National Council on Patient Information and Education (NCPiE) is launching a national education campaign, *Talk Before You Take*, designed to address these gaps and encourage informed patient and healthcare provider engagement and conversation. The campaign and its foundational research have been developed through a grant provided by the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research.

“We want to help patients fully understand how to maximize the benefits and minimize risks from medications,” said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. “This NCPiE project aims to provide healthcare providers and patients with educational materials and information that can spark more conversations during office visits and with the pharmacist.”

“As pharmacists, we are trained to constantly ask ourselves how we can be sure that patients understand instructions provided with medicines,” stated Elizabeth Keyes, RPh., Chief Operating Officer, American Pharmacists Association and Chair of the NCPiE Board of Directors. “This is especially important for patients who have multiple chronic conditions, are likely taking multiple prescriptions and over-the-counter medicines, and typically have more than one prescriber and sometimes even more than one pharmacy. This means that patients and caregivers have to keep track of and manage a great deal of information about different medicines from different sources. All of these factors can lead to a lack of patients' full understanding of their prescriptions' benefits, potential risks, and instructions to promote safe and appropriate medicine use. This new research underscores the need to focus on communications around prescription medications.”

The research was conducted by the Evidence Generation, Value and Access Center of Excellence within Ipsos Healthcare, a global independent research company, with input from the FDA and the Center for Drug Safety and Effectiveness (CDSE), Johns Hopkins Bloomberg School of Public Health. Approximately 2,000 consumers and 800 healthcare professionals across the U.S. were reached via surveys, representing individuals and their caregivers, pharmacists in community-based retail settings, and prescribers, including primary care physicians, nurse practitioners, and physician assistants.

“This is an important undertaking given the critical role that consumer education and empowerment can play in improving safe medication use,” said G. Caleb Alexander, MD, MS, Associate Professor of Epidemiology and Medicine and a co-Director of CDSE.

As part of the *Talk Before You Take* campaign, NCPiE has convened a multi-stakeholder project advisory team to provide expert guidance for communicating essential medication safety and risk information. In addition, NCPiE is partnering with key stakeholder organizations to promote the campaign and disseminate educational materials designed for

healthcare providers and patients. The campaign's website, [TalkBeforeYouTake.org](http://TalkBeforeYouTake.org), will serve as a resource and include free educational materials for download. The campaign seeks to reinforce four important tips for patients and caregivers to guide conversations with healthcare providers:

1. **Talk to your healthcare provider and ask questions about the benefits and potential risks of prescription medicines you take.**
2. **Tell your healthcare provider about *all* of the medicines you are taking—including over-the-counter medicines, vitamins, and dietary supplements.**
3. **Tell your healthcare provider about any allergies or sensitivities that you may have.**
4. **Read and follow the medicine label and directions.**

Visit [TalkBeforeYouTake.org](http://TalkBeforeYouTake.org) to learn more.

Previous NCIPIE medication education campaigns include: [BeMedicineSmart](#), [Medication Use Safety Training \(MUST\) for Seniors](#); National Brown Bag Medicine Review Program; [National "Talk About Your Medicines" Month](#); [BeMedWise – Promoting Safe Use of OTC Medicines](#), and multiple, audience-specific programs addressing prescription drug abuse prevention and the safe use of acetaminophen.

###

#### **About the National Council on Patient Information and Education**

Organized in 1982, the National Council on Patient Information and Education (NCPIE) is a nonprofit coalition of diverse organizations committed to promoting the wise use of medicines through trusted communication for better health. NCIPIE works to address critical medicine safe use issues like adherence improvement, prescription drug abuse prevention, reduction of medication errors, and quality improvements in healthcare provider-patient communication. For more information, visit [www.talkaboutrx.org](http://www.talkaboutrx.org).

#### **About Evidence Generation, Value and Access Center of Excellence, Ipsos Healthcare**

Ipsos Healthcare's Evidence Generation, Value and Access Center of Excellence focuses on providing insights into payer, physician, and patient needs and market barriers and, accordingly, generates or demonstrates clinical, economic, and humanistic value propositions of products and services for optimal access across the market segments and therapy areas. The center employs traditional secondary research, retrospective and prospective observational cohort studies, cross-sectional surveys, and quantitative/qualitative research in the market access arena, leveraging its access to patients, physicians, and payer stakeholders in over 40 countries where Ipsos Healthcare teams operate.

#### **About the Center for Drug Safety and Effectiveness, Johns Hopkins Bloomberg School of Public Health**

The goal of the Center for Drug Safety and Effectiveness is to improve the safe and effective use of medications. Drawing on the combined expertise of the Johns Hopkins Bloomberg School of Public Health and the Johns Hopkins School of Medicine, the Center serves as a nexus for individuals at Johns Hopkins who are involved in research, education, clinical programs, and public service to improve prescription drug use and pharmaceutical policy. For more information, visit [www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/](http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/).

#### **About the U.S. Food and Drug Administration**

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

NCPIE wishes to acknowledge that this work was supported by the U.S. Food and Drug Administration, Center for Drug Evaluation and Research under grant number 5U18FD004653. The content is solely the responsibility of NCIPIE and does not necessarily represent the official views of the Food and Drug Administration.



## Communications Toolkit

*October is Talk about Your Medicines Month:*

*Let's generate conversations about safe medicine use, safe storage and safe disposal.*

---

### Working Together to Increase Communications about Medicines

October marks the 30th **Talk About Your Medicines Month**. TAYMM is an annual opportunity to focus attention on the value that better medicine communication can play in promoting better medicine use and better health outcomes. Initially created by NCPIE and our health education stakeholders as "Talk About Prescriptions Month," TAYMM has expanded to stimulate conversations between consumers and their healthcare providers about all the types of medicines they may take, with a focus on what to know in terms of expected health outcomes, side effects, benefits and potential risks.

The ultimate objective of any communication between patients and their healthcare providers is to improve the patient's health and medical care. Good communication is at the heart of good medicine. In fact, [data](#) have shown that patients reporting good communication with their health providers are more likely to be satisfied with their care, follow advice and adhere to the prescribed treatment. Of course, communication is a two-way street. Consumers need to be aware of the questions to ask, and healthcare providers in turn must be able to share medical information in a meaningful way that their patients are able to understand and act on. To that end, Talk About Your Medicines Month empowers both.

Whether or not you are a patient health advocacy organization, medical society or clinical organization, we encourage you to use this Talk About Your Medicines Month communications toolkit to help encourage and stimulate conversations. Our theme this year: **Safe Use. Safe Storage. Safe Disposal.**

**BELOW** is a toolkit of materials and graphics to share to educate your own members, constituents and audiences about TAYMM and to stimulate conversations about safe medicine use, storage and disposal. The toolkit includes:

- Newsletter "blurb"
- Facebook posts
- Twitter posts
- Graphics to share

We hope you can use these in your own channels to help us stimulate conversations about the safe use, safe storage and safe disposal of medicines throughout Talk About Your Medicines Month this October. Thank you in advance for your collaboration and engagement.

With thanks,

*Ray Bullman*

Executive Vice President,  
National Council on Patient Information and Education

## Communications Toolkit: Talk About Your Medicines Month

### “Blurb” for e-newsletters:

October marks the 30th [Talk About Your Medicines Month](#), an annual opportunity to focus attention on the value that better medicine communication can play in promoting better medicine use and better health outcomes. Of course, communication is a two-way street. Consumers benefit from being proactive in asking questions and seeking information about their medicines; and healthcare providers in turn must be able to share medical information in a meaningful way that their patients are able to understand and act on. Visit [www.TalkAboutRx.org](http://www.TalkAboutRx.org) to access tools and resources to stimulate conversations focused on Talk About Your Medicines Month’s 2015 theme: Safe Use. Safe Storage. Safe Disposal.

### *Suggested social media posts, to customize per your memberships and audiences however you best see fit:*

<b>Week 1 Focus: Introducing TAYMM</b>	
Facebook:	<ul style="list-style-type: none"> <li>• Good communication is at the heart of good medicine. October is Talk About Your Medicines Month, an annual opportunity to focus attention on the value that better medicine communications can play in promoting safe medicine use and better health outcomes. Tips, tools and handouts about safe medicine use, storage and disposal are available at <a href="http://www.TalkAboutRx.org">www.TalkAboutRx.org</a>.</li> <li>• Oct is Talk About Your Medicines Month. Arm your patients with the info to use, store and dispose of their medicines safely #TAYMM</li> </ul>
Twitter:	<ul style="list-style-type: none"> <li>• October is Talk About Your Medicines Month. Are you well informed about the meds you take? Use this list of questions <a href="http://bit.ly/TAYMM">http://bit.ly/TAYMM</a></li> <li>• Good communication is at the heart of good medicine. Kick start conversations with list helpful list of questions <a href="http://bit.ly/TAYMM">http://bit.ly/TAYMM</a></li> <li>• Talk About Your Medicines: safe use, safe storage &amp; safe disposal. Informed = healthy. #TAYMM</li> <li>• Too many patients are unaware of potential medication risks/side effects. Oct is Talk About Medicine Month. Arm your patients with info.</li> </ul>
Graphic#1:	Share “October is Talk About Your Medicines Month” <b>graphic #1</b> , provided as jpeg
<b>Week 2 Focus: Safe Use</b>	
Facebook:	<ul style="list-style-type: none"> <li>• It’s Talk About Your Medicines Month, and today we’re talking about safe use. Always read the label and other accompanying information that accompanies your medicines. Whether you are taking prescription or an OTC product, the label contains important information about dosing, as well as any potential risks or side effects. Never take more than the label directs. Learn more safe use tips <a href="http://www.talkaboutrx.org/rxmonth2015.jsp">here</a> (hyperlink: <a href="http://www.talkaboutrx.org/rxmonth2015.jsp">http://www.talkaboutrx.org/rxmonth2015.jsp</a>)</li> <li>• When you have a visit with your healthcare providers, do you talk about the medicines you take? Good communications about your medicines can mean better health outcomes for you overall. October is Talk About Your Medicines Month. Use this list of recommended questions to discuss with your healthcare provider, in October – or any time of the year. [IMAGE]</li> </ul>
Twitter:	<ul style="list-style-type: none"> <li>• Ask your healthcare provider these questions before taking a new medicine <a href="http://bit.ly/TAYMM">http://bit.ly/TAYMM</a> #TAYMM</li> <li>• Make sure you’re using meds safely. Ask these questions at your next visit with your health provider <a href="http://bit.ly/TAYMM">http://bit.ly/TAYMM</a> #TAYMM</li> <li>• If you can answer all the questions on this list, chances are you’re using your medicines safely &amp; responsibly. <a href="http://bit.ly/MedQs">http://bit.ly/MedQs</a> #TAYMM</li> </ul>

	<ul style="list-style-type: none"> <li>• If u can't answer these questions about your meds, then Talk About Your Medicines Month is time to find answers <a href="http://bit.ly/TAYMM">http://bit.ly/TAYMM</a> #TAYMM</li> <li>• Good communication about medicine use can translate into better health outcomes for your patients <a href="http://bit.ly/TAYMM">http://bit.ly/TAYMM</a> #TAYMM</li> <li>• What common questions do your patients ask @ the meds they take? Are these Qs on the list? If not they should be <a href="http://bit.ly/TAYMM">http://bit.ly/TAYMM</a> #TAYMM</li> </ul>
Graphic#2:	<p>Share the <b>graphic #2</b>: <b><i>Have a conversation about safe medicine use.</i></b> Can you answer these questions about the medicines you take?</p> <ol style="list-style-type: none"> <li>1. What specifically is the medicine for?</li> <li>2. How and when do I take it, and for how long?</li> <li>3. What side effects should I expect, and what should I do about them?</li> <li>4. Should I take it on an empty stomach or with food?</li> <li>5. Is it best to take it in the morning or evening?</li> <li>6. Will it work safely with any other medicines I'm taking?</li> <li>7. How should I store this medicine – room temperature, or in the refrigerator?</li> </ol>
<b>Week 3 Focus: Safe Storage</b>	
Facebook:	<ul style="list-style-type: none"> <li>• It's Talk About Your Medicines Month, and today we're talking about safe storage. If you are a parent with young children at home – or a grandparent who spends time with young grandchildren – make sure your medicines are stored up and away and out of reach and sight of curious young children. If you or your guests keep pills in purses or jacket pockets, make sure those are out of reach too. (hyperlink to: <a href="http://www.upandaway.com">www.upandaway.com</a>)</li> </ul>
Twitter:	<ul style="list-style-type: none"> <li>• Responsible use of medicines includes storing them securely. Keep all meds out of reach of curious youngsters. #TAYMM <a href="http://bit.ly/TAYMM">http://bit.ly/TAYMM</a></li> <li>• Got young children at home? Talk to houseguests about keeping their meds up and away to keep your kids safe. <a href="http://www.UpandAway.org">www.UpandAway.org</a> #TAYMM</li> <li>• Responsible use of medicines includes storing them securely. Talk to your patients about safe storage. #TAYMM</li> </ul>
Graphic#3:	<p>Share <b>graphic #3</b>: <b><i>Have a conversation about safe medicine storage</i></b> Approximately 60,000 young children are brought to the emergency room each year because they got into medicines that were left within reach. Are the medicines in your home stored safely?</p>



### Week 4 Focus: Safe Disposal

Facebook	<ul style="list-style-type: none"> <li>• It's Talk About Your Medicines Month, and today we're talking about safe disposal. Can you take medicines that have expired? What is safe to throw in the trash, and what should you flush or return via a "take back" program at your local pharmacy? Use this helpful resource from the FDA. (hyperlink: <a href="http://1.usa.gov/1LfaM2">http://1.usa.gov/1LfaM2</a> )</li> <li>• Don't keep unused or expired medicines sitting around. Dispose of them properly. For most medicines, the FDA recommends mixing them with something undesirable like used coffee grounds, sealing them in a ziplock bag and putting them in the household trash. For prescription vials, be sure peel or scratch off the label to remove your personal information. Learn more best practice disposal tips from FDA, and know the few meds they say should be flushed instead of trashed. (HYPERLINK: <a href="http://1.usa.gov/1LfaM2">http://1.usa.gov/1LfaM2</a>)</li> </ul>
Twitter	<ul style="list-style-type: none"> <li>• When did you last clean out your household medicine cabinet? Toss expired &amp; unused meds using these tips #TAYMM <a href="http://bit.ly/TAYMM">http://bit.ly/TAYMM</a></li> <li>• Responsible use of medicines includes disposing of them properly. Talk to your patients about safe disposal or take-back practices. #TAYMM</li> </ul>
Graphic#4	<p>Share the <b>graphic #4</b>:  <b><i>Have a conversation about safe medicine disposal.</i></b>        Most unused or expired medicines can be disposed of by following these 3 steps:</p> <ol style="list-style-type: none"> <li>1. Mix medicines with an unpalatable substance such as kitty litter or used coffee grounds.</li> <li>2. Place the mixture in a container or sealed plastic bag.</li> <li>3. Throw the container in your household trash.</li> </ol> <p>There are some exceptions. Get more drug disposal info at <a href="http://www.talkaboutRx.org">www.talkaboutRx.org</a></p>

Discuss the  
Benefits  
and Risks of  
Prescription  
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## ABOUT NCPIE's *Talk Before You Take* CAMPAIGN

*Talk Before You Take* is a research-based public education campaign designed to encourage and improve communications between healthcare providers (HCPs) and patients about their medicines. Through the completion of a quantitative web-based survey, *Knowledge, Attitudes & Behaviors Concerning Risk & Safety Information of Medicines: A Survey of patients/Patients and HCPs in the U.S.*, NCPIE assessed patients' reported receipt, understanding, use and preferences for information about their medicines—with a parallel assessment of healthcare providers HCPs—to ascertain gaps/disconnects and opportunities to stimulate and improve patient—healthcare provider communication to maximize the *benefits* and minimize potential *risks* of prescribed medication. *Talk Before You Take* messages and educational materials were developed in alignment with these research findings. NCPIE is partnering with key stakeholder organizations to promote the campaign and disseminate educational materials designed for HCPs and patients. Additionally, the campaign will be supported by media outreach, and this website, as a resource for patients and HCPs to download free materials to promote high-quality patient-provider engagement.

The National Council on Patient Information and Education and Education (NCPIE) is pleased to recognize the following organizations for their input in formulating the research agenda and the *Talk Before You Take* campaign:

- American Academy of Physician Assistants
- Caregivers Action Network
- Center for Health and Risk Communication, George Mason University
- Center for Medicare and Medicaid Services (CMS)
- Center for Drug Safety and Effectiveness (CDSE), Johns Hopkins Bloomberg School of Public Health
- Elsevier/ Gold Standard Drug Information Publisher
- Enhance Value
- Institute for Safe Medication Practices
- National Association of Nurse Practitioners in Women's Health
- National Consumers League
- National Osteoporosis Foundation

Discuss the  
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and Risks of  
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Medicines



## HCP PROVIDERS > Talking Points

As a healthcare provider (HCP), you know that it's important that your patients understand the *benefits*, potential *risks* and other key information to help promote safe and appropriate medicine use. Your communications approach can help clarify patients' concerns and questions about taking certain medications when prescribed or recommended as part of a treatment regimen.

Nearly half of Americans take a prescription medicine, and over 20% take at least three. Yet new research shows that approximately 62% of patients are not aware of any safety warnings about their prescription medicines, and 10% of patients, unaware of possible severe reactions to or side effects of the medicines they are taking, actually experience a serious drug reaction. Along with other data, these findings underscore the need to stimulate effective conversations about prescriptions with your patients.

As an HCP, it's a given that one of your goals is to establish strong working relationships and effective communication with your patients, who turn to you first when they have questions about their health. The following facts and tips are designed to stimulate conversations about prescription medicines.

### Facts

According to NCPIE's Knowledge, Attitudes and Behaviors Concerning Risk and Safety Information of Medicines: A Survey of Consumers/Patients and HCPs in the US:

- **Approximately** 62% of patients and caregivers are not aware of any safety warnings about their medicines.
- **Only** 38% of patients and caregivers report being aware of safety warnings, and of those who report being aware of a warning, the majority (75%) do not recall which medicine it is for or what the warning is about.
- **10%** of patients who are unaware of the possibility of a severe reaction or side effect to any of the medicines they are taking, experience a serious drug reaction.
- **While** 85% of HCPs report that their patients adhere to their treatment plans, only 56% of patients report high to very high adherence.
- **HCPs** believe that patients and caregivers do not ask enough questions, nor do they take notes or fully understand the risks associated with taking medicines. In spite of these factors, HCPs believe they establish good working relationships with their patients.
- **Most** consumers prefer both written and verbal communication about drug safety when visiting the HCP (50%) or while filling prescriptions at a pharmacy (48%).
- **Over** half of consumers (58%) prefer HCPs to verbally describe the risks associated with medicines.

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## Talking Points

These facts shed new light on how important HCP/patient communication is to medicine adherence improvement and a balanced discussion of a prescription medicine's benefits and potential risks, opening the door to more productive conversations. While you are probably incorporating most if not all of the following tips, they will remind you that, "you don't know what your patients don't know!"

1. **Remember** that your patients might have questions once they walk out the door.
2. **Reassure** your patients that there are no silly questions.
3. **Insist** that your patients read and follow the directions on the medicine label.
4. **Urge** your patients to take a family member or friend to doctors' appointments to take notes and ask questions.
5. **When** your patients pick up their medications, encourage them to talk to the pharmacist if they have questions. It's also a good idea for your patients to review their medications with the pharmacist.

Interested in improving your patient conversations? Check out these ready-to-use tools. Learn more about the **Talk Before You Take** Campaign.

© Ipsos Healthcare. "Knowledge, Attitudes and Behaviors Concerning Risk and Safety Information of Medicines: A Survey of Consumers/Patients and HCPs in the U.S." An Internal Report (supported by FDA CDER Grant number 5U18FD004653). 2013. Washington, DC.

Discuss the  
Benefits  
and Risks of  
Prescription  
Medicines



## PATIENTS > Talking Points

If you are one of the millions of Americans who takes a prescription medicine, ask yourself: “Do I fully understand the *benefits* and potential *risks* of the medicines I’m taking?” If your response is “no,” you are not alone. Recent research developed by the National Council on Patient Information and Education data:

- 85% of healthcare professionals report that their patients adhere to their treatment plans, but only 56% of patients report high to very high adherence.
- Approximately 62% of patients and caregivers are not aware of any safety warnings about their medicines, and 10% of patients unaware of the possibility of a severe reaction or side effect of any of the medicines they are taking actually experience a serious drug reaction.<sup>i</sup>

This should come as no surprise. How many times have YOU walked out the doctor’s office and said to yourself, “I forgot to ask that question?” Here are **four tips** to guide your conversation with your healthcare provider to help ensure that you get all of your questions asked—even those that perhaps you hadn’t thought of!

1. **Talk** to your healthcare provider and ask questions about the benefits and potential risks of prescription medicines you take.
2. **Tell** your healthcare provider about *all* of the medicines you are taking—including over-the-counter medicines, vitamins, and dietary supplements.
3. **Tell** your healthcare provider about any allergies or sensitivities that you may have.
4. **Read** and follow the medicine label and directions.

When you talk to your healthcare provider, the following questions can help you understand how your new medicine will affect you before you start taking it. It’s also helpful to keep and share an up-to-date list of all medicines you’re taking with your healthcare providers at every visit.

### Questions to ask your Healthcare Provider

1. **What’s** the name of the medicine, and what is it for?
2. **How** and when do I take it, and for how long?
3. **What** side effects should I expect, and what should I do about them?
4. **Should** I take this medicine on an empty stomach or with food?
5. **Should** I avoid any activities, foods, drinks, alcohol or other medicines while taking this prescription?
6. **If it’s** a once-a-day dose, is it best to take it in the morning or evening?
7. **Will** this medicine work safely with any other medicines I’m taking, including over-the-counter medicines?
8. **When** should I expect the medicine to begin to work, and how will I know if it’s working?

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9.

10. **Is there** any additional written information I should read about the medicine?

Remember—*always* follow up with your healthcare provider if you still have questions or concerns about your medicine.

i Ipsos Healthcare. *“Knowledge, Attitudes and Behaviors Concerning Risk and Safety Information of Medicines: A Survey of Consumers/Patients and HCPs in the U.S.”* An Internal Report (supported by FDA CDER Grant number 5U18FD004653). 2013. Washington, DC.

# **Attachment 5**



**National Association of Boards of Pharmacy**

1600 Feehanville Drive • Mount Prospect, IL 60056-6014

Tel: 847/391-4406 • Fax: 847/391-4502

Web Site: [www.nabp.net](http://www.nabp.net)

nabp

# Internet Drug Outlet Identification Program

Progress Report for State and Federal  
Regulators: April 2015

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## **National Association of Boards of Pharmacy**

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nabp

### **INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: April 2015**

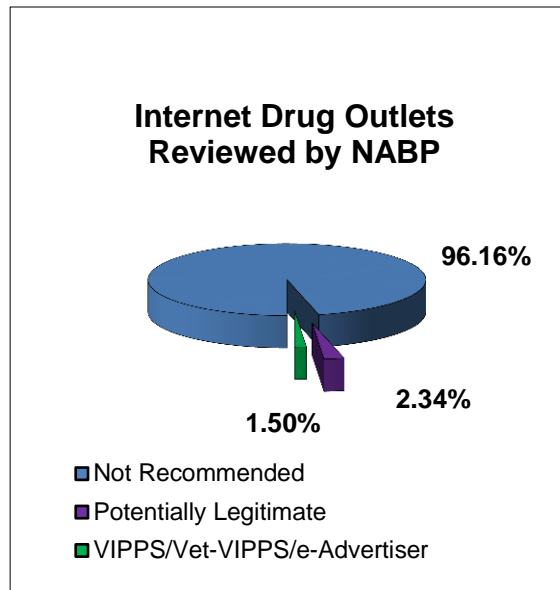
#### **I. INTRODUCTION**

Anyone can register a .com domain name. There are no eligibility requirements, no screening process, and no restrictions on how the website may be used. The same is true of most open registries. It is quick, easy, and inexpensive to launch and operate a website. This fact alone should give consumers pause to consider the source before they buy something as critical as medication from an unknown source over the Internet. The fact that the National Association of Boards of Pharmacy<sup>®</sup> (NABP<sup>®</sup>) has found 96% of nearly 11,000 websites selling prescription medicine online to be out of compliance with pharmacy laws and patient safety standards is further cause for concern. Many public health agencies and patient safety advocates worldwide echo this concern.

Still, public health advocates find that one of the primary challenges in protecting consumers from illegal online drug sellers is the lack of awareness of the potential health and safety risks posed by fake online pharmacies. This public health threat was the impetus for NABP's development and launch of the .pharmacy Top-Level Domain (TLD). Use of the .pharmacy TLD is restricted to website operators that meet program standards for safe and legal practice. The .pharmacy initiative aims to provide consumers around the world a means for easily identifying safe and legal online pharmacies and related resources. Alongside this initiative, NABP has made consumer education one of its primary objectives in 2015. Sharing patient safety information through television, radio, online advertising, and social media, NABP's multi-channel public outreach campaign, discussed further in Section III of this report, is well under way.

## II. RESULTS

A. Findings of Site Reviews to Date: As of March 31, 2015, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 10,965 Internet drug outlets selling prescription medications. Of these, 10,544 (96.16%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards. These sites are listed as Not Recommended in the “Buying Medicine Online” section under Consumers on the NABP website, as well as on NABP’s



AWAR<sub>x</sub>E<sup>®</sup> Prescription Drug Safety website, [www.AWARERX.ORG](http://www.AWARERX.ORG). Of the websites identified by NABP as Not Recommended, the majority were found to be dispensing prescription drugs without a valid prescription. In fact, for each of the past seven years that NABP has been reviewing rogue Internet drug outlets, this was by far the most common reason sites were listed as Not Recommended. These include sites dispensing drugs based solely on an online questionnaire, as well as those requiring no prescription at all. For most, dispensing without a valid prescription was one of several other concerning activities observed. Many also offer foreign and unapproved drugs. Both of these factors pose a public health risk that undermines the regulations put in place in the United States and other developed countries to set standards for the practice of pharmacy, standards for medication safety and efficacy, and regulations for safeguarding the medication supply chain from counterfeit drugs. Most sites selling drugs illegally online do not post any address, and nearly half register their domain names anonymously. The 10,544 Internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table below.<sup>1</sup>

Of the total 10,965 sites reviewed, 257 (2.34%) appear to be potentially legitimate, ie, meet program criteria that could be verified solely by looking at the sites and their domain name registration information. One hundred sixty-four (1.50%) of the 10,965 reviewed sites have been

---

<sup>1</sup> It should be noted that the research findings NABP reports herein and on the Not Recommended list include the total number of websites selling prescription drugs to US patients that NABP staff has reviewed and found to be out of compliance with program standards, including those sites that were found to be noncompliant at the time of review but may since have been deactivated. It should also be noted that the numbers reported here do not represent the entire universe of websites selling prescription drugs illegally, but, rather, a representative sampling of the online environment over the last seven years.

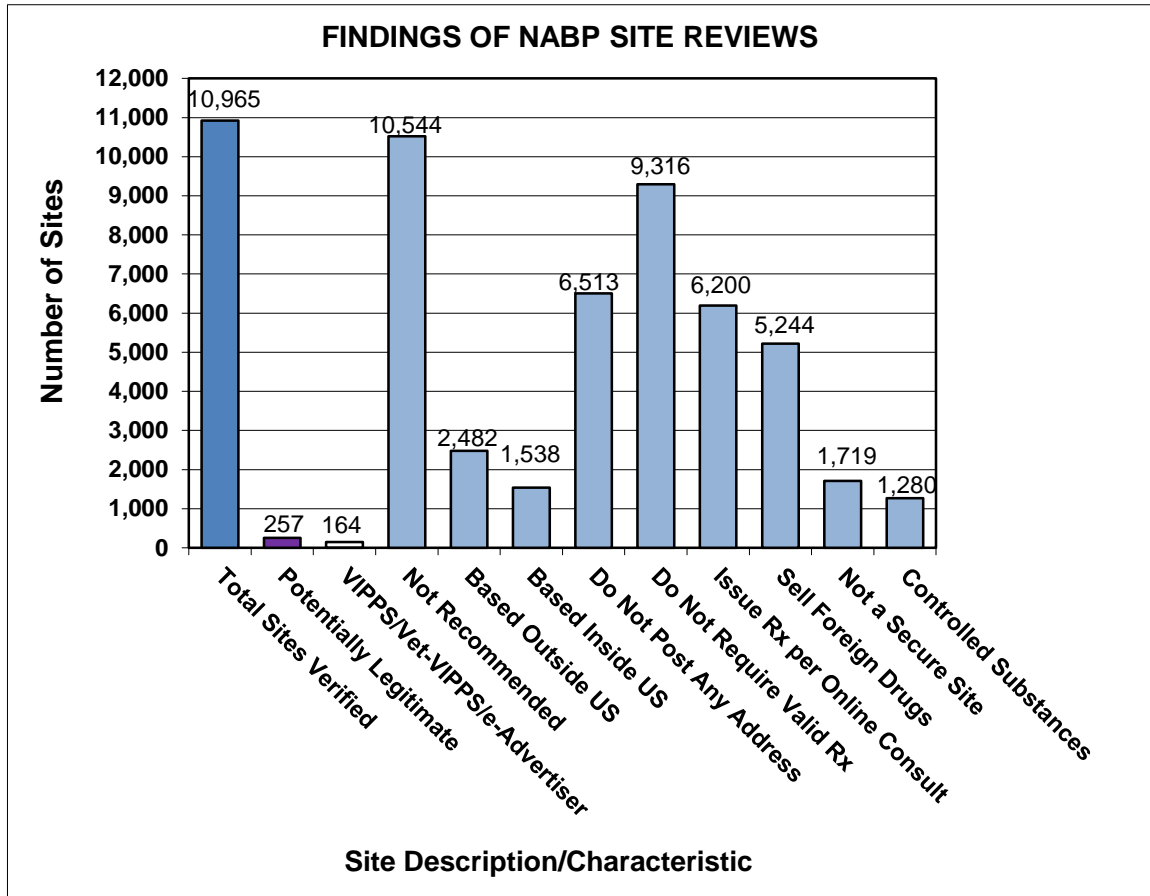
accredited through NABP's Verified Internet Pharmacy Practice Sites<sup>®</sup> (VIPPS<sup>®</sup>) or Veterinary-Verified Internet Pharmacy Practice Sites<sup>®</sup> (Vet-VIPPS<sup>®</sup>) programs, or approved through the NABP e-Advertiser Approval<sup>CM</sup> Program.

### **Not Recommended Sites**

Physical Location:	2,482 (23.5%) outside US
	1,538 (14.6%) inside US
	6,513 (61.8%) no location posted on website
Prescription Requirements:	9,316 (88.4%) do not require valid prescription
	6,200 (58.8%) issue prescriptions per online consultations or questionnaires only
Medications:	5,244 (49.7%) offer foreign or non-FDA-approved medications
	1,280 (12.1%) dispense controlled substances
Encryption:	1,719 (16.3%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	4,405 (41.8%) outside US
	5,675 (53.8%) inside US
	461 (4.4%) have unknown server locations
Affiliations:	9,576 (90.8%) appear to have affiliations with rogue networks of Internet drug outlets

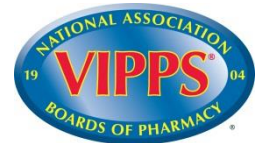
*Sites listed as Not Recommended, in total, as of March 31, 2015*

The standards against which NABP evaluates Internet drug outlets are provided in the appendix of this report.



Findings of NABP website reviews, in total, as of March 31, 2015

- B. Recommended Internet Pharmacies: NABP, along with many patient safety advocates, continues to recommend that US patients use Internet pharmacies accredited through the VIPPS and Vet-VIPPS programs when buying medication online. These sites have undergone and successfully completed the thorough NABP accreditation process, which includes a review of all policies and procedures regarding the practice of pharmacy and dispensing of medicine over the Internet, as well as an on-site inspection of facilities used by the site to receive, review, and dispense medicine. Currently, 64 VIPPS and Vet-VIPPS pharmacy sites are listed as Recommended Internet Pharmacies. Several more applications are in progress.






- C. NABP e-Advertiser Approval Program: Sites that were granted e-Advertiser Approval status do not fill new prescription drug orders via the Internet, and thus are ineligible for VIPPS, but accept refill requests from their existing customers, provide drug information or pharmacy information, or offer other prescription drug-related services. Sites that were granted e-Advertiser Approval status have been found to be safe, reliable, and lawful. These sites are listed on the NABP website as Approved e-Advertisers. Currently, 100 entities are listed on the NABP website as Approved e-Advertisers, and several more applications are in progress.



### III. CONSUMER EDUCATION CAMPAIGN

- A. Public Service Announcements: In light of the public health risks associated with illegal online drug sellers, NABP has made consumer education a priority in 2015 and is reaching out through multiple channels, including television, radio, online advertising, and social media. NABP has produced and distributed public service announcements (PSAs) throughout the country to encourage the safe purchase and use of medications. The video, “A Trustworthy Source,” portrays the importance of obtaining medications from a legitimate pharmacy operating within the laws and safety standards established to protect patient health.



A Trustworthy Source – 60 seconds

As part of its consumer education campaign, NABP has posted an informational video on the .pharmacy website at [www.safe.pharmacy/buying-safely](http://www.safe.pharmacy/buying-safely). The video, “A Trustworthy Source,” portrays the importance of obtaining medications from a legitimate pharmacy operating within the laws and safety standards established to protect patient health.

The image shows a video player interface for a 60-second video titled "A Trustworthy Source". The video frame depicts a man in a blue long-sleeved shirt sitting at a wooden dining table with a young boy in a plaid shirt. They are both looking at something on the table, possibly a toy or a book. In the background, a woman in a yellow top is standing in a kitchen area. The video player has a large play button in the center and a close button in the top right corner.

Results of the consumer education campaign via television have been excellent. In March 2015, the PSAs aired 2,344 times, which translates to 11.39 million audience impressions. Results for radio have also been good. As of March 31, the PSAs aired 1,259 times, which translates to 9.55 million audience impressions. A Spanish version of the radio PSA was also recorded and will soon be running. NABP also reached out to bloggers with its public health message, and embarked on a search-intent and behavioral marketing campaign. In such a campaign, a consumer's online activity prompts .pharmacy banner ads to appear while they are using the Internet. As a result, the banner ads were seen 3.73 million times, and the ads were clicked on 13,374 times, exceeding the benchmark click-through rate by four times. In addition, planning for a satellite/Internet media tour began in March. This will take place in June and will feature NABP Executive Director/Secretary Carmen A. Catizone, MS, RPh, DPh, as well as an individual who has a personal story about a family member who was harmed by receiving counterfeit drugs by ordering them from a seemingly legitimate online drug outlet.

The AWA<sub>R</sub>x<sub>E</sub> Prescription Drug Safety Program is another avenue through which NABP provides authoritative resources about medication safety, prescription drug abuse, medication disposal, and safely buying medications on the Internet. This program provides consumers with medication safety information through the website, [WWW.AWARERX.ORG](http://WWW.AWARERX.ORG), informational materials, PSAs, and social media. AWA<sub>R</sub>x<sub>E</sub> has a YouTube page, [www.youtube.com/user/AWAxRE](http://www.youtube.com/user/AWAxRE), where the above-referenced video can be viewed, and also has a Facebook page, [www.facebook.com/AWAxRE](http://www.facebook.com/AWAxRE), and a Twitter profile.

- B. .Pharmacy Top-Level Domain: To help raise public awareness of the dangers posed by rogue Internet drug outlets, and to provide an online domain where consumers can be sure the websites they find there are legitimate, NABP continues to publicize the launch of its .pharmacy TLD through multiple channels, including internationally distributed news releases. The .pharmacy TLD website, [www.safe.pharmacy](http://www.safe.pharmacy), has become a hub of information not only for potential registrants but also for consumers. A recent addition to the site is the “Buying Safely” section for consumers, presented in both English and Spanish. Also new to the .pharmacy website is the “Find a .pharmacy Website” page, [www.safe.pharmacy/buying-safely/find-a-pharmacy-website](http://www.safe.pharmacy/buying-safely/find-a-pharmacy-website), which lists all .pharmacy domain name registrants. An online form to report abuse is available on the .pharmacy website, [www.safe.pharmacy/buying-safely/report-abuse](http://www.safe.pharmacy/buying-safely/report-abuse). Alternatively, such reports can be emailed to NABP at [abuse@safe.pharmacy](mailto:abuse@safe.pharmacy).



NABP launched the .pharmacy TLD to provide consumers around the world a means for easily identifying safe and legal online pharmacies and related resources. NABP grants use of the .pharmacy domain only to legitimate website operators that adhere to pharmacy laws in the jurisdictions in which they are based and in which their patients and customers reside, so that consumers can easily find safe online pharmacies. The .pharmacy TLD is in the midst of its final limited registration period and will open for General Availability on June 3, 2015. In General Availability, all entities providing pharmacy-related products, services, or information that meet .pharmacy eligibility standards will be able to apply for and, if approved, register .pharmacy domain names. As of March 31, 2015, NABP has granted approval (in the form of electronic tokens) for 294 domain names, and 78 .pharmacy domain names are currently registered.

Additional information about the .Pharmacy TLD Program, as well as information about buying medicine safely online is available at [www.safe.pharmacy](http://www.safe.pharmacy).

#### **IV. DISCUSSION**

NABP continues to reach out to consumers and regulators worldwide to raise awareness of the risks associated with rogue Internet drug outlets and the value of the .pharmacy domain as a public health initiative. NABP supports the efforts of regulators, enforcement authorities, and patient advocates to contain the global public health threat these rogue sites pose. The Association remains committed to upholding the integrity of the practice of pharmacy – in any practice setting – and ensuring that patients worldwide have access to safe and effective prescription drugs. For further information, please contact Melissa Madigan, policy and communications director, via email at [mmadigan@nabp.net](mailto:mmadigan@nabp.net).

## V. APPENDIX

### Internet Drug Outlet Identification Program Standards

1. **Pharmacy licensure.** The pharmacy must be licensed or registered in good standing to operate a pharmacy or engage in the practice of pharmacy in all required jurisdictions.
2. **DEA registration.** The pharmacy, if dispensing controlled substances, must be registered with the US Drug Enforcement Administration (DEA).
3. **Prior discipline.** The pharmacy and its pharmacist-in-charge must not have been subject to significant recent and/or repeated disciplinary sanctions.
4. **Pharmacy location.** The pharmacy must be domiciled in the United States.
5. **Validity of prescription.** The pharmacy shall dispense or offer to dispense prescription drugs only upon receipt of a valid prescription, as defined below, issued by a person authorized to prescribe under state law and, as applicable, federal law. The pharmacy must not distribute or offer to distribute prescriptions or prescription drugs solely on the basis of an online questionnaire or consultation without a preexisting patient-prescriber relationship that has included a face-to-face physical examination, except as explicitly permitted under state telemedicine laws or regulations.

**Definition.** A valid prescription is one issued pursuant to a legitimate patient-prescriber relationship, which requires the following to have been established: a) The patient has a legitimate medical complaint; b) A face-to-face physical examination adequate to establish the legitimacy of the medical complaint has been performed by the prescribing practitioner, or through a telemedicine practice approved by the appropriate practitioner board; and c) A logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.

6. **Legal compliance.** The pharmacy must comply with all provisions of federal and state law, including but not limited to the Federal Food, Drug, and Cosmetic Act and the Federal Controlled Substances Act (including the provisions of the Ryan Haight Online Pharmacy Consumer Protection Act, upon the effective date). The pharmacy must *not* dispense or offer to dispense medications that have not been approved by the US Food and Drug Administration.
7. **Privacy.** If the pharmacy website transmits information that would be considered Protected Health Information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 164), the information must be transmitted in accordance with HIPAA requirements, including the use of Secure-Socket Layer or equivalent technology for the transmission of PHI, and the pharmacy must display its privacy policy that accords with the requirements of the HIPAA Privacy Rule.
8. **Patient services.** The pharmacy must provide on the website an accurate US street address of the dispensing pharmacy or corporate headquarters. The pharmacy must provide on the website an accurate, readily accessible and responsive phone number or secure mechanism via the website, allowing patients to contact or consult with a pharmacist regarding complaints or concerns or in the event of a possible adverse event involving their medication.
9. **Website transparency.** The pharmacy must not engage in practices or extend offers on its website that may deceive or defraud patients as to any material detail regarding the pharmacy, pharmacy staff, prescription drugs, or financial transactions.

10. **Domain name registration.** The domain name registration information of the pharmacy must be accurate, and the domain name registrant must have a logical nexus to the dispensing pharmacy. Absent extenuating circumstances, pharmacy websites utilizing anonymous domain name registration services will not be eligible for approval.
11. **Affiliated websites.** The pharmacy, website, pharmacy staff, domain name registrants, and any person or entity that exercises control over, or participates in, the pharmacy business must not be affiliated with or control any other website that violates these standards.

# **Attachment 6**



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

## COMMUNICATION AND PUBLIC EDUCATION COMMITTEE MEETING MINUTES

Date: October 6, 2015

Location: Department of Consumer Affairs  
1747 N Market Blvd – Room 186  
Sacramento, CA 95834

Committee Members Present: Debbie Veale, RPH, Chair  
Ramón Castellblanch, PhD, Vice Chair, Public Member  
Ryan Brooks, Public Member  
Lavanza (Cheryl) Butler, RPH  
Rosalyn Hackworth, Public Member

Committee Members Not Present: Ricardo Sanchez, Public Member

Staff Present: Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Laura Freedman, DCA Staff Counsel  
Laura Hendricks, Staff Analyst  
Ed Selznick, Public Information Officer  
Debbie Damoth, Staff Services Manager I

The meeting was called to order at 10:03 a.m. Chairperson Debbie Veale welcomed those in attendance. Chairperson Veale announced a quorum was not established but the committee will begin with items that do not require a quorum to vote.

Board members present: Debbie Veale, Lavanza Butler, and Rosalyn Hackworth.

Note: Ryan Brooks arrived 10:08 a.m. and Ramón Castellblanch arrived at 10:11 a.m.

Board members not present: Ricardo Sanchez.

Chairperson Veale announced agenda items will be taken out of order as a quorum wasn't established and the committee is unable to vote on items. Ms. Veale started with Agenda Item 11.

### **Item 11 - Review and Discussion of Articles on Issues of Interest**

Chair Veale stated there were four very good articles attached: "When Drug Addicts Work in Hospitals, No One is Safe," "Safe Medicine Disposal Options," "6 Questions You Should Ask Your Pharmacist," and "Find a Doctor Near You." Ms. Veale asked for board comment and requested the articles be posted to the board's Web site. Ms. Veale also noted the hospital pharmacy article about technicians stealing and distributing drugs was disturbing.

Executive Officer Virginia Herold commented placing articles in the committee packet brings some core knowledge to the committee as a whole and contributes to the idea of future articles in *The Script*.

Assistant Executive Officer Anne Sodergren inquired about the hospital pharmacy article. Ms. Sodergren was concerned whether the approaches used by the technician charged with the crimes in the story were of benefit to highlight weaknesses in the hospital pharmacy system. Ms. Sodergren added it would be good to inform hospitals that events by previous diverters have identified opportunities where hospitals inadvertently encourage these actions.

Ms. Herold added when a hospital chooses not to report someone stealing or becoming addicted to drugs, there are lasting ramifications because data is not tracked, and the person is able to be hired by other facilities. A personnel shortage in the health care field causes this to often occur.

Ms. Veale inquired about the Hepatitis C article to see if an expert could talk to the board to ensure the board's regulations are appropriate and if the board needs to address any weakness in board regulations. Chairperson Veale asked that board staff research this.

Board member Ryan Brooks arrived at 10:08 a.m.

Ms. Herold commented that is the reason the articles are included, to trigger interest. The board can encourage pharmacies and hospitals to maintain control of their drugs, but the reality is there is a larger issue at hand.

Ms. Veale suggested board staff reach out to the hospitals with this information. She pointed out in other diversion cases, diverters were taking medication out and putting saline in place of the stolen medication resulting in patients being shorted their medication. Ms. Herold added it's a problem for ambulances as well as hospitals because health care workers mistakenly think the patient has already been administered the drug, but they haven't as the drugs have been



diverted. Ms. Herold added often the patient is not even anesthetized. Ms. Veale requested the board add this as a point of interest. Ms. Herold then stated she had a meeting the following day with a hospital association and she will bring it up to them

Board Member Ramón Castellblanch arrived at 10:11 a.m.

Ms. Veale asked for public comment. There were no comments from the public.

### **Item 10 – Public Outreach Activities Conducted by the Board**

Chairperson Veale presented and distributed a list of outreach activities. Ms. Veale commented that the Executive Officer was fairly busy.

Ms. Veale asked for board comment. The committee discussed a television interview with Telemundo. Ms. Herold emphasized that outreach to the Spanish speaking population was important. Ms. Butler contributed that she attended the board's outreach on October 3<sup>rd</sup> and it was really good.

Ms. Veale asked for public comment. There were no comments from the public.

### **Item 9 – Update on the Script**

Executive Officer Virginia Herold reported the board will release the fall issue of *The Script* shortly pending the Governor's action on the CURES Bill. The winter issue will be released prior to the end of the year.

### **Item 1 - Requests for Waivers of Requirements for Patient-Centered Labels as Provided in California Business and Professions Code Section 4076.5(d)**

Chairperson Veale recused herself from Agenda Item #1 to avoid conflict of interest. Vice Chair Ramón Castellblanch led the discussion for Agenda Item #1.

#### **Background:**

The statutory requirements for patient-centered labels contain a provision that allows the board to provide a waiver from the requirements in certain circumstances.

Below are the provisions that provide the waiver from section 4076.5(d):

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

storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.

- (e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:
  - (A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
  - (B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
  - (C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.
  - (D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.
- (2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

The board has heard several requests from several entities over the years, but has never approved a waiver.

The recommendation of the committee – whether to grant or deny -- will be provided to the board for ratification at the October Board Meeting

Waivers have been requested by Coram CVS/Specialty Infusion Services and BioRx, LLC.

Ms. Lauren Berton, Director of Pharmacy Regulatory Affairs, CVS Health, which includes Coram CVS Specialty Infusion Services, introduced Patricia Igarashi, Pharmacist and Branch Manager in Hayward, California. Ms. Berton stated Ms. Igarashi will be able to provide the board with answers to their questions.

Ms. Berton requested an exemption from California Code of Regulations section 1707.5 regarding patient-centered label requirements for prescription drugs. Ms. Berton presented an overview of services that Coram provides, showed a sample label for review and provided documents to demonstrate compliance to exemption criteria listed specifically in Business and Professions Code section 4076.5 that would allow Committee to grant an exemption to California Code of Regulation section 1707.5. Ms. Berton requested an exemption for all 8 California Coram pharmacies.

A sample label from TPN products was provided in the meeting materials. Ms. Berton demonstrated there are multiple ingredients in the product. Ms. Berton stated the sample labels on board's Web site are not applicable to this practice setting. Ms. Berton continued each product is patient specific and there could be more ingredients than the example. Ms. Berton indicated a label that meets the requirements of the California Code of Regulation section 1707.5 would need a legal sized sheet that would not fit on the actual TPN bag.

Ms. Berton indicated Business and Professions Code section 4076.5 (e) (1) allows the Board to grant an exemption if certain exemption criteria are met. She stated Coram is seeking an exemption from California Code of Regulation section 1707.5 and also Business and Professions Code section 4076.5 (e) (2). Ms. Burton stated Coram believes they comply with the criteria.

Ms. Berton closed stating Coram understands the board has never granted an exemption to the patient-centered regulation requirements. However, requested the committee consider a two-year probationary exemption.

Vice Chair Castellblanch thanked Ms. Burton and indicated the committee may have a few questions.

Public Board Member Rosalyn Hackworth inquired to Ms. Herold if the board has been out onsite inspection visits to ensure Coram's compliance. Ms. Herold indicated that the board has been involved as part of compliance. However, the board would not be able to inspect a home where infusions are being administered.

Ms. Herold asked Ms. Berton if Coram's labels are currently compliant. Ms. Berton answered that the labels are not compliant at this time. Ms. Hackworth recommended the committee bring the issue back to the full board. Vice Chair Castellblanch asked if they brought any of the bags that are too small for the labels. Ms. Berton apologized that they did not bring any samples.

Ms. Igarashi explained that on a normal TPN, the bags are about the size of a 2 liter bottle and the current label fits right on the bag. Vice Chair Castellblanch asked if the compliant label would fit onto the bag. Ms. Berton added that it would be overlapping the sides of the bag and pharmaceutically inelegant. Additionally, she added the information would be stretched across the bag and one would have to turn the bag multiple times to read it.

Ms. Herold stated inspections are prompted by consumer complaints. However, the focus of the inspector at the time is resolving the consumer complaint and they may not be looking for non-compliant labels. Ms. Herold added it's a good reminder for the board to follow up in this area. Vice Chair Castellblanch stated he believed there should be some sort of inspection system in place so these current violations can be caught. Ms. Berton stated Coram has had inspections and have been cited for violations but whether the label has been cited for as an issue of non-compliance is hit or miss.

Vice Chair Castellblanch called for additional board comment and public comment. There was no additional board comment and no public comment.

**Motion:** Recommend to the board that Coram be granted a two year conditional waiver and Coram be required to self-report complaints to the board. Mr. Brooks requested Coram brings a sample bag to the full board meeting.

M/S: Brooks/Hackworth

Support: 4    Oppose: 0    Abstain: 1

Vice Chair Castellblanch called for public comment. There was no public comment.

Ms. Herold indicated BioRx was contacted but there didn't appear to be a representative for BioRx at the committee meeting. Chairperson Veale asked if the committee would like BioRx to appear. Dr. Castellblanch indicated BioRx should appear before the committee. Mr. Brooks inquired if their request was of an urgent nature and BioRx misunderstood the committee's request to appear, could BioRx address the board directly at the October board meeting. Chairperson Veale believed this to be reasonable. Ms. Herold indicated the board will reach out to BioRx to clarify the requirement.

Vice Chair Castellblanch returned control of the committee to Chairperson Debbie Veale. .

## **Item 2 - Discussion of the Patient Consultation Survey Questionnaire Released in July 2015 for Possible Revision and Future Use**

### **Background:**

At the July Board Meeting, the board reviewed the results of a short questionnaire made available to the public via Survey Monkey regarding patient consultation. Over 1,000 individuals responded to this survey.

During the discussion on the results of the survey, there were questions raised about the quality of the questions themselves. The board asked that this committee take a look at the questionnaire and see if it could be improved.

During this part of the meeting, the committee reviewed the questionnaire and results

### **Discussion:**

Ms. Veale indicated the survey was a good place to start but should be done by a professional survey taker.

Ms. Lavanza Butler commented that out of 1,000 pharmacists suggested it was significant to note that 80% indicated the problem with performing patient consultations was that their workload was too high. Ms. Butler indicated the question and answer were appropriate due to insufficient staffing.

Chairperson Veale identified the question "What barriers do you have to performing patient consultations?" is a leading question as it gives the pharmacists a reason to tell us about barriers. Ms. Veale thought there should be a more neutral way to ask the question. Mr. Brooks concurred with Ms. Veale that the question leads someone to a conclusion. Ms. Butler stated if you change the question the claim of the workload being too high will still going to come out.

Mr. Brooks questioned the board's purpose when workload of a business is too high. Mr. Brooks believes staffing concerns are a business process and doesn't believe the Board of Pharmacy can do anything about it.

Chair Veale preferred improving the survey and inquired to the resources within the Department of Consumer Affairs. Ms. Herold stated that the survey was strictly a temperature gauge to receive some answers on basic questions from the field. Ms. Herold indicated there may be a unit that puts together refined survey questions, but also asked if we really need another survey for a while unless we have some focus of what to do with the data.

Mrs. Veale expressed concern if the board is not addressing issues such as consultation in the pharmacy. She stated the committee needs to know why consultation is not regularly performed, and whether the issue involves additional education, training, or staffing problems. Ms. Veale indicated the next step is doing something about it, but she is not comfortable moving on it based on this survey. Ms. Herold agreed that was a fair assumption.

Mr. Brooks indicated the answer will remain the same and suggested posing the question to industry.

Ms. Veale indicated the answer of "too high a workload" means many different things to different people and that it's too broad and questions what we need to do to initiate change for pharmacists to positively impact the consulting process.

Dr. Castellblanch expressed that instead of passing the consultation issue on for another 10 to 15 years that we should step up enforcement and hand out more citations and fines.

Ms. Veale stated there could be some tasks that could transfer to the technicians which could be addressed now and might free up the pharmacists to consult with patients. Ms. Veale stated currently, the pharmacists are stretched too far working at the window constantly, on the computer doing quality assurance tasks, as well as supervising. She indicated there could be some regulatory situations where the board could assist with the workload issue.

Ms. Hackworth respectfully disagreed because that just increases the supervisory role of the pharmacist as they would have to watch the technicians even tighter than they do now, and that would, in turn, increase the workload of the pharmacist.

Mr. Brooks suggested supporting legislation to provide a full-time consultant at each pharmacy. However, he noted the board can't walk into a pharmacy and tell them how to run their business as that is not our role.

Ms. Herold suggested bringing the conversation to the full board. Ms. Veale indicated the committee must decide whether this survey was well done or is a more robust survey required.

Mr. Brooks inquired about seeking legal counsel on whether we can proceed in any particular manner.

Mr. Castellblanch stated the consultation issue is at a crisis level and the committee must put this item in front of the full board to discuss. Mr. Castellblanch offered this to be a perfect time to bring the issue up with businesses and they could possibly come up with their own business solution.

Ms. Herold added it's important to add anonymity to the survey because many respondents believe there might be repercussions if it comes back to them. She believed there was value to the previous limited survey.

**Motion:** 1) Bring before the full board for discussion the results from the current limited survey, 2) Discuss if the committee should prepare a broader survey, and 3) Request legal options available to invoke change.

Chairperson Veale asked for public comment. A member of the public explained she wrote an article on medication errors as a pharmacist. She believed the board needs to address workload to protect the pharmacists and consumers.

M/S: Brooks/Castellblanch

Support: 5    Oppose: 0    Abstain: 0

**Item 3 - Request to Augment Information on the Board's Website Regarding the State's Emergency Contraception Protocol**

Background:

For a number of years, California has had a protocol that allows pharmacists to provide emergency contraception to patients who request it. The protocol was developed by a group of sponsors for the enabling legislation, vetted and approved by the board and the Medical Board.

Recently, the board received a request from Professor Sally Rafie, PharmD, BCPS, from UCSD's School of Pharmacy. Dr. Rafie will joined the committee by telephone and provided information about components she believes would provide better information to pharmacists who provide emergency contraception and educational items for the public who may seek emergency contraception.

Additionally, Dr. Rafie requested the board's assistance in sharing a new emergency contraception reference for pharmacists and patients. She stated that she is aware of confusion about the regulations surrounding emergency contraception access with the numerous changes in the last few years.

Discussion:

Dr. Sally Rafie, PharmD, BCPS, from UCSD's School of Pharmacy joined the committee meeting via telephone call. Dr. Rafie is a women's health advocate and has no connection to any of the emergency contraceptive products offered, stated that after the many changes by the FDA regarding emergency contraceptives there is confusion among pharmacists and staffers who provide the service as well as within the public, and utilization has been low. California is a leader in this area and is the only state to have added the new product, Ella, to the protocol.

The committee found Dr. Rafie's information included in the meeting materials to be very informative and her ideas of placement to expose these protocol facts to both the pharmacists and the public very clear and helpful. Ms. Veale asked Ms. Herold if Dr. Rafie's materials were suitable for placement on the board's Web site and in *The Script*. Ms. Herold replied that she has sent the information to the Board's legal counsel and is waiting for an answer.

Ms. Herold also stated she sent the same information to the board's consultant on women's health issues. The board's consultant had a different perspective on listing products. The committee felt the first page of Dr. Rafie's handout was helpful; however, the committee was concerned that the second page displayed actual products that may be misconstrued as board endorsement or advertising.

Dr. Castellblanch suggested if the products were listed by their generic names that might be acceptable to list because the product is available in many generic forms.

Ms. Herold also requested Dr. Rafie send the board a letter from the Reproductive Health Technologies Project or from another group that has been a proponent of the protocol over the years, stating that distributing this information would be a beneficial step for the cause, and thereby further validate placing the information on the board's web site. Dr. Rafie replied she could facilitate that request.

Ms. Veale asked for public comment. There was no public comment.

**Motion:** Recommend to the board placing the information on the board's Web site provided the product brand names, pictures, and prices are deleted as well as, request a follow up with legal counsel on appropriateness.

M/S: Butler/Hackworth

Support: 5    Oppose: 0    Abstain: 0

**Item 4 - Discussion Surrounding that October is "Talk About Prescriptions Month"**

Background:

Every October, the National Council on Patient Information and Education (NCPIE) promotes consumer education themes. This year, the theme is again "Talk About Your Medications

Month.” The goal is to “focus attention on the value that better medicine communication can play in promoting better medicine use and better health outcomes.”

In their press release, NCPIE states:

The ultimate objective of any communication between patients and their healthcare providers is to improve the patient's health and medical care. Good communication is at the heart of good medicine. In fact, data have shown that patients reporting good communication with their health providers are more likely to be satisfied with their care, follow advice and adhere to the prescribed treatment. Of course, communication is a two-way street. Consumers need to be aware of the questions to ask, and healthcare providers in turn must be able to share medical information in a meaningful way that their patients are able to understand and act on. To that end, Talk About Your Medicines Month empowers both.

The board may want to promote patient consultation as part of the board’s contribution to this educational campaign, and for patient education.

Discussion:

Ms. Herold stated there is currently nothing on the board’s Web site but the board will be issuing a press release shortly with the addition of the board’s new Public Information Officer, Ed Selznick. Ms. Herold reported the board could promote to patients to understand their medicines and talk with their pharmacist.

**Item 5 - Update on the Redesign of the Board’s Website in 2015**

Board Webmaster Victor Perez continues his work on redesigning the board’s Web site to make it more user-friendly. A snapshot of the new design was provided at the July Board Meeting. Mr. Perez plans to complete the redesign by the end of the year.

Mr. Victor Perez will continue to work on the Web site with a goal of finishing the work by the end of 2015. At Mr. Brook’s suggestion, the Chair and Vice Chair will review the Web site prior to release. The board may have another press release announcing the update.

**Item 6 - .Pharmacy Domain and Options for the Board to Distribute Public Information Via such a Website**

Background:

As discussed at prior meetings, the National Association of Boards of Pharmacy has established a .pharmacy (pronounced as “dot pharmacy”) top level domain suffix system that will identify websites that comply with NABP’s standards. This is like the “Good Housekeeping Seal” of approval. According to the NABP, of the 10,000 websites it has investigated, 97 percent do not



conform to standard requirements for pharmacies. One component of the .pharmacy system is the offering to state boards of pharmacy the opportunity to establish .pharmacy websites for their use. The Board of Pharmacy's .pharmacy website is [www.CAboard.pharmacy](http://www.CAboard.pharmacy), which currently links to our [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) website.

**Discussion:**

Executive Officer Herold reported there are now dot pharmacy suffixes which feed into the Top-Level Domain of dot pharmacy. Ms. Herold stated the CA State Board of Pharmacy now has a suffix that leads directly into the board's Web site by typing in [www.caboard.pharmacy](http://www.caboard.pharmacy) and that half-the U.S. State Boards of Pharmacy, plus many legitimate national and international entities, are part of the dot pharmacy community. Continuing, she pointed out the purpose is to help people find NABP certified pharmacy sites and not an unregistered, possibly fake and dangerous drug mill.

Ms. Herold presented a 60 second PSA developed by the NABP regarding the .pharmacy domain that has aired thousands of times on television and radio. Many patients don't realize that when they go on-line for cheaper and more convenient drugs they can be very dangerous, so the dot pharmacy sites educates them to avoid these sites and directs them toward legitimate online and brick-and-mortar pharmacies.

Mr. Brooks suggested that the board should begin discussing possible legislation that can be introduced where any pharmacy or drug company selling into California is required to have the .pharmacy suffix. Mr. Brooks continued this would allow a consumer who does not see the .pharmacy designation will steer clear of what is quite possibly a counterfeit drugs operation. Mr. Brooks inquired whether the .pharmacy model should be adopted to help protect consumers. Mr. Brooks recommended further discussion at committee level and bring in legal advisors for advisement of commerce law.

**Motion:** Discuss at the committee level possible legislation to require .pharmacy Web site address for all pharmacies and companies shipping into California as well as consult with Legal counsel.

M/S: Brooks/Butler

Chairperson Veale called for public comment. There was no public comment.

Support: 5    Oppose: 0    Abstain: 0

## **Item 7 - Discussion on development of a Report on the Activities of the Prescription Drug Abuse Subcommittee**

### **Background:**

Over the last two years, the board convened a Prescription Drug Abuse Subcommittee to deal with issues relating to prescription drug abuse. Seven subcommittee meetings were held. Minutes of these subcommittee meetings can be found on the board's Web site.

Recently, Chairperson of the subcommittee, Ramón Castellblanch offered to write a report summarizing the major work of this subcommittee. Dr. Castellblanch provided a draft copy of the report to the committee.

Chairperson Veale turned the discussion lead over to Dr. Castellblanch.

### **Discussion:**

Dr. Castellblanch submitted a comprehensive outline of a report that he will be writing soon from work with the Prescription Drug Abuse Sub-Committee.

One particular area the Board has been proactive in is in the "Red Flags" area of the report, creating regulations requiring pharmacists to take continuing education on "Red Flags" as well as developing a Board brochure on the topic of "Red Flags." Dr. Castellblanch submit a completed and final report before the next committee meeting and will distribute copies to everyone ahead of time so board members may review for discussion. Mr. Brooks commended Dr. Castellblanch's report.

The committee recessed for a break at 12:00 p.m. and resumed at 12:08 p.m.

Mr. Books returned to the meeting at 12:15 p.m.

## **Item 8 – Presentation on Prescription Drug Abuse Activities in Northern California Counties**

Vice Chair Castellblanch invited Aglaia Panos provide a presentation on prescription drug abuse activities in Contra Costa, Alameda and Marin Counties. Dr. Panos accepted the committee's invitation to present at the October committee meeting.

Dr. Aglaia Panos and Dr. Pam Gumbs, presented information regarding the fight against prescription drug abuse in Marin, Alameda, and Contra Costa County. Dr. Panos provided the committee with an example in Marin county where officials instituted a policy and placed it on a public poster stating that opioids prescriptions will not be given out at Hospital Emergency Room. Since that policy was established, opioid prescriptions dropped 40% in Marin County. The RX Save Marin committee has made great strides with unique methods, opening up dialogues between physicians, pharmacists and patients. Alameda and Contra Costa County has also made similar advancements in reducing prescription drug abuse.

The Bay Area County Committee members left copies of all their materials with the Board. These materials will be inserted into future Committee materials.

**Item 12 - Public Comment for Items Not on the Agenda, Matters for Future Meetings**

Chairperson Veale would like to add agenda items for next committee meeting on CURES and some other topics such as education on opioids, Naloxone, red flags, and consumer information. Ms. Herold advised that much information on those topics is already on the website, and there are certain areas that our legal department has prohibited the Board from placing into the website for public consumption at this point. Additional topics to be added to future agendas include UCSD/Consumer Reports, and information for 13/14/15 year olds regarding prescription drug abuse.

Ms. Veale adjourned the meeting was adjourned at 12:30 p.m.