California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

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

Report of the Communication and Public Education Committee Meeting held January 20, 2016.

a. Report on the Presentation by Department of Health Care Services Pharmacist James Gasper Promoting Naloxone and Buprenorphine Access

Dr. James Gasper, BCPP, Psychiatric and Substance Use Disorder Pharmacist of the Pharmacy Benefits Division at the California Department of Health Care Services, presented to the committee on the current state of opioid addiction and opioid overdose deaths in California and nationally. Dr. Gasper discussed potential interventions that pharmacists can make today to improve access to treatment with the opioid overdose antidote naloxone and other forms such as buprenorphine.

Dr. Gasper provided to the committee information indicating an increase in the number of opioid and heroin overdose deaths in the US. Specifically in California, the number of opioid deaths in northern rural California counties from 2008-2012 ranges from 11.2-23.9 deaths per 100,000 deaths where the statewide average is 4.9 deaths per 100,000 deaths. Dr. Gasper attributed this in part to a lack of methadone maintenance in rural/northern counties in California. Solutions presented by Dr. Gasper to help solve this problem included safe prescribing practices, naloxone distribution, and access to treatment for opioid addiction.

A copy of Dr. Gasper's presentation may be found in **Attachment 1**.

b. Discussion on Development of Regulations to Allow for the Waiver of Patient-Centered Label Requirements (Business and Professions Code Section 4076.5(d))

Chairperson Veale reviewed the requirements for the waiver of patient-centered labels pursuant to Business and Professions Code section 4073.5(d). Currently, the process for a licensee requesting the waiver is to come before the committee for approval of the waiver which is then ratified by the full board. The development of the proposed regulations

would allow for this decision to be made at the board staff level, provided the licensee has demonstrated meeting the required elements of section 4073.5(d).

Dr. Gray discussed issues with the accrediting requirement and the word "parenteral" included in (g)(2). He stated that "parenteral" is defined as "other than by enteral route by mouth or rectum." Dr. Gray also noted that the compounding regulations now include eye drops, ear drop, or vaginal suppository.

The committee made a motion to add the proposed language to the appropriate subsection of section 1707.5; incorporate the definition provided by Dr. Gray; add "include other accrediting agencies"; and delegate to the Executive Officer and board staff the authority to sign off on waivers.

Recent Update

Upon further evaluation, board staff recommends amending California Code of Regulation section 1703 to more efficiently achieve the committee's intent to delegating the authority to approve label waivers to the Executive Officer. Based on this additional review, the revised draft language is provided below and may also be found in **Attachment 2**.

Draft Proposal to Amend Section 1703 of Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:
§ 1703. Delegation of Certain Functions.

The power and discretion conferred by law upon the board to receive and file accusations; issue notices of hearing, statements to respondent and statements of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and delivery or mailing of copies of decisions under Section 11518 of said code; issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code; make changes to its regulations without regulatory effect pursuant to Title, California Code of Regulations section 100; and approve waivers pursuant to Section 4076.5 (e) are hereby delegated to and conferred upon the executive officer, or, in his or her absence from the office of the board, the acting executive officer.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4311, Business and Professions Code.

c. Consideration of Request for Waiver of Requirements for Patient-Centered Labels as Provided in California Business and Professions Code Section 4076.5(d) from Access IV

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 follow-up contacts by a nurse or pharmacist.
> (D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.
> (2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

The board has heard several requests from several entities over the years and approved the first waiver in October 2015 to Coram/CVS.

Subsequently, the board received a waiver request from Access IV. At the January 2016 Communication and Public Education Committee, Ms. Ramona Moenter, General Manager presented Access IV's request for waiver grant an exemption to Business and Professions Code section 4076.5 (e) (2) and California Code of Regulation section 1707.5.

Pharmacist Moenter confirmed to the committee that Access IV does meet requirements outlined in section as well as provided the committee with a copy of Access IV's Home Infusion Therapy Patient Information packet. Ms. Moenter verified Access IV is in compliance with AB 1073.

A copy of Access IV's request for waiver, select monographs and Home Infusion Therapy Patient Information packet is included in **Attachment 3**.

Committee Recommendation (Motion): Recommend to the board that Access IV be granted a two year conditional waiver. Require Access IV to self-report complaints to the board.

d. Consideration of Issuing a Revised Patient Consultation Survey Questionnaire

At the October 2015 board meeting, President Gutierrez asked the committee to develop a broader patient consultation survey, as the initial survey conducted in early 2015 was intended only to start the conversation regarding patient consultation.

The committee discussed entities that could assist the committee in the development of a survey including the Department of Consumer Affairs, schools of pharmacy, and associations for the survey to pharmacists. Steve Gray of Kaiser offered many contacts with survey expertise such as UCSB, Kaiser Family Foundation, and USC School of Business.

Chairperson Veale directed staff work with Dr. Castellblanch and research survey options. Board staff will continue to research and report at the March 2016 committee meeting.

e. Update on Information on the Board's Website Regarding the State's Emergency Contraception Protocol

At the October 2015 committee meeting, Dr. Sally Rafie, BCPS, from UCSD's School of Pharmacy requested that the committee reevaluate the emergency contraception information provided on the board's website. The committee requested Dr. Rafie provide letters of endorsements from reproductive organizations supporting her position that posting such information on the board's website would assist in public education.

Additionally, the committee asked Dr. Rafie to provide the educational materials without reference to brand names, so as not to confuse the posting on the board's website with an endorsement for a particular brand of contraception.

Dr. Rafie participated via telephone conference at the January committee meeting. Dr. Rafie presented a letter of support from Executive Director Kelly Cleland, MPA MPH of the American Society for Emergency Contraception (ASEC); President and CEO Jessica Arons of the Reproductive Health Technologies Project (RHTP); and Chair Brooke Griffin, PharmD, BCACP of the American College of Clinical Pharmacy Women's Health Practice & Research Network. Dr. Rafie also presented updated educational material for the board's website without brand name identification or pricing information.

The committee motioned to post the Emergency Contraception: A Guide for Pharmacies and Retailers to the board's website. The board's website reflects the updated brochure as of February 9, 2016. A copy of the brochure and the letter of support may be found in **Attachment 4**.

Committee Recommendation (Motion): Post the Emergency Contraception: Guide for Pharmacies and Retailers on the board's website.

f. Update on the Redesign of the Board's Website

Chairperson Veale and Dr. Castellblanch met with Webmaster Victor Perez and board management to discuss the progress of the website redesign. The new website design is scheduled for release in late spring 2016. Chairperson Veale and Dr. Castellblanch will continue to meet with board staff to oversee the progress of the redesign project.

g. Discussion on .Pharmacy Domain

1. Options for the Board to Distribute Public Information Via the Board's Website

Chairperson Veale deferred this item until the board's website has been redesigned. After the completion of the website redesign the committee will discuss additional information to provide on the board's website.

2. Option of Sending a Letter of Support for .Pharmacy Domain

Chairperson Veale indicated board staff worked with NABP staff to draft a letter of support for the .Pharmacy program.

During the meeting, the committee reviewed the requirements of the program and discussed if it would be appropriate for the board to support the program. Staff indicated that if the committee would like more information on the .Pharmacy program Ms. Herold could provide a presentation at a future committee meeting as she serves on the NABP's .Pharmacy Committee.

A copy of the draft letter of support for the board as well as program requirements may be found in **Attachment 5**.

Committee Recommendation (Motion): Send a letter of support to the NABP for their .Pharmacy domain initiative.

h. Discussion Regarding Prescription Label Translations of Directions for Use

Chairperson Veale reported Assembly Bill 1073 was approved by the Governor on October 11, 2015. The bill requires a pharmacist to use professional judgment to provide a patient

with directions for use of a prescription, consistent with the prescriber's instructions.

AB 1073 also requires a prescriber to provide translated directions for use, if requested, and authorizes the dispenser to use the translations made available on the board's website to comply with the requirement. Dispensers are not required to provide translated directions for use beyond what the board has made available. However, the bill does authorize a dispenser to provide his or her own translated directions for use to comply with the requirement. Veterinarians are exempt from the requirement to provide translated directions for use. The provisions of the bill went into effect on January 1, 2016.

The committee directed board staff to release a public service announcement immediately. The public service announcement was released on February 10, 2016. The release was translated into Chinese, Korean, Vietnamese, Russian and Spanish. Overall the release was sent to over 800 media outlets as indicated below:

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

The information was added to the board's website as a new topic on the homepage. Board staff contacted the Department of Consumer Affairs' (DCA) Public Affairs Office for assistance in disseminating the message through DCA's website, Facebook and Twitter account.

The committee directed staff to develop a communication plan for information dissemination regarding the availability of written translations. The committee also discussed developing draft language for regulations requiring pharmacies to post information for consumers regarding the availability of written translations. Board staff will report their progress to the committee at the March meeting.

Kimberly Chen from the California Pan-Ethnic Health Network offered assistance in the dissemination information. Additionally, board staff will contact Assembly member Ting's office.

Copies of the press releases in English and translated to Spanish, Chinese, Vietnamese, Korean and Russian can be found in **Attachment 6**.

i. Report on Development of FAQs Received From ask.inspector@dca.ca.gov

Chairperson Veale reported the board has implemented a program which gives licensees the opportunity to call and ask general questions to one of the board's pharmacist

inspectors. This call-in service is available Tuesdays and Thursdays from 8:00 am to 4:30 pm. In addition, licensees may submit an email request to a pharmacist inspector at ask.inspector@dca.ca.gov.

Ms. Sodergren reported that the board is working on developing the FAQs for the licensees as well as consumers as both populations ask different types of questions. The board has developed the first FAQs for licensees and will be posting them to the board's website as well as including them in the next newsletter. Chairperson Veale indicated posting the FAQs on the website once approved was acceptable.

j. CURES 2.0 Communication to Licensees

Chairperson Veale reported that the Department of Justice (DOJ) recently announced another milestone in its conversion to CURES 2.0. Specifically, the DOJ announced that beginning January 8, 2016, the upgraded prescription drug monitoring program is available. As part of this transition, on or after January 8, 2016, all current registrants are required to update their registration in the new 2.0 environment to ensure access to the system. This can be done electronically.

Ms. Veale stated that according to the DOJ, CURES 2.0 will be available to all registrants that use Microsoft Internet Explorer Version 11.0 or greater, Mozilla FireFox, Google Chrome, or Safari when accessing the system. Registrants that do not currently have access to one of those specified internet browsers will be able to continue to access the prior version of CURES until the legacy system's retirement, at that time the updated browser must be used.

Chairperson Veale reported the board is working with the DOJ to develop "Frequently Asked Questions" to assist registrants with understanding CURES 2.0. The board will send out updates via its subscriber alert system as it learns additional information from the DOJ. Questions regarding these changes should be directed to cures@doj.ca.gov .

At the meeting a representative of CPhA reported to the committee that at least 10 pharmacists are having issues logging in and added that CPhA has limited contact with DOJ. The representative explained that the pharmacists are prompted to enter a new password; however, when they attempt to enter a new password there is an error screen. It was noted that some pharmacists were able to log-in after waiting 1-2 days after receiving the error message. Ms. Sodergren offered to help the members work with the DOJ to solve their log-in problem.

Ms. Sodergren reported that after January 8, everyone has to re-register online in a streamlined fashion in CURES 2.0 environment. Ms. Sodergren reported that the board has requested that the DOJ produce a tutorial. She added that the DOJ has requested that all issues be addressed to DOJ via email. The board has requested a list of common issues

from DOJ so that an FAQ can be developed to help direct people who are experiencing problems.

Chairperson Veale asked for an update on CURES 2.0 at the next meeting.

k. Update on The Script Newsletter

Chairperson Veale reported Board staff has written the Winter issue of *The Script* newsletter. Staff reported that the Winter issue is currently under legal review, and will be issued soon.

l. Update on Media Activity

Chairperson Veale reported on the media activity for the board. A copy of the media activity report can be found in **Attachment 7**.

m. Update on Public Outreach Activities Conducted by the Board

Chairperson Veale reported on the public outreach activities conducted by the board. A copy of the media activity report can be found in **Attachment 8**.

n. Future Committee Meeting Dates

The future Communication and Public Education Meeting dates have been set as the following dates:

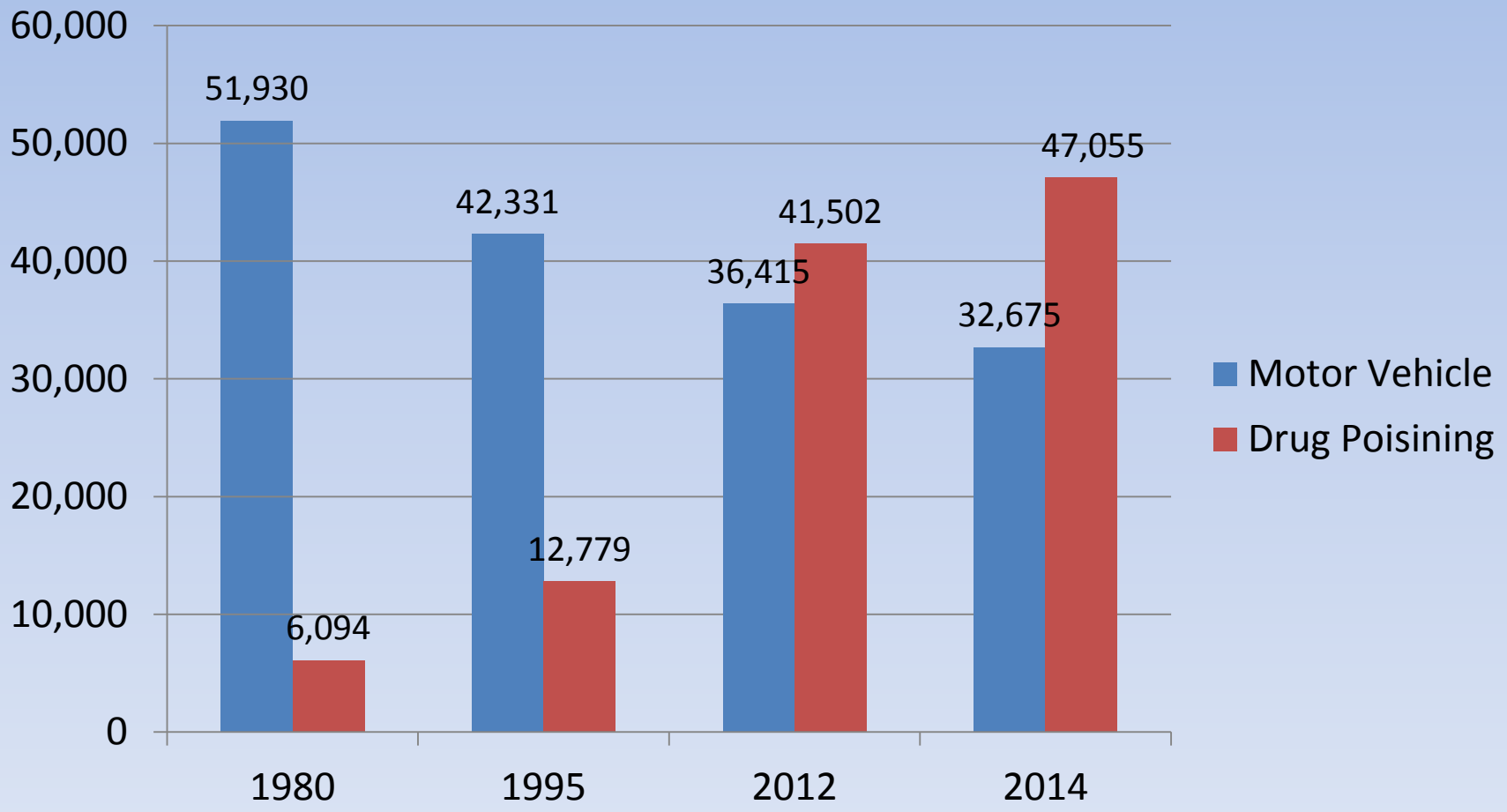
- March 23, 2016
- May 25, 2016
- July 6, 2016

Attachment 1

Opioid Overdose Trends and the Role of Community Pharmacists

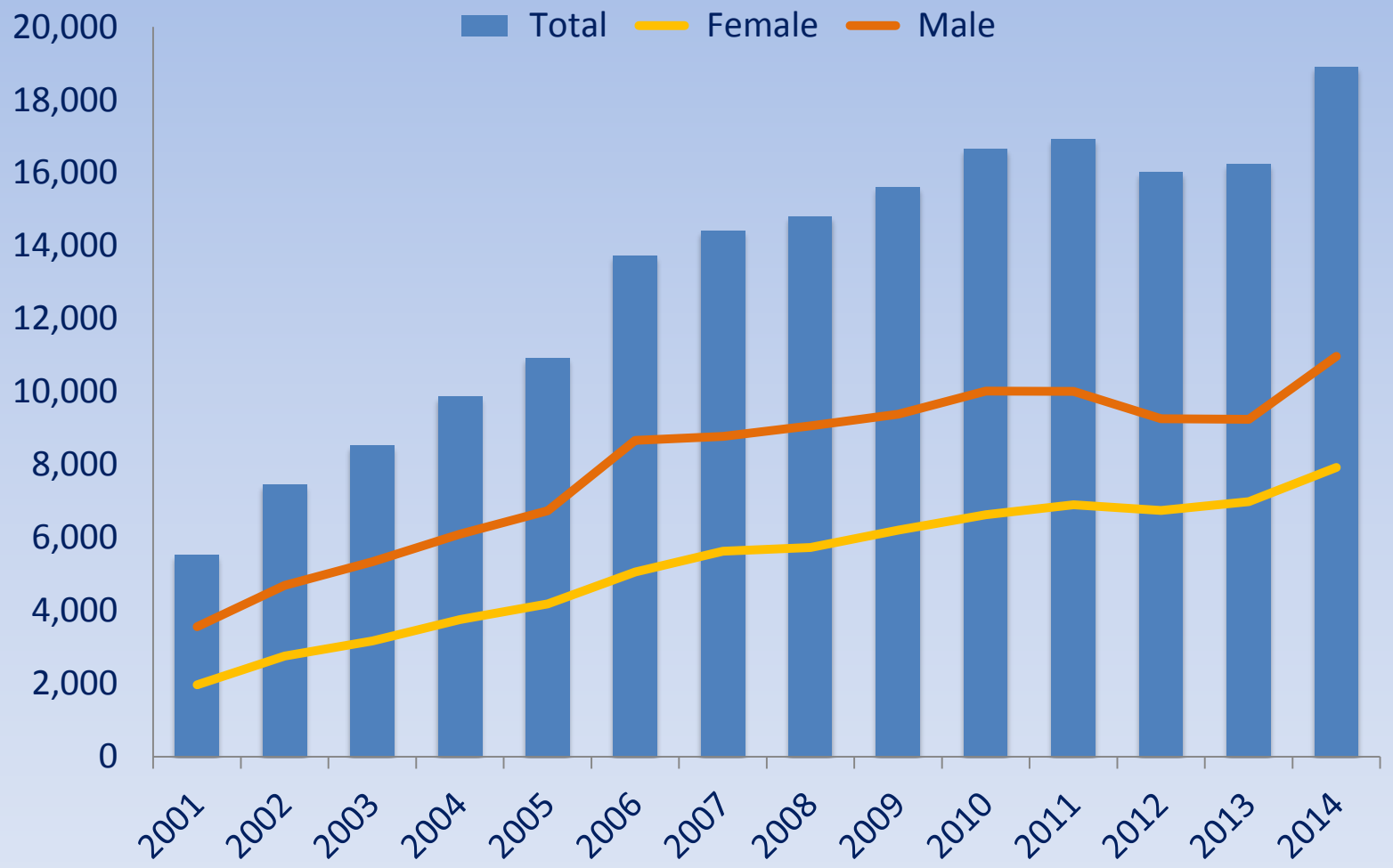
James J. Gasper, PharmD, BCPP
Pharmacy Benefits Division
Department of Health Care Services
james.gasper@dhcs.ca.gov

Drug Overdose Deaths in the U.S.



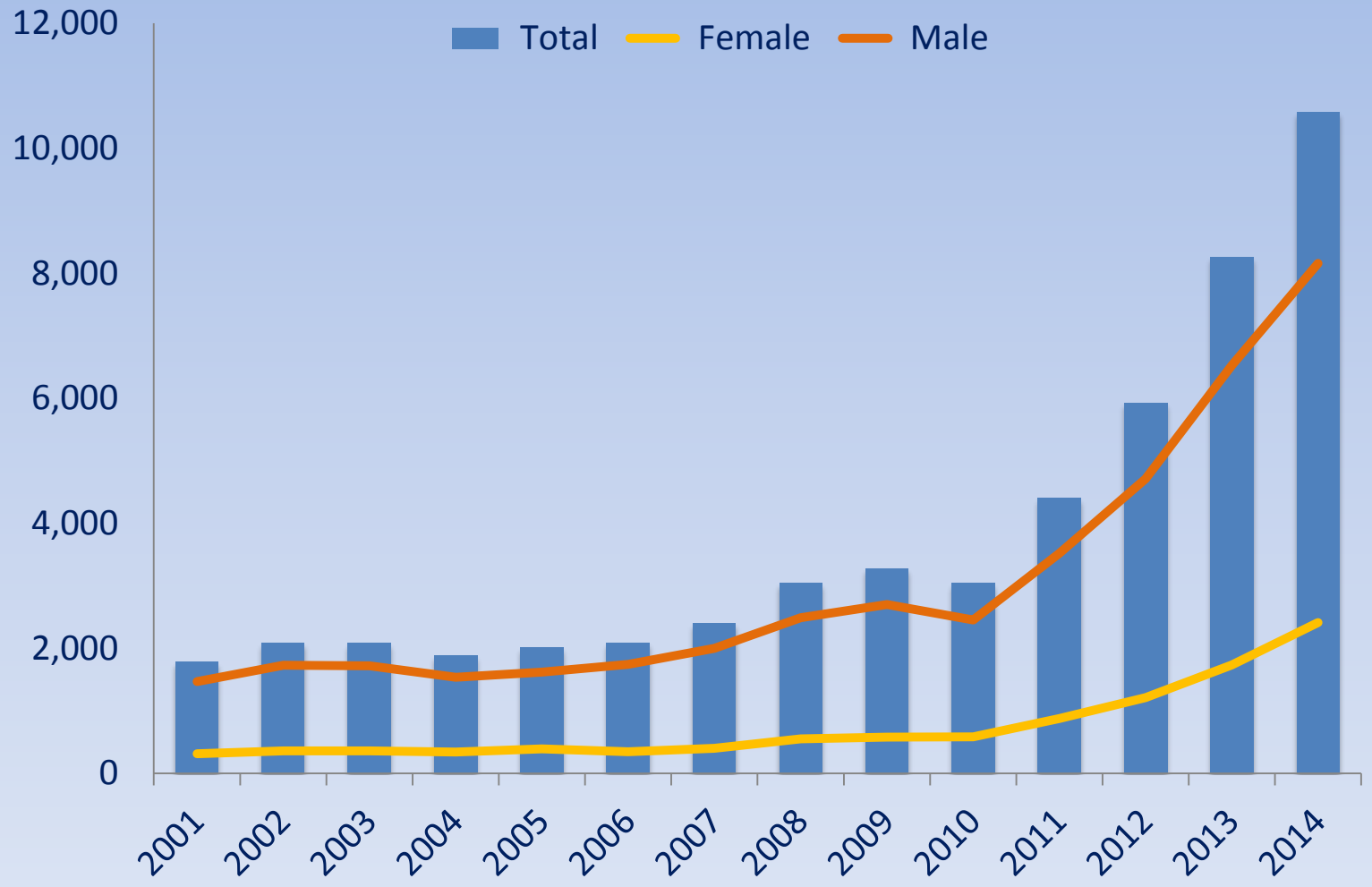
Warner M, et al. Drug Poisoning Deaths in the United States 1980-2008. National Center for Health Statistics 2011;81:1-8. Jones CM. Prescription Drug Abuse and Overdose in the United States. Presented at Third Party Payer and PDMP Meeting 2012. MMWR January 1, 2016.

Overdose Deaths: Prescription Opioids



Source: National Center for Health Statistics, CDC Wonder

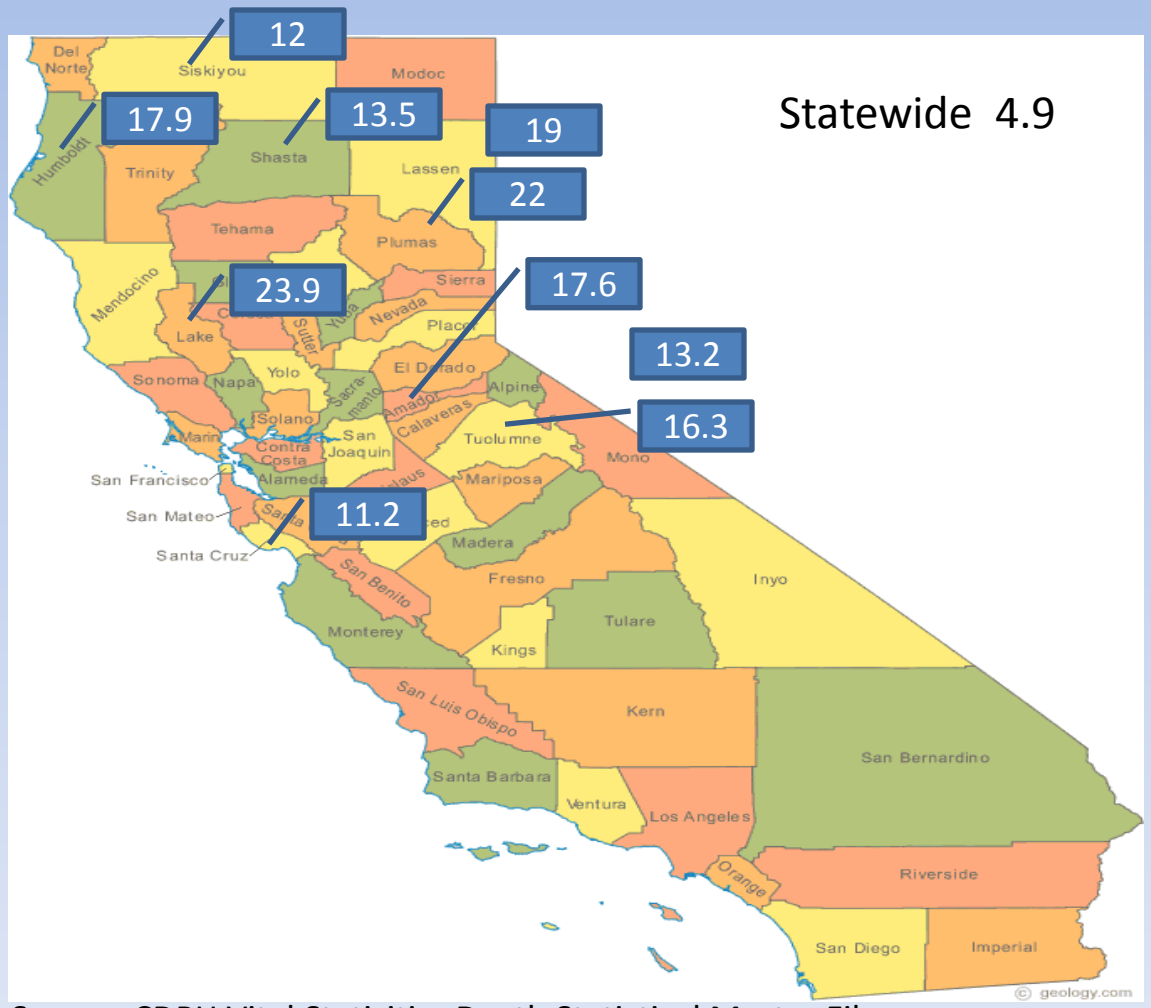
Overdose Deaths: Heroin



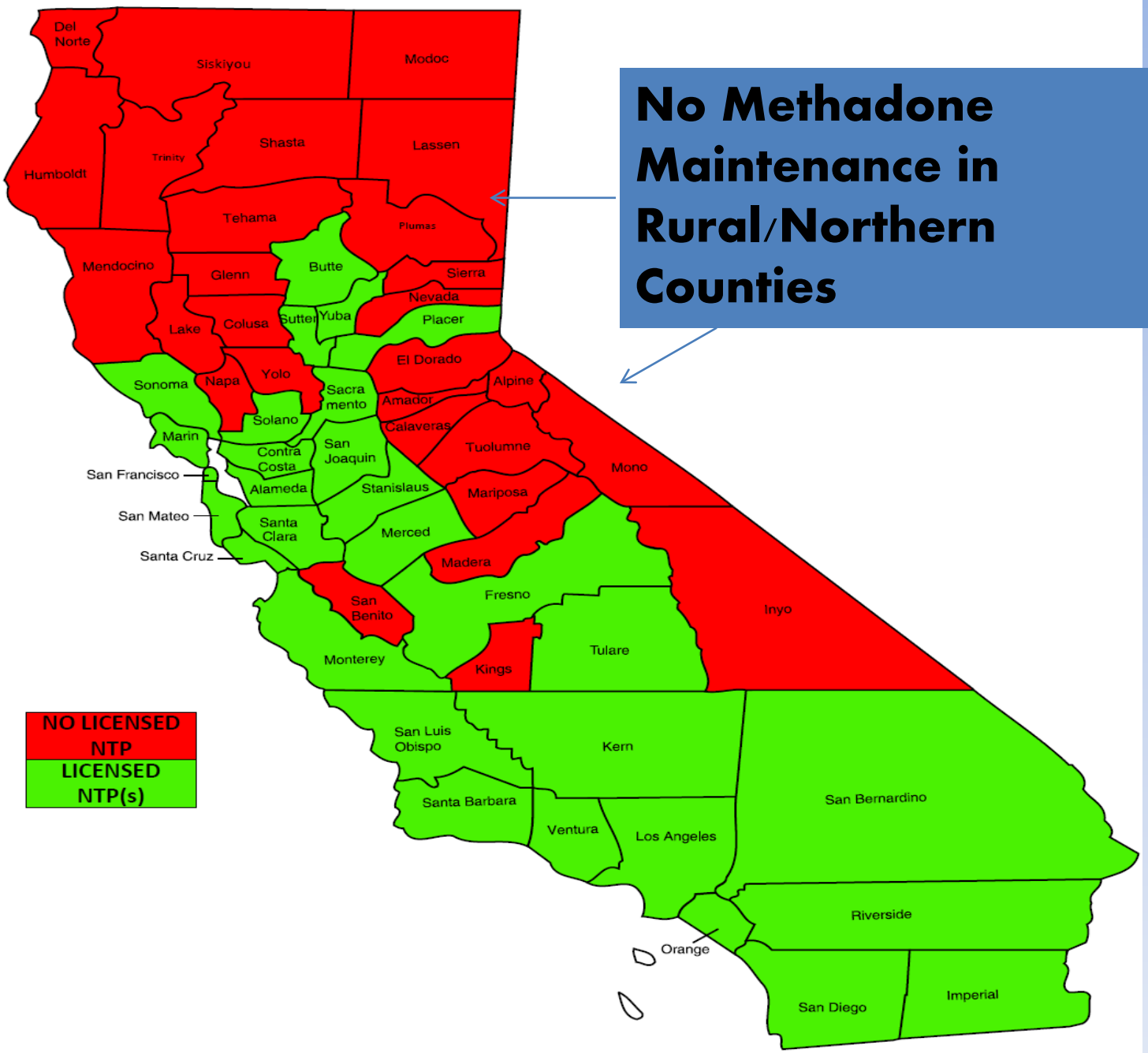
Source: National Center for Health Statistics, CDC Wonder

Overdose Deaths in California

5 year totals: 2008-2012 (All opioids, All intents) rate per 100,000



Source: CDPH Vital Statisitics Death Statistical Master File
Prepared by CDPH, Safe and Active Communities Branch
Report generated from http://epicenter.cdph.ca.gov on Dec 19, 2014


No Methadone Maintenance in Rural/Northern Counties
Del Norte
Siskiyou
Modoc
Humboldt
Trinity
Shasta
Lassen
Tehama
Plumas
Mendocino
Glenn
Butte
Sierra
Nevada
Lake
Colusa
Sutter
Yuba
Placer
El Dorado
Sonoma
Napa
Yolo
Sacra mento
Alpine
Amador
Solano
Calaveras
Marin
Contra Costa
San Joaquin
Tuolumne
Mono
San Francisco
Alameda
Stanislaus
Mariposa
San Mateo
Santa Clara
Merced
Santa Cruz
Madera
Fresno
Inyo
San Benito
Monterey
Kings
Tulare
NO LICENSED NTP
LICENSED NTP(s)
San Luis Obispo
Kern
Santa Barbara
Ventura
Los Angeles
San Bernardino
Riverside
Orange
San Diego
Imperial

California's Gap in Treatment Access

	Rate per 1000 residents
Past Year Opioid Abuse or Dependence	7.6
Buprenorphine Capacity	3.4
Methadone Capacity	1.3

Gap = 2.9 per 1,000 or >100,000

Jones et al. Am J Public Health 2015;105:e55-63
2014 census of licensed slots reported by CA Department of Health Care services

Treatment Saves Lives

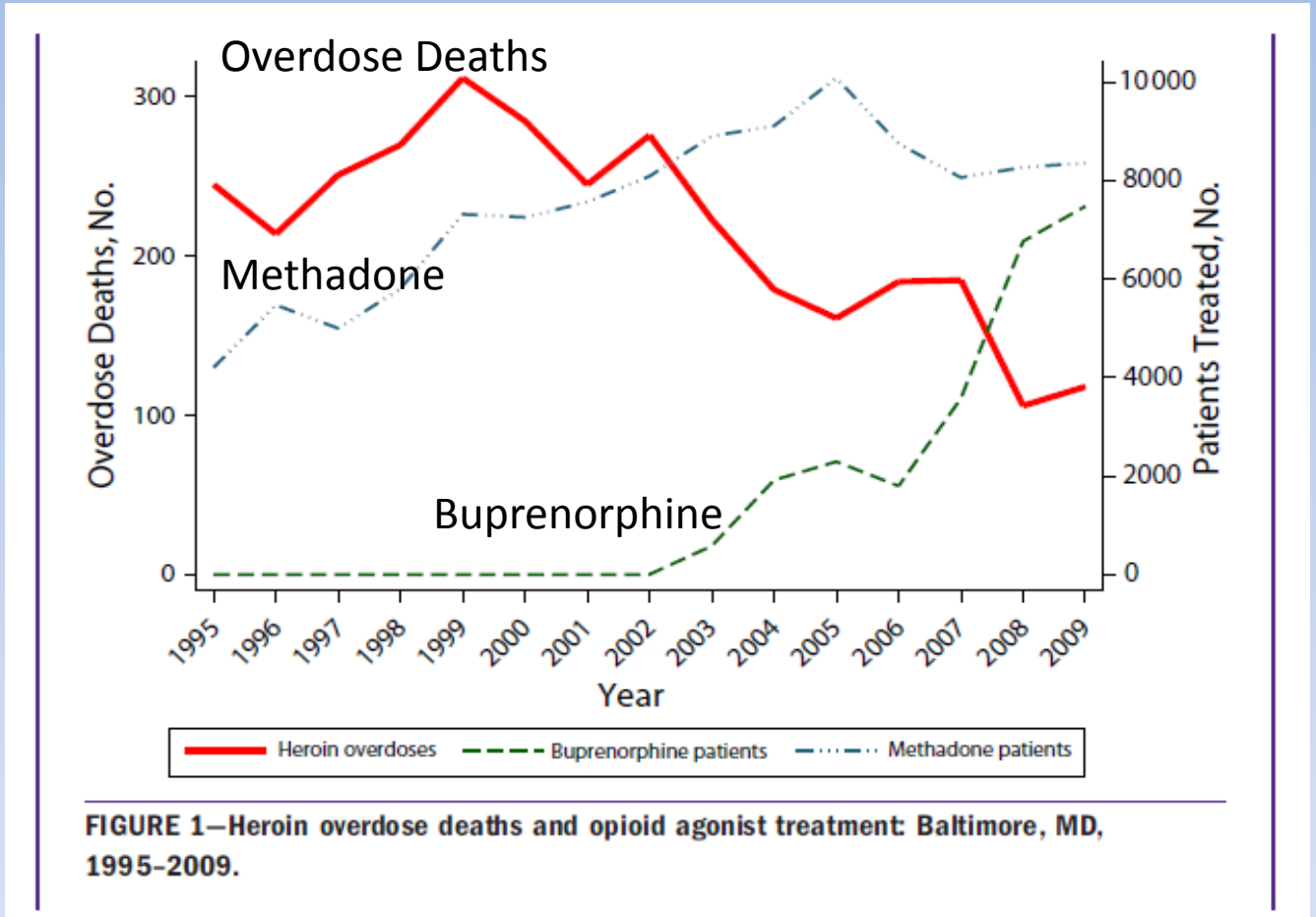


FIGURE 1—Heroin overdose deaths and opioid agonist treatment: Baltimore, MD, 1995–2009.

Schwartz et al. Am J Public Health 2013;103:917-922

The Solutions

- Safe prescribing practices
- Naloxone distribution
- Access to treatment for opioid addiction

Naloxone Pharmacy Access Timeline

September 2014	AB 1535 signed
January 2015	4052.01 implemented
April 2015	emergency regulations

Making Naloxone Happen

- Training availability
- Pharmacy adoption of policies and marketing of naloxone access
- Proactive patient selection by pharmacists

Making Naloxone Happen

- Affordable commercial naloxone product
- Clarity on who is the “prescriber on record”
- Third party reimbursement for pharmacist NPI’s

Increasing Access to Treatment

- Active participation in buprenorphine treatment by pharmacists

- Need to partner with local prescribers for collaborative care of buprenorphine patients

Increasing Access to Treatment

- Willingness of pharmacies and pharmacists to become remote methadone dispensaries for OBOT methadone programs

- Particularly needed in rural areas where methadone clinics do not exist

Attachment 2

Draft Proposal to Amend Section 1703 of Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1703. Delegation of Certain Functions.

The power and discretion conferred by law upon the board to receive and file accusations; issue notices of hearing, statements to respondent and statements of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and delivery or mailing of copies of decisions under Section 11518 of said code; issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code; make changes to its regulations without regulatory effect pursuant to Title, California Code of Regulations section 100; and approve waivers pursuant to Section 4076.5 (e) are hereby delegated to and conferred upon the executive officer, or, in his or her absence from the office of the board, the acting executive officer.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4311, Business and Professions Code.

Attachment 3

January 15, 2016

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

Subject: Request for Exemption – Patient Centered Labels (1707.5)

The California offices of Access IV are requesting an exemption to the Patient Centered labeling requirements as outlined in section Article 4, Section 4076.5. In that section the rules spell out the requirements that must be met in order to have the Board consider such exemption. Access IV meets all of these requirements, which are addressed as follows:

Joint Commission Accreditation:

Access IV is a provider of home infusion services and is accredited for these services by The Joint Commission. The four pharmacies listed below are accredited under AxelaCare Holdings, Inc., organizational ID 473713. Attached as **Exhibit A** are the current accreditation certificates for the four sites, as well as a screen print of the Joint Commission's Quality Check web site showing their accreditation status. The complete results of the accreditation survey that was conducted in April of 2015 can be provided if requested.

Patient Education:

As an integral part of Access IV's services, all patients are provided written and hands-on education as part of their start of care. Nurses provide the on-site care, while the office-based pharmacists provide education and support telephonically. Written education materials are provided as part of this start of care and include a welcome packet, administration directions, drug information, etc. Due to the nature of the compounded sterile products dispensed, patients receive weekly deliveries and all patients are contacted prior to delivery to review and assess adherence, compliance, tolerance to the medication(s), medication and supply usage, etc. If laboratory monitoring has been ordered by the prescriber, labs are reviewed and the prescriber contacted if necessary as part of the weekly medication review. **Exhibit B** will be available at the meeting, including samples of the education materials, including the patient handbook, drug information, and administration instructions.

Care Plan:

All patients have a care plan prepared at the start of care based on the prescriber's orders, as well as an assessment of the patient, their home environment, etc. The plan of care is updated as necessary. **Exhibit C** includes copies of templates utilized for the initial Pharmacist Assessment/Care Plan, 24-72 hour Pharmacist Follow-up Assessment, Additional Care Plan Assessment, and Refill Assessment.

Access IV has implemented a patient-centered label, but is seeking an exemption due to limitations in the pharmacy dispensing system. Examples are attached as **Exhibit D.** Specifically, due to limitations in the label width and number of characters that can fit in the direction field, the system is cutting off words, etc. when printing, although all information looks correct on the computer screen.

This in turn has increased the time required for the pharmacists to process a prescription due to having to print a label, review for missing words, adjust the text in the direction field, reprint, etc. It also increases the opportunity to have product labeled with incomplete directions. Also the larger font (12 pt, BOLD) is resulting in a label that looks busy, is sometimes hard to follow, etc. The original label uses a smaller font size similar to the branch's address.

The exemption requirements addressed above are followed by all the Access IV branches listed below, including following a common core set of policies and procedures for the company, provision of initial and ongoing education, care plan development and review and patient monitoring based on the prescribers' orders and/or prescriptions. Patients are contacted weekly and as stated above, that contact includes a review of compliance, adherence and tolerance to the drug(s).

The four Access IV sites requesting this exemption are:

Access IV
4610 Northgate Blvd, Suite 130
Sacramento, CA 95834
License Nbr: 53890
Sterile Cmpd: 99867
PIC: Lynn Day (44383)

Access IV
455 Reservation Road, Suite G
Marina, CA 93933
License Nbr:53892
Sterile Cmpd: 99868
PIC: Jonathan Vessey (53348)

InfuSource, LLC dba Access IV
170 Professional Center Drive,
Suite C
Rohnert Part, CA 94928
License Nbr: 53893
Sterile Cmpd: 99866
PIC: Maria Ledezma (43965)

ARC Infusion, LLC dba Access IV
12604 Hiddencreek Way, Suite C
Cerritos, CA 90703
License Nbr: 53891
Sterile Cmpd: 100742
PIC: Wawan Natapraya (46801)

Thank you for considering this request and the opportunity to present it to the Board of Pharmacy Communication and Public Education Committee. Should any additional information be needed or requested, please feel free to contact me at the phone number or email address below.

Respectfully,

Ramona Moenter, RL, MBA

Ramona Moenter, R.Ph., MBA
General Manager
(916) 648-0124
rmoenter@accessiv.com

Lynn Day, Pharm.D.
Pharmacist-in-charge
(916) 648-0124
lday@accessiv.com

EXHIBIT A

Access I.V.

Cerritos, 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

April 18, 2015

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD
Chair, Board of Commissioners

ID #473713
Print/Reprint Date: 08/03/2015

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.

Access IV, LLC

Marina, 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

April 18, 2015

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD
Chair, Board of Commissioners

ID #473713
Print/Reprint Date: 08/03/2015

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

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Access I.V.

Rohnert Park, 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

April 18, 2015

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD
Chair, Board of Commissioners

ID #473713
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Access IV, LLC

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

April 18, 2015

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD
Chair, Board of Commissioners

ID #473713
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The Joint Commission

HELPING HEALTH CARE ORGANIZATIONS HELP PATIENTS

Quality Check

Accreditation Quality Report

Symbol Key

- The organization has met the National Patient Safety Goal.
- The organization has not met the National Patient Safety Goal.
- The goal is not applicable for this organization.

Quality Report

Summary of Accreditation Quality Information

AxelaCare Holdings, Inc.
DBA: AxelaCare Health Solutions
Org ID: 473713
15529 College Blvd.
Lenexa, KS 66219
(913)747-3700
axelacare.com

Accreditation Programs	Accreditation Decision	Effective Date	Last Full Survey Date	Last On-Site Survey Date
Home Care	Accredited	4/18/2015	4/17/2015	10/16/2015

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National Patient Safety Goals and National Quality Improvement Goals

			Compared to other Joint Commission Accredited Organizations	
			Nationwide	Statewide
Home Care	2015 National Patient Safety Goals	See Detail	✓	N/A *

* State results are not calculated for the National Patient Safety Goals.

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Sites and Services

*** Primary Location**

An organization may provide services not listed here. For more information refer to the Quality Report User Guide .

Locations of Care	Available Services
Access IV, LLC 455 Reservation Road, Suite G Marina, CA 93933	**Services:** • Durable Medical Equipment • Enteral Equipment and/or Supplies • Enteral Nutrients • External Infusion Pumps and/or Supplies • Parenteral Equipment and/or Supplies • Parenteral Nutrients • Pharmacy, Clinical Consulting Services • Pharmacy/Dispensary,General Services • Supplies
Access IV, LLC 4610 Northgate Blvd, Suite 130 Sacramento, CA 95834	**Services:** • Durable Medical Equipment • Enteral Equipment and/or Supplies • Enteral Nutrients • External Infusion Pumps and/or Supplies • Parenteral Equipment and/or • Parenteral Nutrients • Pharmacy, Clinical Consulting Services • Pharmacy/Dispensary,General Services • Supplies

Supplies

ARC Infusion, LLC
DBA: Access I.V.
12604 Hiddencreek Way, Suite C
Cerritos, CA 90703

Services:
- Durable Medical Equipment
- External Infusion Pumps and/or Supplies
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services

AxelaCare Health Solutions, LLC
450 East 96th Street
Indianapolis, IN 46240

Services:
- Home Health, Non-Hospice Services
- Skilled Nursing Services

AxelaCare Health Solutions, LLC *
15529 College Blvd.
Lenexa, KS 66219

AxelaCare Health Solutions, LLC
15529 College Rd.
Lenexa, KS 66219

Services:
- Durable Medical Equipment
- External Infusion Pumps and/or Supplies
- Home Health, Non-Hospice Services
- Parenteral Equipment and/or Supplies
- Parenteral Nutrients
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services
- Skilled Nursing Services
- Supplies

AxelaCare Health Solutions, LLC
4H Raymond Dr.
Havertown, PA 19083

Services:
- Durable Medical Equipment
- External Infusion Pumps and/or Supplies
- Parenteral Equipment and/or Supplies
- Parenteral Nutrients
- Pharmacy/Dispensary,General Services
- Supplies

AxelaCare Health Solutions, LLC
4514 Cole Ave., Ste 600
Dallas, TX 75205

Services:
- Home Health, Non-Hospice Services
- Skilled Nursing Services

AxelaCare Health Solutions, LLC
One Westbrook Corporate Center; Suite 300
Westchester, IL 60154

Services:
- Home Health, Non-Hospice Services
- Skilled Nursing Services

AxelaCare Health Solutions, LLC
1529 Ambassador Caffery Pkwy
Lafayette, LA 70506

Services:
- Durable Medical Equipment
- External Infusion Pumps and/or Supplies
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services

Guardian Health Systems, LP
DBA: AxelaCare
7512 North Broadway, Suite 308
Oklahoma City, OK 73116

Services:
- Durable Medical Equipment
- Enteral Equipment and/or Supplies
- Enteral Nutrients
- External Infusion Pumps and/or Supplies
- Parenteral Equipment and/or Supplies
- Parenteral Nutrients
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services
- Supplies

Home Care IV of Bend, LLC
DBA: AxelaCare
2065 NE Williamson Court
Bend, OR 97701

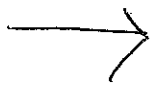
Services:
- Durable Medical Equipment
- Enteral Equipment and/or Supplies
- Parenteral Equipment and/or Supplies
- Pharmacy, Clinical Consulting

- Enteral Nutrients
- External Infusion Pumps and/or Supplies
- Home Health, Non-Hospice Services
- Pharmacy/Dispensary,General Services
- Skilled Nursing Services
- Supplies

Home Infusion With Heart, LLC
DBA: AxelaCare
7602 Park Drive, Suite C
Omaha, NE 68127

Services:

- Durable Medical Equipment
- External Infusion Pumps and/or Supplies
- Parenteral Equipment and/or Supplies
- Parenteral Nutrients
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services
- Supplies



InfuSource, LLC
DBA: Access I.V.
170 Professional Center Drive, Suite C
Rohnert Park, CA 94928

Services:

- Durable Medical Equipment
- Enteral Equipment and/or Supplies
- Enteral Nutrients
- External Infusion Pumps and/or Supplies
- Parenteral Equipment and/or Supplies
- Parenteral Nutrients
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services
- Supplies

Serquinox LLC
DBA: Axelacare
1934 Old Gallows Road
Vienna, VA 22182

Services:

- Home Health, Non-Hospice Services
- Skilled Nursing Services

Serquinox LLC
DBA: AxelaCare
9204 Berger Road, Suite A
Columbia, MD 21046

Services:

- Durable Medical Equipment
- Enteral Equipment and/or Supplies
- Enteral Nutrients
- External Infusion Pumps and/or Supplies
- Home Health, Non-Hospice Services
- Parenteral Equipment and/or Supplies
- Parenteral Nutrients
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services
- Skilled Nursing Services
- Supplies

Sirona Infusion, LLC
460 S. Benson Lane, Suite 11-12
Chandler, AZ 85224

Services:

- Durable Medical Equipment
- Enteral Equipment and/or Supplies
- Enteral Nutrients
- External Infusion Pumps and/or Supplies
- Home Health, Non-Hospice Services
- Parenteral Equipment and/or Supplies
- Parenteral Nutrients
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services
- Skilled Nursing Services
- Supplies

Sirona Infusion, LLC
DBA: AxelaCare
12503 E. Euclid Drive, Unit 80
Centennial, CO 80111

Services:

- Durable Medical Equipment
- Enteral Equipment and/or Supplies
- Enteral Nutrients
- External Infusion Pumps and/or Supplies
- Home Health, Non-Hospice Services
- Parenteral Equipment and/or Supplies
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services
- Skilled Nursing Services
- Supplies

Sirona Infusion, LLC
DBA: AxelaCare
2420 Comanche NE, Suite A5
Albuquerque, NM 87107

Services:

- Durable Medical Equipment
- Enteral Equipment and/or Supplies
- Parenteral Nutrients
- Pharmacy, Clinical Consulting Services

- Enteral Nutrients
- External Infusion Pumps and/or Supplies
- Home Health, Non-Hospice Services
- Parenteral Equipment and/or Supplies
- Pharmacy/Dispensary,General Services
- Skilled Nursing Services
- Supplies

Summit Home Infusion, LLC
3135 New Germany Road, Suite 38
Ebensburg, PA 15931

Services:

- Durable Medical Equipment
- Enteral Nutrients
- External Infusion Pumps and/or Supplies
- Parenteral Equipment and/or Supplies
- Parenteral Nutrients
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services
- Supplies

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The Joint Commission obtains information about accredited/certified organizations not only through direct observations by its employees **...Read more.**

EXHIBIT B

(Available at meeting)

EXHIBIT C

RPh Initial Assessment / Care Plan* For TEST TEST

Date of Birth 08/19/1953

Visit Info

Clinician	Lynn Day	**Visit Date / Time**	01/15/2016 02:53:41 PM
Visit Location		**Visit Type**	

Vital Info

Last / First	TEST, TEST				
Address	14 Lookout Ct			**Drug Allergies**	Penicillins
City / State / Zip	Sacramento, CA		95831	**Other Allergies**	
Diet				**Diabetic**	
Home Phone	916-424-0444			**Code Status**	
Work Phone		**Cell**		**Language**	English
Diagnosis 1	Cellulitis of face - L03.211			**Diagnosis 3**	-
Diagnosis 2	-			**Diagnosis 4**	-

Access / Vital Signs

Access Type		Date	Placed By	
BP	**HR**	**RR**	**TEMP**	**WT (lbs.)**

Clinician Lynn Day **Visit Date / Time** 01/15/2016 02:53:41

#	Question	Answer

Subjective / Objective

1 **Patient age**
2 **Patient sex**
3 **Height**
4 **Patient weight (pounds)**
5 **Is the Weight**
6 **PMH/PSH Summary**
7 **Smoking history:**
8 **Alcohol usage:**
9 **Recreational drug usage:**
10 **Social Issues noted**
11 **Therapy diagnosis reviewed:**
12 **Is this a first dose of medication?**
13 **Therapy Ordered**

RPh Initial Assessment / Care Plan* For TEST TEST

Clinician Lynn Day **Date of Birth** 08/19/1953 **Visit Date / Time** 01/15/2016 02:53:41

#	Question	Answer
	(Drug, Dose, Frequency, length of infusion)	
14	Type of Administration / Device	
15	Expected length of Therapy	
16	Type of IV Access	
17	If other, please list	
18	Number of lumens	
19	Agency or RN contacted?	

Assessment

20	Orders signed and complete	
21	Are the medication orders appropriate for:	
22	Follow up required?	
23	If yes, explain	

Plan

24	Obtain medication profile & assess for potential drug interactions & therapeutic duplications	
25	Monitoring Plan	
26	Labwork orders / changes	
27	Other	
28	Frequency of labwork:	
29	Pharmacist Assessment comments	

RPh 24-72 hr Follow Up Assessment* For TEST TEST

Clinician Lynn Day Visit Date / Time 01/15/2016 02:54:36

#	Question	Answer

Subjective / Objective

1 Verification of Patient Identity

2 If not the patient - enter name and relationship to patient

3 Patient or caregiver can confirm contact information for pharmacy and nursing:

4 Patient / caregiver to confirm the following are available in home:
[NO to any item - please address in planning section]

5 Current Infusion Orders

Assessment

6 Any problems with the infusion of medication we are providing?

7 Medication related side effects

8 Any problems with infusion supplies and / or equipment

9 If answered "YES" to any of the above questions, explain:

10 Allergies confirmed with patient, updated in profile, noting type or severity of reaction if relayed:

11 Social history and PMH reviewed and updated; as needed

12 Pain at present

13 Current pain level (0=none, 10=worst)

14 Pain comments

Nutritional Risk Screening

15 Is this patient full service {AxelaCare nursing and pharmacy}?

16 Diet:

17 Is education / reinforcement required:

RPh 24-72 hr Follow Up Assessment* For TEST TEST

#	Question	Answer
18	Height	
19	Current weight	
20	Usual weight (prior to illness)	
21	Weight loss of greater than 10% over 3 months?	
22	Chronic disease state?	
23	Illness or condition exists that caused decreased PO intake for greater than 5 days?	
24	Does the patient have any of the following nutritional risk factors:	
25	Nutritional Risk	
26	Nutritional Comments	

Medications

#	Question	Answer
27	Medication profile reconciliation performed (open med profile tab & enter / update information)	
28	Drug Utilization Review performed	
29	Medication counseling / education offered by the pharmacist to the patient regarding current medication(s) & OTC(s)	
30	Medication Profile Comments	

Plan

#	Question	Answer
31	Review with patient / caregiver(s) plan for therapy; monitoring, goals and expectations:	
32	Pharmacist Assessment comments	
33	Next RN visit is scheduled for?	/ / : : AM
34	Next physcian or clinic appointment	/ / : : AM
35	Scheduled delivery date:	/ / : : AM

RPh Additional Care Plan Assessment* For TEST TEST

Clinician Lynn Day **Visit Date / Time** 01/15/2016 02:55:07

#	Question	Answer

Subjective / Objective

1 Is additional assessment related a new diagnosis (medication) added for ongoing patient? {e.g. PN patient needing ABX}

2 If yes, please document the additional diagnosis:

3 Is this additional assessment from a change of one medication to a new medication for the same diagnosis

4 If yes, please document the medication to be stopped with reason for change. (e.g.: ceftriaxone 2gm ivp q24 stopped due to elevated ALT at 565)

5 Therapy Ordered (Drug, Dose, Frequency, length of infusion)

6 Expected length of Therapy

7 Is this a first dose of medication?

8 Name & phone of Monitoring Physician

9 Agency or RN contacted?

Assessment

10 Orders obtained & complete as required by state regulations (including RX for Heparin, Saline; Ancillaries and / or Anaphylaxis kit as applicable)

11 Prescription medication is appropriate for:

12 Desired outcome for the treating diagnosis

Plan

13 Medication change

14 Drug Utilization Review performed

15 Labwork orders / changes

16 Monitoring Plan

17 Other patient specific monitoring parameters

Pharmacy Refill Assessment* For TEST TEST

Clinician Lynn Day **Visit Date / Time** 01/15/2016 02:55:40

#	Question	Answer
Subjective / Objective		
1	Date patient called:	/ / : : AM
2	Name of person initiating this form:	
3	Verification of patient identity: [choose two]	
4	If not the patient - enter name and relationship to patient	
5	Any changes to insurance?	
6	New insurance information:	
7	Therapy Type	
8	Current Infusion Orders	
9	Since our last call; are you feeling?	
10	What is the patients current weight? (review / update in med info tab)	
11	Are you having an side effects such as:	
12	Any problems with the infusion of medication we are providing?	
13	Any missed doses?	
14	Any problems with IV site?	
15	If answered "YES" to any of the above questions, explain:	
16	Have you been to the doctors office recently?	
17	If yes, did the physician change any of your medications?	
Plan		
18	Has the Pharmacy Inventory Note been completed for this dispense? (NOTE: Mandatory for all Medicare patients)	
19	Scheduled delivery date:	/ / : : AM
20	Delivery should last through:	/ / : : AM
21	Next physcian or clinic appointment	/ / : : AM
22	Next nursing visit?	/ / : : AM

Pharmacy Refill Assessment* For TEST TEST

#	Question	Answer

Assessment

23	Were issues relayed by the patient requiring clinician follow up?	
24	Clinician intervention comments: [patient and/or prescriber]	
25	Were there medication profile changes made?	
26	Medication profile comments:	
27	Pharmacy Labwork Review	
28	Labwork Review Comments	
29	Patient information assessed by this clinical pharmacist and appropriate to continue current orders as noted in EMR	
30	Pharmacist Assessment comments	

EXHIBIT D

Access I.V.
4610 Northgate Boulvard Ste 130
Sacramento, CA 95834-1154

[redacted]

Rx# 01100377 Date Filled: 11/11/15

TPN 3 in 1 3250 ml (Mon-Fri) **#5**

-Directions:

ON MON-FRI. Add MVI to bag & mix well. Infuse one bag over 16hrs via CADD pump. Pump prog: Tot Res Vol = 3350ml, Tot Vol Inf = 3250ml, Taper 0,Taper down = 2hrs. Warm bag to room temp prior to use. Compounded by Access.

up

Exp: 11/20/15 RPH: LD Storage: Keep Refrigerated

exp 11/08/2016

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard Ste 130
Sacramento, CA 95834-1154

[redacted]

Rx# 01100371 Date Filled: 11/11/15

TPN 3:1 2500 ml MWF **#3**

-Directions:

Infuse 2400ml TPN IV daily over 12 hour via CADD Pump prog: Res Vol:2550 ml Inf Vol:2500ml Period: 12 Hr Taper Up/Down 1 Hr up and 1Hr Allow to warm to room temperature prior to Add 10ml Infuvite just prior to use DAILY.

down

Exp: 11/20/15 RPH: AB Storage: Keep Refrigerated

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard Ste 130
Sacramento, CA 95834-1154

[redacted]

Rx# 01100377 Date Filled: 11/11/15

CEFTAZIDIME 5 GM/ NS 230ML **#6**

-Directions:

Infuse contents of one Eclipse over 22 hours once as directed. Begin infusion at same time each day. Remove from refrigerator 2-3 hours prior to Do Not Heat.

daily

Fixed this in system (modified label) — but was on screen as this label reads.

Exp: 11/25/15 RPH: RM Storage: Keep Refrigerated

EOT 11/20/15

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154
916-648-0124 DEA#: FA3534004

[redacted]

Rx #: 0110037844 11/20/15 Qty: 1

Anaphylaxis Kit 1 EA

Manuf: **Misc**

Directions:
Mild reaction give diphenhydramine 50mg, (2 caps) slow infusion. If needed, give 2 additional (50mg) For moderate reaction, give 50mg diphenhydramine and STOP inf. For severe breathing problem, give 50mg IV diphenhydramine,EpiPen,Saline, call 911

Storage:

Discard After: 12/20/15 RPh: AB

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154
916-648-0124 DEA#: FA3534004

[redacted]

Rx #: 0110037154 09/22/15 Qty: 4

HIZENTRA 10GM SUB Q WEEKLY

Manuf: **CSL**

Directions:
Withdraw a total of 10 gm (50 ml) into 60 ml syringe infuse subcutaneously once weekly via Freedom 60 pump. Dose will infuse over approximately 65 ~~using F-900 tubing and 3 sites~~ dose = 10gm per week.

Storage: Room Temperature

Discard After: 08/27/16 RPh: LD

[redacted]

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154 916-648-0124

[redacted]

RX# 0110035040 Date Filled: 10/27/2014

DiphenhydrAMINE Capsule # 2

Storage:

Warning: FOR ORAL USE ONLY

Take 1-2 capsules (25-50 mg) by mouth prior to IVIG infusion as needed

Manuf: **MAJOR PHARMACEUTICALS**

Refills: 12 RPh: LD Exp Date:10/27/2015

CAUTION: Federal law prohibits transfer of this drug person other than the patient for whom

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154 916-648-0124

[redacted]

RX# 0110035041 Date Filled: 10/27/2014

Acetaminophen Oral Tablet 325 # 8

Storage: Room Temperature

Warning: FOR ORAL USE ONLY

Take 1-2 tablets (325-650 mg) by mouth prior to IVIG infusion as needed

Manuf: **MAJOR PHARMACEUTICALS**

Refills: 12 RPh: LD Exp Date:10/27/2015

CAUTION: Federal law prohibits transfer of this drug person other than the patient for whom

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154
916-648-0124 DEA#: FA3534004

[redacted]

Rx #: 0110037155 08/28/15 Qty: 1

Anaphylaxis kit

Directions: Manuf: **DEY LABS**

Slow infusion. If **Mild reaction, give diphenhydramine 50mg (2 caps) needed give additional 50mg. Moderate** reaction, give **diphenhydramine 50mg & stop infusion.** For severe **reaction with breathing problem, give** diphenhydramine **50mg IM, EpiPen, and call 911**

Storage: Room Temperature

Discard After: **08/27/16** RPh: LD

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

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Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154 916-648-0124

[redacted]

RX# 0110034805 Date Filled: 10/15/2014

Isosource HN Liquid # 180

Storage:

Warning: FOR ENTERAL USE ONLY

Start bolus feed using 1/2 can 6x daily.
Increase by 1/2 can per feeding as tolerated

Manuf: **NESTLE HEALTHCARE NUTRITION**

Refills: 3 RPh: LD/m Exp Date:09/02/2015

CAUTION: Federal law prohibits transfer of this drug person other than the patient for whom

ACCESS IV An AxelaCare® Company

4610 Northgate Blvd, Suite 130
Sacramento, CA 95834
(831) 384-808 [Main]
(831) 384-8065 [Fax]

November 23, 2015

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 85634

Subject: Request for Exemption – Patient Centered Labels (1707.5)

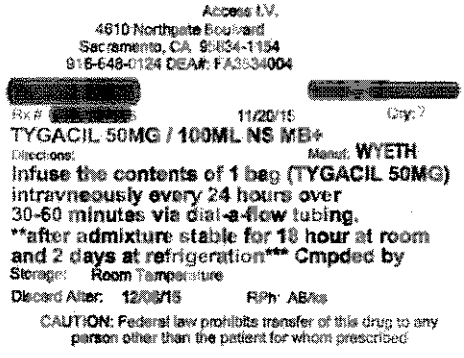
Access IV is requesting an exemption to the Patient Centered labeling requirements as outlined in section Article 4, Section 4076.5. In that section the rules spell out those requirements that can be met to have the board consider such exemption.

Access IV is a provider of home infusion services and is accredited by The Joint Commission. The four pharmacies listed below are accredited under AxelaCare Holdings, Inc., organizational ID 473713. Results of the accreditation survey that was conducted in April of 2015 can be provided if requested.

As part of Access IV's services provided, all patients are provided education as part of their start of care. Nurses provide on site care, while the office based pharmacists provide education and support telephonically. Written education materials are provided as part of this start of care and include a welcome packet, administration directions, drug information, etc. Due to the nature of the compounded sterile products dispensed, patients receive weekly deliveries and all patients are contacted prior to a delivery to review and assess adherence, compliance, tolerance to the medication(s), medication and supply usage, etc. If laboratory monitoring has been ordered by the prescriber, labs are reviewed and the prescriber contacted as part of the medication review.

All patients have a care plan prepared at the start of care based on the prescriber's orders, and an assessment of the patient, their home environment, etc. The plan of care is updated as necessary.

Access IV has implemented a patient centered label but is seeking an exemption due to limitations in the pharmacy dispensing system. An example is found to the right, and several others are separately attached. Specifically, due to the limitations of the label width and number of characters that can fit in the direction field, the system is cutting off words, etc. when printing, although all information looks correct on the screen. This in turn has increased the time required for the pharmacists to process a prescription due to having to print a label, review for missing words, adjust the text in the direction field, reprint, etc.


Access I.V.
4610 Northgate Boulevard
Sacramento, CA 95834-1154
916-648-0124 DEA#: FA2834004

[redacted]

Rx# [redacted] 11/20/15 Qty: 7

TYGACIL 50MG / 100ML NS MB+

Directions: Manuf: **WYETH**

Infuse the contents of 1 bag (TYGACIL 50MG) intravneously every 24 hours over 30-60 minutes via dial-a-flow tubing. **after admixture stable for 10 hour at room and 2 days at refrigeration* Cmpded by**

Storage: **Room Temperature**

Discard After: **12/08/15** RPh: **AB/ks**

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Experience. The Difference.

It also increases the opportunity to have product labeled with incomplete directions. Also the larger font (12 pt, BOLD) is resulting in a label that looks busy, sometimes hard to follow, etc. The original label uses a smaller font size similar to the branch's address.

All the Access IV branches listed below follow a common core set of policies and procedures for the company, provide initial and ongoing education, care plan development and review and patient monitoring based on the prescribers' orders and/or prescriptions. Patients are contacted weekly and as stated above, that contact includes a review of compliance, adherence and tolerance to the drug(s).

The four sites requesting this exemption include:

Access IV
4610 Northgate Blvd, Suite 130
Sacramento, CA 95834
License Nbr: 53890
Sterile Cmpd: 99867
PIC: Lynn Day (44383)

Access IV
455 Reservation Road, Suite G
Marina, CA 93933
License Nbr:53892
Sterile Cmpd: 99868
PIC: Jonathan Vessey (53348)

InfuSource, LLC dba Access IV
170 Professional Center Drive, Suite C
Rohnert Part, CA 94928
License Nbr: 53893
Sterile Cmpd: 99866
PIC: Maria Ledezma (43965)

ARC Infusion, LLC dba Access IV
12604 Hiddencreek Way, Suite C
Cerritos, CA 90703
License Nbr: 53891
Sterile Cmpd: 100742
PIC: Wawan Natapraya (46801)

Thank you for considering this request and we look forward to having further discussions with the Board. Should any additional information be needed or requested, please contact myself at the phone number or email address below.

Respectfully,

Ramona Moenter, RPh, MBA

Ramona Moenter, R.Ph., MBA
General Manager
(831) 384-8080
rmoenter@accessiv.com

Lynn Day, PharmD
Pharmacist-in-Charge
(831) 384-8080
lday@accessiv.com

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154
916-648-0124 DEA#: FA3534004

[redacted] [redacted]

Rx #: 0110037844 11/20/15 Qty: 1

Anaphylaxis Kit 1 EA

Directions: Manuf: **Misc**

Mild reaction give diphenhydramine 50mg, slow infusion. If needed, give 2 additional 50mg. For moderate reaction, give 50mg diphenhydramine **and STOP inf. For severe breathing problem, give 50mg IV diphenhydramine,EpiPen,Saline, call** 911

Storage:

Discard After: **12/20/15** RPh: AB

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard Ste 130
Sacramento, CA 95834-1154

[redacted]

Rx# 01100377 Date Filled: 11/11/15

TPN 3 in 1 3250 ml (Mon-Fri) **#5**

Directions:

ON MON-FRI. Add MVI to bag & mix well. Infuse one bag over 16hrs via CADD pump. Pump prog: Tot Res Vol = 3350ml, Tot Vol Inf = 3250ml, Taper O,Taper down = 2hrs. Warm bag to room temp prior to use. Compounded by Access.

up

Exp: 11/20/15 RPH: LD Storage: Keep Refrigerated

exp 11/08/2016

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard Ste 130
Sacramento, CA 95834-1154

[redacted]

Rx# 01100371 Date Filled: 11/11/15

TPN 3:1 2500 ml MWF **#3**

Directions:

Infuse 2400ml TPN IV daily over 12 hour via CADD Pump prog: Res Vol:2550 ml Inf Vol:2500ml Period: 12 Hr Taper Up/Down 1 Hr up and 1Hr Allow to warm to room temperature prior to Add 10ml Infuvite just prior to use DAILY.

down

Exp: 11/20/15 RPH: AB Storage: Keep Refrigerated

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard Ste 130
Sacramento, CA 95834-1154

[redacted]

Rx# 01100377 Date Filled: 11/11/15

CEFTAZIDIME 5 GM/ NS 230ML **#6**

Directions:

Infuse contents of one Eclipse over 22 hours once as directed. Begin infusion at same time each day. Remove from refrigerator 2-3 hours prior to Do Not Heat.

daily

Fixed this in system (modifier label) — but was on screen as this label reads.

Exp: 11/25/15 RPH: RM Storage: Keep Refrigerated

EOT 11/20/15

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard Ste 130
Sacramento, CA 95834-1154

[redacted]

Rx# 01100377 Date Filled: 11/11/15

TPN 3 in 1 3250 ml (Mon-Fri) #5

Directions:

ON MON-FRI. Add MVI to bag & mix well. Infuse one bag over 16hrs via CADD pump. Pump prog: Tot Res Vol = 3350ml, Tot Vol Inf = 3250ml, Taper 0,Taper down = 2hrs. Warm bag to room temp prior to use. Compounded by Access.

up

Exp: 11/20/15 RPH: LD Storage: Keep Refrigerated

exp 11/08/2016

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard Ste 130
Sacramento, CA 95834-1154

[redacted]

Rx# 01100371 Date Filled: 11/11/15

TPN 3:1 2500 ml MWF #3

Directions:

Infuse 2400ml TPN IV daily over 12 hour via CADD Pump prog: Res Vol:2550 ml Inf Vol:2500ml Period: 12 Hr Taper Up/Down 1 Hr up and 1Hr Allow to warm to room temperature prior to Add 10ml Infuvite just prior to use DAILY.

down

Exp: 11/20/15 RPH: AB Storage: Keep Refrigerated

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard Ste 130
Sacramento, CA 95834-1154

[redacted]

Rx# 01100377 Date Filled: 11/11/15

CEFTAZIDIME 5 GM/ NS 230ML #6

Directions:

Infuse contents of one Eclipse over 22 hours once as directed. Begin infusion at same time each day. Remove from refrigerator 2-3 hours prior to Do Not Heat.

daily

Fixed this in system (modifier label) — but was on screen as this label reads.

Exp: 11/25/15 RPH: RM Storage: Keep Refrigerated

EOT 11/20/15

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154
916-648-0124 DEA#: FA3534004

[redacted] [redacted]

Rx #: 0110037844 11/20/15 Qty: 1

Anaphylaxis Kit 1 EA Manuf: **Misc** (2 caps)

Directions:

Mild reaction give diphenhydramine 50mg, (slow) infusion. If needed, give 2 additional (50mg) For moderate reaction, give 50mg diphenhydramine **and STOP inf. For severe breathing problem, give 50mg IV diphenhydramine,EpiPen,Saline, call** 911

Storage:

Discard After: 12/20/15 RPh: AB

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154
916-648-0124 DEA#: FA3534004

[redacted]

Rx #: 0110037154 09/22/15 Qty: 4

HIZENTRA 10GM SUB Q WEEKLY

Manuf: **CSL**

Directions:

Withdraw a total of 10 gm (50 ml) into 60 ml (Freedom 60) syringe **infuse subcutaneously once weekly via pump. Dose will infuse over approximately 65 using F-900 tubing and 3 sites dose = 10gm per week.**

Storage: Room Temperature

Discard After: 08/27/16 RPh: LD

[redacted]

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154 916-648-0124

[redacted]

RX# 0110035040 Date Filled: 10/27/2014

DiphenhydrAMINE Capsule # 2

Storage:

Warning: FOR ORAL USE ONLY

Take 1-2 capsules (25-50 mg) by mouth prior to IVIG infusion as needed

Manuf: **MAJOR PHARMACEUTICALS**

Refills: 12 RPh: LD Exp Date:10/27/2015

CAUTION: Federal law prohibits transfer of this drug person other than the patient for whom

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154 916-648-0124

[redacted]

RX# 0110035041 Date Filled: 10/27/2014

Acetaminophen Oral Tablet 325 # 8

Storage: Room Temperature

Warning: FOR ORAL USE ONLY

Take 1-2 tablets (325-650 mg) by mouth prior to IVIG infusion as needed

Manuf: **MAJOR PHARMACEUTICALS**

Refills: 12 RPh: LD Exp Date:10/27/2015

CAUTION: Federal law prohibits transfer of this drug person other than the patient for whom

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154
916-648-0124 DEA#: FA3534004

[redacted]

Rx #: 0110037155 08/28/15 Qty: 1

Anaphylaxis kit

Directions: Manuf: **DEY LABS**

Slow infusion. If **Mild reaction, give diphenhydramine 50mg (2 caps) needed give additional 50mg. Moderate** reaction, give **diphenhydramine 50mg & stop infusion.** For severe **reaction with breathing problem, give** diphenhydramine **50mg IM, EpiPen, and call 911**

Storage: Room Temperature

Discard After: **08/27/16** RPh: LD

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154 916-648-0124

[redacted]

RX# 0110034805 Date Filled: 10/15/2014

Isosource HN Liquid # 180

Storage:

Warning: FOR ENTERAL USE ONLY

Start bolus feed using 1/2 can 6x daily.
Increase by 1/2 can per feeding as tolerated

Manuf: **NESTLE HEALTHCARE NUTRITION**

Refills: 3 RPh: LD/m Exp Date:09/02/2015

CAUTION: Federal law prohibits transfer of this drug person other than the patient for whom

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154
916-648-0124

Patient Drug Education Monograph

Monograph For Gammagard Liquid [redacted]

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088

Issue Date: January 13, 2016

This information should not be used to decide whether or not to take this medicine or any other medicine. Only your health care provider has the knowledge and training to decide which medicines are right for you. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from your health care provider. You must talk with your healthcare provider for complete information about the risks and benefits of using this medicine.

GENERIC NAME: Immune Globulin Injection (IV) (i MUNE GLOB ue lin)

WARNING: The chance of blood clots may be raised with this drug. The chance may be higher in older people, if you have to be in a bed or chair for a long time, if you take estrogen products, or if you have certain catheters. Some health problems like thick blood, heart problems, or a history of blood clots raise the chance of having blood clots. Blood clots can happen if you do not have any of these health problems. Call your doctor right away if you have numbness or weakness on 1 side of your body; pain, redness, tenderness, warmth, or swelling in the arms or legs; change in color of an arm or leg; chest pain or pressure; shortness of breath; fast heartbeat; or coughing up blood. Talk with your doctor. Very bad and sometimes deadly kidney problems have happened with human immune globulin products. Kidney problems are more common in people using products that have sucrose. The chance may be raised if you have kidney problems, high blood sugar (diabetes), fluid loss (dehydration) or low blood volume, a blood infection, or proteins in the blood that are not normal. The chance may also be raised if you are 65 or older, or if you take other drugs that may harm the kidneys. Talk with your doctor. COMMON USES: It is used to stop or lower the harshness of other infections in people with a weak immune system. It is used to treat immune thrombocytopenia (ITP). It is used treat chronic inflammatory demyelinating polyneuropathy (CIDP). It is used to treat Kawasaki disease. It may be given to you for other reasons. Talk with the doctor.

HOW TO USE THIS MEDICINE: HOW IS THIS DRUG BEST TAKEN? Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely. It is given as an infusion into a vein over a period of time. HOW DO I STORE AND/OR THROW OUT THIS DRUG? This drug will be given to you in a hospital or doctor's office. You will not store it at home. Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets. Check with your pharmacist about how to throw out unused drugs. WHAT DO I DO IF I MISS A DOSE? Call the doctor to find out what to do.

CAUTIONS: Tell dentists, surgeons, and other doctors that you use this drug. If you have a latex allergy, talk with your doctor. Talk with your doctor before getting any vaccines. Use with this drug may either raise the chance of an infection or make the vaccine not work as well. Have blood work checked as you have been told by the doctor. Talk with the doctor. This drug may affect certain lab tests. Be sure your doctor and lab workers know you take this drug. This drug is made from human plasma (part of the blood) and may have viruses that may cause disease. This drug is screened, tested, and treated to lower the chance that it carries an infection. Talk with the doctor. If you are on a low-salt or salt-free diet, talk with your doctor. Some of these products have salt. If you have

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154
916-648-0124

Patient Drug Education Monograph

Monograph For Gammagard Liquid

[redacted]

high blood sugar (diabetes), talk with your doctor about which glucose tests are best to use. Some patients who have immune globulin therapy for the first time or who have not had it within the past 8 weeks may have a risk for certain side effects. These may be fever, chills, nausea, or vomiting. This may also happen in people who switch brands of immune globulin. Tell the doctor right away if any of these side effects occur. If you are 65 or older, use this drug with care. You could have more side effects. Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant. Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

POSSIBLE SIDE EFFECTS: WHAT ARE SOME SIDE EFFECTS THAT I NEED TO CALL MY DOCTOR ABOUT RIGHT AWAY? WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect: Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat. Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain. Fever or chills. Change in color of skin to a bluish color like on the lips, nail beds, fingers, or toes. Feeling very tired or weak. Seizures. Bloating. Change in thinking clearly and with logic. Swelling. Very bad dizziness or passing out. A heartbeat that does not feel normal. Any bruising or bleeding that is not normal. Mood changes. Muscle or joint pain. Change in speech. Change in eyesight. Blurred eyesight. Shakiness. Sweating a lot. Very bad belly pain. Dark urine or yellow skin or eyes. Very bad irritation where the shot was given. This drug may raise the chance of a very bad brain problem called aseptic meningitis. Call your doctor right away if you have a headache, fever, chills, very upset stomach or throwing up, stiff neck, rash, bright lights bother your eyes, feeling sleepy, or change in thinking clearly and with logic. WHAT ARE SOME OTHER SIDE EFFECTS OF THIS DRUG? All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away: Irritation where this drug is given. Headache. Loose stools (diarrhea). Feeling tired or weak. Back pain. Cough. Sore throat. Stuffy nose. Dizziness. Flushing. Cramps. Upset stomach or throwing up. Belly pain. These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects at http://www.fda.gov/medwatch.

BEFORE USING THIS MEDICINE: WHAT DO I NEED TO TELL MY DOCTOR BEFORE I TAKE THIS DRUG? All products: TELL YOUR DOCTOR: If you have an allergy to immune globulin or any other part of this drug. TELL YOUR DOCTOR: If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs. TELL YOUR DOCTOR: If you have IgA deficiency. TELL YOUR DOCTOR: If you have too much proline in your blood (hyperprolinemia). Gammaplex: TELL YOUR DOCTOR: If you are not able to break down fructose. TELL YOUR DOCTOR: If your child is an infant or baby and it is not known if they are able to break down sucrose or fructose. Do not give this drug to yout child if this is the case. This is not a list of all drugs or health problems that interact with this drug. Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

OVERDOSE: If you think there has been an overdose, call 1-800-222-1222 (the American Association of Poison Control Centers), your local poison control center (http://www.aapcc.org), or emergency room (ER) right away.

Access I.V.
4610 Northgate Boulvard
Sacramento, CA 95834-1154
916-648-0124

Patient Drug Education Monograph

Monograph For Gammagard Liquid

[redacted]

ADDITIONAL INFORMATION: If your symptoms or health problems do not get better or if they become worse, call your doctor. Do not share your drugs with others and do not take anyone else's drugs. Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor. Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins. Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.

Peripherally Inserted Central Catheter (PICC)


APPLY SOAP

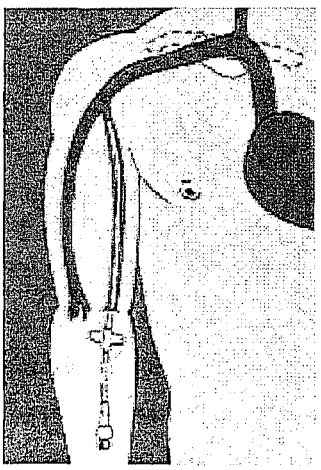

LATHER


RINSE

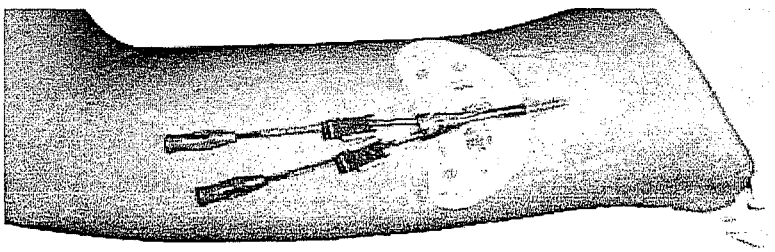

DRY

One of the most important ways to prevent an infection is to wash your hands. Washing your hands is the first step before you begin to set up your medication and supplies. You should use either liquid soap or an alcohol based hand gel, making sure you first remove any visible dirt. Rub your hands together for at least 15-20 seconds. Scrub all surfaces, including the backs of hands, wrists, between fingers and under fingernails. Rinse well under running water if using soap. Dry your hands on a paper towel or a clean cloth towel. Turn off faucet using the towel. If using an alcohol-based hand gel, let gel air dry, and do not rinse under water or towel dry.

Peripherally Inserted Central Catheter (PICC) – a long catheter that is used to deliver medications that cannot be given through a shorter catheter. The catheter is trimmed to the length just right for you and made of a special soft material and inserted 8 to 20 inches into the vein.



A PICC is designed to stay in the vein for a long period of time. This catheter tip is positioned inside a vein in your chest just above the heart, called the superior vena cava. The medication quickly mixes with the blood and taken to other parts of the body



1. The area where the PICC catheter enters your arm must be covered with a protective dressing. The dressing will help to hold the catheter in place and keep the area clean and protected from germs. Protect your PICC as it can be accidently pulled out when snagged. The catheter may be anchored in place by using a special anchoring device to prevent the catheter from moving. There may also be a small disc around the insertion site. Some physicians request an additional antibiotic disc.

2. If the PICC is placed near your elbow you may need to limit the movement of the joint. You may need to straighten your arm to help the medication infuse.

3. With your PICC, you may resume most normal activities. Your nurse will instruct you in the type of activity permitted. You may also be able to bathe. If so, the nurse will give you specific instructions such as: cover the entire dressing and catheter hub/stopper with water-repellant material (e.g., Saran Wrap or plastic), tape all edges so that the outer covering is watertight. If the dressing becomes wet, report it to your nurse.

4. To avoid infection, the dressing, usually a clear bandage placed over the insertion site, should be changed every week if the dressing is not clean or becomes wet. Occasionally a gauze dressing will be used. This dressing needs to be changed every 3 days. Always wash your hands before handling the catheter or touching the area.

5. To keep your catheter open to flow, it may be flushed with a sterile solution such as normal saline and an anti-clotting solution, such as heparin solution to prevent blood clots from forming inside the catheter. Flushing your catheter is extremely important in order to keep it open. Your catheter should always be flushed after medication administration. Your nurse or doctor will tell you what solution should be used and how often it should be flushed.

6. As a safeguard, NEVER use sharp instruments such as scissors near your catheter (to avoid accidentally cutting your catheter).

7. Inspect the insertion site regularly for any redness, swelling, pain, or drainage and never touch the catheter insertion site.

8. At the end of your PICC, a nurse will make sure that there is a needleless hub attached. Only the nurse should remove this component. If you are unable to reach the needleless connector, the nurse will attach an extension set to your PICC. This will allow you to hold your PICC with one hand, while you connect your flushes or medications with your other hand. Your nurse will instruct you to flush your PICC. Some PICC lines need an additional step to prevent the line from clotting and a heparin flush is needed.

9. Call AxelaCare for assistance if any of the following occurs:

    - PICC IV site showing redness, tenderness/streak up arm
    - Catheter becomes unhooked or broken
    - IV fluid leaking from PICC exit site
    - PICC will not infuse or flush after checking for closed clamps, straightening arm and tubing

See important contacts page for more information.

BodyGuard Pump


APPLY SOAP


LATHER


RINSE


DRY

One of the most important ways to prevent an infection is to wash your hands. Washing your hands is the first step before you begin to set up your medication and supplies. You should use either liquid soap or an alcohol based hand gel, making sure you first remove any visible dirt. Rub your hands together for at least 15-20 seconds. Scrub all surfaces, including the backs of hands, wrists, between fingers and under fingernails. Rinse well under running water if using soap. Dry your hands on a paper towel or a clean cloth towel. Turn off faucet using the towel. If using an alcohol-based hand gel, let gel air dry, and do not rinse under water or towel dry.

New Bag — Install Tubing in Pump

1. **Close** the clamp on the new medication bag/tubing set. To close the clamp, pull the tubing down into the narrow part of the clamp.
2. **Open** the pump door by pulling down on the metal door latch located on the right side of the pump.
3. **Locate** the BLACK tubing piece which fits into the grooves on the far right side. **Fit** the BLACK tubing piece into the grooves with the smooth side facing out.

4. **Press** the BLACK tubing piece all the way in and guide the softer tubing section to the left through the tubing channel.

5. **Close** the pump tubing door until you hear it click shut.

Starting the Pump:

1. **Turn** the pump on by pressing the ON/OFF button.
2. The display screen will show self-testing information for a few seconds as the pump powers up.
3. The next screen will show the pre-programmed information.

   Press button.
4. **Open** all clamps. The next screen will display: **START INFUSION?**

   Press button to start infusion.

Stopping/Pausing the Pump:

1. **Stop** the infusion by pressing the STOP/NO button.
2. The screen will display:

** **NOTE:** After pressing the STOP/NO button, you have 2 min. to turn off the power. At the end of 2 min. if you haven't turned off the power, the pump will alarm to remind you to take action.

3. Turn the power off by **pressing** and **holding** the ON/OFF button until the bar on the screen turns completely black.

Restarting or Resuming Infusion:

** If you stopped the pump during an infusion and are ready to turn the pump back on, follow the instructions below:

1. Turn the pump on by **pressing** the ON/OFF button.
2. The display screen will show self-testing information for a few seconds as the pump powers up.
3. The next screen will display:

** If you paused your infusion and it was not complete **press** button.

If you stopped the infusion and it was complete **press STOP/NO button.

4. The next screen will show the pre-programmed information. **Press** button.
5. **Open** all clamps. The next screen will display:

Press button to start infusion.

Recharging the Battery:

1. Your pump has a rechargeable battery. **Connect** the charger cable to the pump's DC port by matching the cable plug to the slot and prongs inside of the DC port. **Plug** into the outlet in your wall.

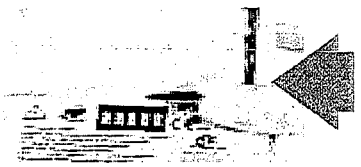
2. The charger light on the adapter plugged into your wall will be Red until the battery is fully charged, then the light turns Green.

3. To disconnect the charger cord, **press** the black button on the cable plug and **pull** the plug out of the DC port.

Rechargeable battery life: With a flow rate of 125mL/hr battery lasts16-18 hr, at 5mL/hr battery lasts 36 hr.

** If you lose power and are unable to charge your pump you have been provided disposable batteries and battery pack.

1. To install the batteries: **Stop** the infusion by following instructions under "Stopping the Pump."
2. **Locate** the battery case on the back of the pump. **Pull** up on the battery case release tab. **Lift** up the right side of the battery case to remove it from the pump.



3. **Insert** the disposable batteries and case into the pump. **Insert** the left side of the case first. Then **push** down on the right side until the release tab clicks into place. **Push** the tab down to ensure the case is secure. Follow instructions under "Starting the Pump."

Disposable battery life: With a flow rate of 125mL/hr batteries last 8-10 hr.

Priming the Pump: *(Only applies to certain therapies)*

1. Follow instructions under "Installing Tubing & Starting the Pump". Make sure you are not connected to tubing set.
2. **Press** the PRIME/PIGGY button, the screen will display:

   PRIME
   Disconnect Patient
   Press OK to Start

3. **Press** button.
4. Use the keypad buttons to enter the amount of fluid to be primed. This is usually 10mL for TPN and 5-6mL for all others.
5. **Press** the button to start priming the tubing set.

   Pump stops automatically when priming is complete. You can stop priming at any time by pressing the STOP/NO button. Repeat steps above to prime additional fluid.
6. When tubing has been primed and there is no air left in line, connect tubing set to your IV catheter. Twist until tightened. **Open** the clamps on the tubing set and on your IV.

   Press button to start infusion.

To Check Battery Level:

1. While pump is operating, press the button 2 times.

   The battery level screen displays a black bar showing the current level of battery power. If less than one-third of the black bar is left, follow instructions to recharge battery. The pump's low-battery alarm comes on when battery has about 30 min. before total power loss.

Alarm Message	What it Means	What to Do
Air/Up Occlusion	Blockage of tubing between medication bag and pump Large air bubble in tubing Medication bag is empty	**1. Press** STOP/NO to silence alarm. **2. OPEN** clamps; un-pinch tubing. If you still can't solve the alarm call your nurse. **3.** To restart infusion **press**
Down Occlusion	Blockage of tubing between you and pump	**1. Press** STOP/NO to silence alarm. **2. OPEN** clamps; un-pinch tubing. If you still can't solve the alarm call your nurse. **3.** To restart infusion **press**
Pump Unattended	2 minutes have passed without control button being pressed	**Press** to continue pump programming.
Door Open	Pump door is open	**1.** Close pump door. **2. Press** to restart.
Low Battery	Battery power is low. Pump will lose all power and stop in about 30 minutes.	Follow instructions under "Recharging Battery". Then **press** to restart.
End Battery	Battery empty, pump has stopped	Follow instructions under "Recharging Battery". Then **press** to restart.
End Program	Infusion complete	**1. Press** STOP/NO to silence alarm. **2.** To start new infusion follow instructions under "New Bag". **3.** If no need to start another infusion **press** ON/OFF to turn off.
Error XX (#)	Pump malfunction	**1. Press** to display 2-digit error number. **2.** Write down number. **3. Press** STOP/NO to silence alarm. **4. Press** ON/OFF to turn off. **5. Call** your nurse or pharmacist.

Home Infusion Therapy

PATIENT INFORMATION

AXELA

Experience. The Difference.

Name: _____

Doctor: _____

Phone: _____

Nurse: _____

Phone: _____

Signature Required Documents

- ❑ Release of Information / Consent For Treatment / AOB
- ❑ Receipt of Privacy Practices form

(If Applicable)

- ❑ Pump Rental Agreement
- ❑ State Specific Home Health form
- ❑ Other _____

Table of Contents

Welcome and General Information

Based on your medical condition, your physician has determined that you are a candidate for home infusion therapy. The Pharmacy and Home Health staff are ready to assist you in improving your health status in the comfort of your own home. The information in this packet will serve as a resource to be used with your physician's instructions and to reinforce the specialized teaching you have received. The education we provide combined with your knowledge of your medical condition and therapy will allow you to be successful in carrying out the procedures.

Our interdisciplinary team consisting of Nurses, Pharmacists and Registered Dieticians will work together as needed to provide the highest quality of care. The nurses will teach you and your caregivers proper techniques to care for your type of therapy. These techniques may appear complicated at first; however, with practice you will gain confidence in your ability to perform them with ease.

Most insurance companies require that patients and/or caregivers participate in as much of their own care as possible. On admission and the first several visits as needed, your pharmacy and home health nurse will be instructing you and a caregiver on your therapy. As you become comfortable, your nurse will have you demonstrate the tasks he or she has taught you. Patients who are independent in their care generally feel confident and correctly perform their therapy after 2-3 visits. You will then be seen as needed according to your medical condition, needs and physician's orders. Your pharmacists, dietitians and support personnel will work with you to manage your supplies and deliveries and will monitor the medications you are receiving for effectiveness and any adverse reactions that may occur with any medication that you receive.

Remember, you are never alone. Our professional health care team is available to assist you 24 hours a day, 7 days a week at: 916-648-0124. If you have any questions or concerns regarding your therapy at home, please call and let us know.

Thank you,

Ramona Moenter, R.Ph., MBA
General Manager

AxelaCare® is committed to
empowering people in the **pursuit** and
delivery of **exceptional** patient **care**.

"Behind every Gold Seal of Approval"
is an organization committed to quality."
The Joint Commission

Important Contacts

Nurse

Name: _____ Phone: _____

Name: _____ Phone: _____

Pharmacy

Name: _____ Phone: _____

Name: _____ Phone: _____

Patient Services

Name: _____ Phone: _____

Billing Department

Name: _____ Phone: _____

Complaints/Feedback

Branch Manager

Name: Ramona Moenter, R.Ph., MBA Phone: 916-648-0124

Email: _____

Nurse Manager

Name: _____ Phone: _____

Email: _____

In case of emergency, dial 911.

Community Resources

If you are looking for something related to your health or community services and can't find it on this quick reference list, please call.

Sacramento

Adolescent Health Program
916-875-6022

Adult Mental Health Access Team
916-875-1055 TTY/TDD:
916-874-8070

Alcohol & Drug System of Care
916-874-9754

Arthritis Foundation:
info.nca@arthritis.org
415-356-1230

California Department of Social Services
916-651-6960

California Diabetes Program
916-552-9888

California Smokers
Helpline: 1-800-NO-BUTTS

Child Abuse Hotline:
916-875-KIDS (5437)

Disease Reporting Service
916-875-5881

Elder Adult Abuse Reporting
916-874-9377

Emergency Medical Services
916-875-9753

Health & Human Services
916-875-9753

HIV/Communicable Disease Prevention
916-875-6022

Medline Plus
www.hlm.nih.gov/medlineplus.com

MY MED SCHEDULE
www.mymedschedule.com

Pharmaceutical Reference
www.drugs.com

Poison Control
800-876-4766

The Institute for Safe Medication Practices
www.ismp.org/tools/deful.asp

Women Infants Children Program
wic@saccounty.net
916-876-5000

Other

Administration for Children & Families
(Adoption, Child Care, Child Support, Child Abuse, Family Services, Foster Care, Community Services, Emergency & Disaster Response, Temporary Assistance, and more.)
www.acf.hhs.gov

Center for Medicare & Medicaid Services (CMS)
877-267-2323
www.cms.gov

Disaster Distress Helpline
www.samhsa.gov
[24/7 hotline]
800-985-5990

Eldercare Locator
www.eldercare.gov
800-677-1116

Health Information Privacy (HIPAA)
www.hhs.gov/ocr/privacy

Medicaid
www.medicaid.gov

Medicare Service Center
800-MEDICARE
800-633-4227

Medicare Fraud & Abuse
800-HHS-TIPS
1-800-447-8477

National Domestic

Violence [24/7 hotline]
800-799-7233

National Alliance on Mental Illness
www.nami.org
800-950-6264

National Center on Elder Abuse
www.ncea.aoa.gov
800-677-1116

National Child Abuse Hotline
www.childhelp.org
800-422-4453

National Sexual Assault Hotline
www.rainn.org
[24/7 hotline]
800-656-4673

National Weather Service
www.weather.gov

National Suicide Prevention
[24/7 hotline]
800-273-TALK (8255)

National Hunger Hotline
Monday to Friday
9 am to 6 pm EST
866-3hu-ngry
866-348-6479
Or
877-8ha-mbre
877-842-6273
Español

Poison Control American Association of Poison Control Centers (AAPCC)
Poison Help Line [24/7]
800-222-1222

U.S. Department of Health and Human Services
370 L'Enfant Promenade, S.W.
Washington, D.C. 20447
www.hhs.gov

About Your Care

Home Infusion Therapy Basics

What is Home Infusion Therapy?

A doctor may prescribe a treatment called Home Infusion Therapy when a patient is ready to leave the hospital or following a doctor's office visit. Home Infusions are given through a catheter or needle intravenously (through a vein in the arm). Infused medicines are prepared by trained home infusion pharmacists and delivered to the home. Infusions are usually prescribed when the medicine is not available orally (by mouth) or topically (skin creams and patches).

Why are infusions given over other methods?

Many medicines are more effective when they are infused. Infused medicines are delivered directly into the blood stream, bypassing the digestive system which may dilute their potency and effectiveness. The goal is to help patients resume normal activities sooner and with fewer restrictions.

Is Home Infusion Therapy safe? Yes.

- Research shows it is just as safe as a hospital
- There is a lower exposure of getting infections
- Enjoy the comfort and safety of your home
- During long-term infusions, a patient can resume normal home activities

How long does an infusion take?

The actual time of the infusion varies. It can take as little as 30 minutes or as long as 7 hours. The length of the infusion depends on the type of medication and the required dosage. Depending on the medication and the doctor's orders, infusions can be given daily, weekly, biweekly, monthly or even less often.

Will I have to operate equipment?

Sometimes, but infusion equipment used in the home is much easier to operate than the equipment used in the hospital. Your nurse will provide easy to follow instructions, so you are completely comfortable before you operate equipment.

What is a Central Line?

Some infusions require a Central Line which is a port placed in the vein prior to release from the hospital. This implanted device remains for the duration of treatment, allowing medications and other solutions to be delivered directly to the bloodstream. A nurse will use the line to administer medication, provide line care and access the line for blood draws if needed.

What should I do to prepare for a home infusion?

Your doctor may suggest taking an over-the-counter pain reliever or medicine for itching because that can sometimes be a side effect.

Other suggestions are to:

- Wear comfortable and loose fitting clothing
- Drink plenty of fluids
- Choose a comfortable place to sit at home, such as a recliner, sofa or bed
- Check with your doctor for specific instructions

What does an infusion feel like?

Patients sometime experience a mild discomfort when the infusion is first started. It feels similar to getting blood drawn at a doctor's office. Some patients experience mild headaches, feel a little tired or a bit fatigued during the infusion.

How will I feel after an infusion?

Feelings can differ depending on the type of medication that is infused. Some patients feel tired and want to go to sleep, while other patients may have a feeling of high energy for 24-48 hours after the infusion. Patients should check with their doctor to learn more about their specific medication.

How are medications ordered, delivered and stored?

A doctor, nurse or hospital personnel will contact a Home Infusion Pharmacy to order appropriate medicines, as well as all necessary supplies, and coordinate delivery to the home. Typically a week's supply is delivered each time. Clear and concise instructions on how to store the specific medications and supplies required for treatment are also provided.

How do I learn more?

In an emergency situation, dial 911 immediately. Non-urgent questions about individualized treatment should be directed to a your doctor or nurse. The professional staff at AxelaCare is also available 24 hours a day, 7 days a week to answer questions about Home Infusion Therapy.

All information and treatment descriptions are intended for educational purposes only. Talk to your doctor before making and lifestyle or treatment changes.

Medications and Supplies

A company representative from the pharmacy will call you to arrange a date for your first home delivery. This delivery will be larger than routine deliveries, and will include all of the medications and supplies you, your caregiver or nurse will need to administer your infusion therapy at home.

The home infusion pharmacy will regularly send you shipments of replacement supplies. The length of time between deliveries will depend on the needs of your therapy. You will be called before each shipment to schedule a delivery time that is convenient for you. Someone should be home when your medications and supplies are delivered. If you cannot be home to receive your delivery, please call the pharmacy to make alternative delivery arrangements. In addition, if you should stop therapy, if your therapy changes or if your supply needs change for any reason, such as a hospital stay, please call the pharmacy.

Because many of the medications you receive need to be kept at controlled temperatures (e.g. refrigerated), they will be shipped in special packaging that helps to maintain a safe temperature. These packages should not be left out in either direct sunlight or areas of the home (e.g. front porches, garages, etc.), that can reach extreme temperatures, either hot or cold.

! Before using the supplies: Be sure your name appears on each prescription label and box received. Check the expiration date on all medications and solutions. Do not use outdated or expired items. Double check all items for damage. Should you identify any discrepancies, immediately contact the pharmacy.

Receiving Deliveries

Your supplies will be brought by a reliable delivery service which could include a company delivery representative, local courier service or common carrier (e.g. FedEx, UPS). At the time of delivery, the driver may ask you to sign a "delivery receipt." Before signing the receipt, it is very important that you check the following:

✓ Does the number of boxes delivered match the number of boxes listed on the delivery receipt? If it differs, write the correct number of boxes on the receipt before signing.

✓ Are all the supplies in good condition? Check for signs of hidden damage, such as water marks, holes, dents or leaks. Remember; do not sign the delivery receipt until you are sure you have everything that is listed on the delivery receipt.

It is important that you sign the delivery ticket and either return it to the delivery representative, or mail it back to the pharmacy in the supplied, stamped, pre-addressed envelope.

Storing Your Medications and Supplies

✓ Do not let a shipment sit untouched. Be sure to check each item for storage requirements. Some of your supplies may need refrigeration or special handling. The pharmacy will tell you how to store these items. You should set aside a separate area in your home for storing your infusion therapy supplies. Non-refrigerated supplies must be stored at room temperature. A temperature of 72°F is best.

- ✓ Supplies should be stored away from direct sunlight, in an area that is segregated, if possible from other household items. If stored in the refrigerator, it is ideal to use one of the vegetable crispers for drug storage. Medications should not be stored against the back of the refrigerator as items tend to freeze.

- ✓ When you put your supplies away, place the new items behind any reserve supplies. Always use the oldest supplies first. This way, you will never need to throw away any supplies because the expiration date has passed.

Returns

According to pharmacy laws, no medications or supplies can be returned for credit. The pharmacy will work with you to ensure you receive the right amount of medication and supplies for your therapy.

Maintenance of Equipment Provided

You may be provided with durable medical equipment (DME or an infusion pump) during the course of your home infusion therapy. It is your responsibility and right to care for, use as instructed and return rental equipment in good condition, normal wear and tear expected. You will be provided instruction on how to properly operate and maintain your equipment. Equipment should be kept clean in accordance with the provisions in the 'Waste Disposal' section below. If instructed by your nurse or pharmacist the device should be plugged into an electrical outlet for charging.

Handling Delivery Problems

If you have a problem with your delivery, please follow these guidelines. If you have a delivery problem not listed below, please contact your pharmacy.

- ✓ Damaged Goods – Write in the number of damaged boxes and type of damage on the delivery receipt before signing it. Tell the driver to return the damaged goods to your home infusion pharmacy listed on the return address label. Then, call the pharmacy to make arrangements for a replacement delivery.

- ✓ If you find damaged items inside the boxes after the driver has left, call the pharmacy and they will tell you what to do.

- ✓ Incomplete Shipment or delivery – Make a list of the missing items on the packing list. Then call the home infusion pharmacy to make arrangements for a complete order.

- ✓ Incorrect Supplies – Call your home infusion pharmacy right away, as soon as you find any missing or extra supplies or medications. You will be given futher directions. Keep the items in question away from your regular supplies so you don't use them by mistake.

- ✓ Late Delivery – If your delivery does not arrive during the time period discussed, please call your home infusion pharmacy.

Disposal of Medications and Supplies

Just as there are germs normally present on your hands and skin, there can be normal germs within your body. To avoid contact with these germs, by yourself and others, it is important to dispose of your supplies correctly.

Any sharps, for example needles and syringes with needles, should be placed in the special red "sharps" box or a hard plastic or metal container with lid. Syringes used for flushing do not need to be in the sharps container. Any remaining drug solutions, the drug container and tubing should be disposed of as you have been instructed.

According to policy, the pharmacy may pick up your "sharps" container or may ask you to mail it back.

Instructions for Using the Mail Back Sharps Disposal System

1. Call AxelaCare pharmacy and ask that a new container be sent with your next delivery
2. Place the full container in the plastic bag provided and seal the plastic bag with the twist tie provided
3. Place the plastic bag with unit into the inner box and securely seal the box with tape
4. Place the inner box into the white outer shipping box and securely seal the outer box using the lock closure system. Place a strip of tape over the lock closure
5. Take the manifest document out of the clear plastic pouch on the side of the box. Please sign and date the form. Return the form to the plastic pouch
6. Write your return address on the top of the box in the space provided
7. Take the box to any US Post Office or give to any postal carrier for mailing

Again, remember to keep all drugs, needles and supplies in a safe place, away from small children, pets, and/or adults that may become confused.

Waste Disposal

Proper disposal of waste in the home environment will insure safety and provide infection control for you and others, such as your family. Please follow these steps when handling wastes:

1. All needles, syringes and other related equipment should be disposed of in a puncture-resistant safety container like a "Sharps-tainer". Needles should not be re-capped, bent, broken, removed from syringes, or otherwise handled. The safety container should be placed in a garbage bag (local law permitting) and then into a trashcan with a tight-fitting lid. Blood and body wastes can be carefully poured down the drain or flushed down a toilet connected to a sanitary sewage system. In rural areas, consult your County Health Department for proper disposal.

2. Pour all excess or unused medications into a toilet and flush (local law permitting). Cut IV bags open with scissors to gain entry.

3. Tissues, soiled dressings, used tampons and sanitary pads and diapers should be discarded into a plastic lined bag. This bag should be placed in another garbage bag and then into a trashcan with a tight-fitting lid. Follow local regulations for solid waste management.

4. A protective gown should be worn by caregivers in any situation where contact with blood or body fluids is likely.

5. Soiled sheets, towels and clothing should be stored in a container lined with plastic bag until laundered. Laundry should be done in hot water. Dirty dishes should be washed immediately in detergent and hot water.

6. Leftover portions of food should be thrown away right away.

Chemotherapy

Read this section carefully if you are receiving chemotherapy at home prescribed by your physician.

There are many types of treatment for cancer. Intravenous medication is one of the treatments you may receive. This therapy can be safely given in the home. It is given at home to decrease the time you spend either hospitalized, in the clinic and/or because it is a part of a cycle that is known to be effective when given over a more prolonged time frame.

Your nurse or pharmacist will give you written information about the medication (chemotherapy) that you are receiving at home. They will discuss the possible side effects of the medication and steps you might do to help decrease, diminish or prevent side effects. It is important for you to know what the side effects might be and when to report them to your physician and/or the nurse or pharmacist.

Some chemotherapy drugs require special handling. Your nurse and pharmacist will discuss the handling. The written medication information you will receive will discuss this as well. You will be given a Chemotherapy (Chemo) Spill Kit to keep at home and have available should the unlikely event arise that you will need to have it.

Please understand that our staff is aware having a diagnosis which requires chemotherapy can be very stressful to you and your family. We are available for questions regarding chemotherapy at home and to assist you in receiving the support and help that may be needed to assist you and your family.

Handling Chemotherapy

Due to the nature of the potential for exposure to the toxic effects of the chemotherapy that you may be receiving, we are providing information for the special handling of those drugs. The pharmacy will dispose of your chemotherapy waste after your therapy is completed.

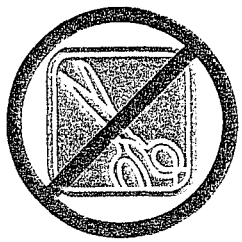
- ✓ Always be sure to wear latex or vinyl gloves that are disposable.
- ✓ Wear gloves when handling body fluids such as blood or vomit of a person who has received chemotherapy within the last 2 days (48 hours).
- ✓ If you have a chemotherapy leakage, do not touch the chemotherapy drug. Wear disposable latex or vinyl gloves if there is any need to touch or clean up a chemotherapy spill.
- ✓ You may contact the pharmacy at any time for questions regarding chemotherapy leakage. If you are concerned about a spill or leakage you can also call a restoration cleaning company for assistance.
- ✓ If any spillage of a chemotherapy drug occurs, follow the directions contained in the Chemo Spill Kit. If you do not have access to your kit, clean the area with lots of soap and water. Wipe the liquid with paper towels and dispose of the towels in your chemotherapy waste container.
- ✓ Wash your hands using soap and water after cleaning up any chemotherapy drug spillage.

Access Device Information

Your doctor has ordered medication or fluid for you that must be given in to the blood stream. This is done with an intravenous catheter or access device.

Infusion therapy involves the administration of medication through a needle or catheter. It is prescribed when a patient's condition is so severe that it cannot be treated effectively by oral medications. Typically, "infusion therapy" means that a drug is administered intravenously, but the term also may refer to situations where drugs are provided through other non-oral routes, such as intramuscular injections and epidural routes (into the membranes surrounding the spinal cord).

Never use scissors or sharp instruments near your access device



With any access device, a number of complications or problems can occur. Proper care of your access device will prevent many of these problems. The following chart will help you troubleshoot various problems and get the appropriate help, when necessary.

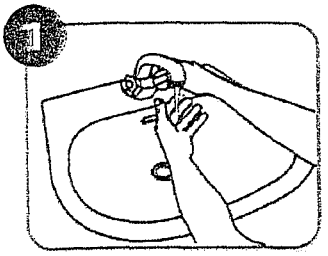
Problem	Possible Cause	What to Do
Pain, redness at area around access device	Access device is causing irritation to the body	Do not put any solution into the access device. Call nurse or physician
Swelling or hardened area around access device	Access Device may have slipped out of the correct place inside your body	Do not put any solution into the access device. Call nurse or physician
Leaking around the access device	Loose connection between tubing and access device. Access device may have slipped out of correct position	Inspect and tighten all connections and change tubing cap, if so instructed. Notify nurse or physician of problem. If so instructed, remove all bandages and check skin area for leaks
Solution won't flow into access device	▪ Tubing may be kinked or clamps closed ▪ Solution may be lower than access device ▪ Pump incorrectly set up or malfunctioning ▪ Access device may be clotted or plugged	▪ Inspect tubing and correct any kinks. Open clamps. ▪ Elevate solution above level of body ▪ Review pump function ▪ Do not force any solution into the access device. Notify nurse
Solution container leaks	Incorrect spiking of the container; defective container	Discard leaking container and use another. Notify your nurse

Problem	Possible Cause	What to Do
Blood visible in access device	▪ Pump is not running ▪ Solution is lower than body level ▪ Tubing connections are loose	▪ If you use a clamp, use it to clamp the tube near your body. ▪ Reconnect the tubing ▪ If bleeding is heavy or persists, dial your emergency telephone number.
Air entering access device	Loose connections. Broken tubing.	If you have a clamp, use it immediately. Tighten connections. If you experience difficulty breathing or chest pain, call your emergency telephone number.
Fever above 100°F. drainage, tenderness, pain, redness at area around access device	Possible infection	Notify your nurse
Rash or itching around access device	Possible allergy to tape, ointment, or bandage	Discuss with your nurse
General body itching, swelling of face /hands, difficulty breathing	Possible allergy to medicine	Stop infusion. Call your nurse. If breathing is difficult call emergency phone number.
Blood on the dressing that is greater than a dime-size spot.		Do not remove the dressing. Call your nurse.
The catheter becomes damaged		Clamp the end of the catheter so that blood does not escape and air and/or microorganisms do not get in. Call your nurse or go to the emergency room
Arm or chest swelling. Discomfort anywhere along the catheter		Call your nurse

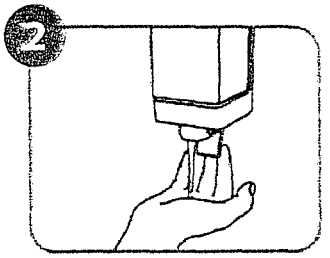
If you are in a situation that you feel is a danger to your health, such as a sudden difficulty when breathing, either go directly to the Emergency Center, or dial 911 for emergency assistance.

Hand Washing

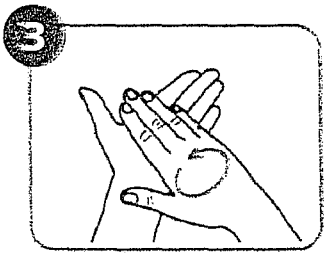
The most important step you can take in preventing an infection is to thoroughly wash your hands.



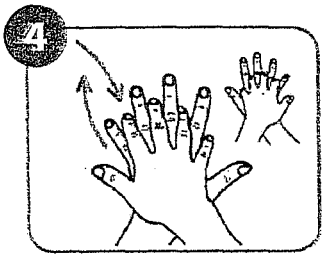
Wet hands with water



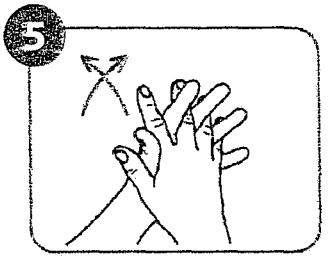
Apply enough soap to cover all hand surfaces



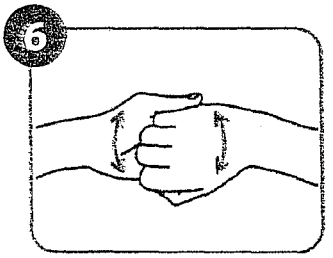
Rub hands palm to palm



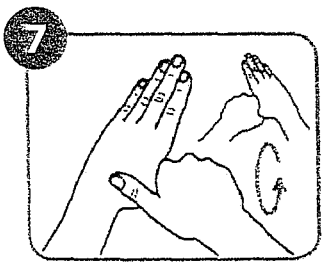
Right palm over left dorsum with interlaced fingers and vice versa



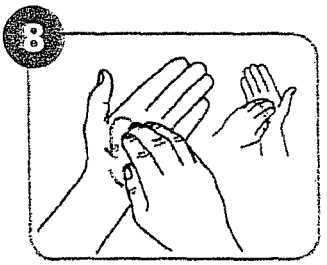
Palm to palm with fingers interlaced



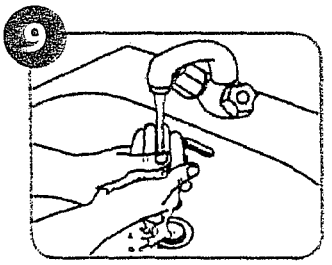
Backs of fingers to opposing palms with fingers interlocked



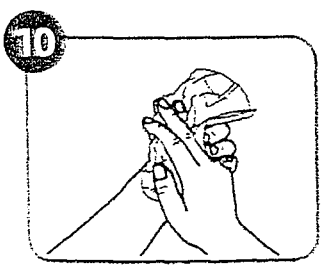
Rotational rubbing of left thumb clasped in right palm and vice versa



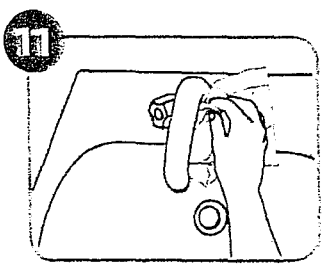
Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa.



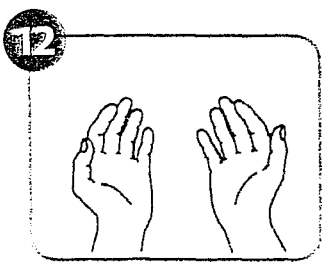
Rinse hands with water



Dry thoroughly with a single use towel



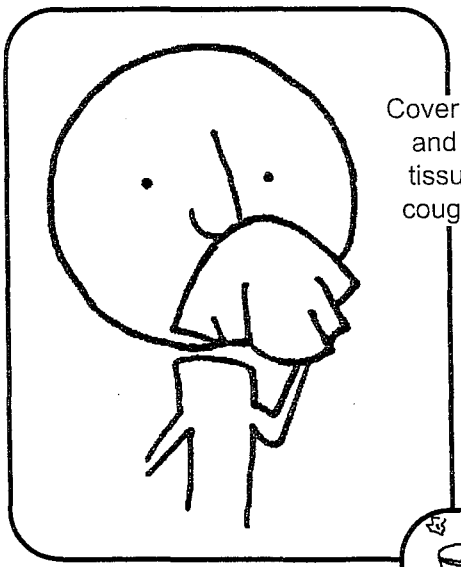
Use towel to turn off faucet



...and your hands are safe.

Stop the spread of germs that make you and others sick!

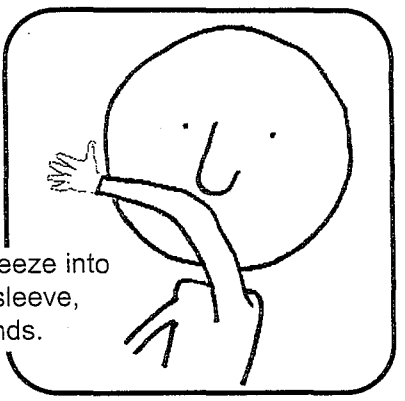
Cover your Cough

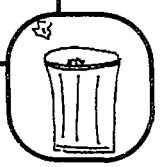


Cover your mouth and nose with a tissue when you cough or sneeze

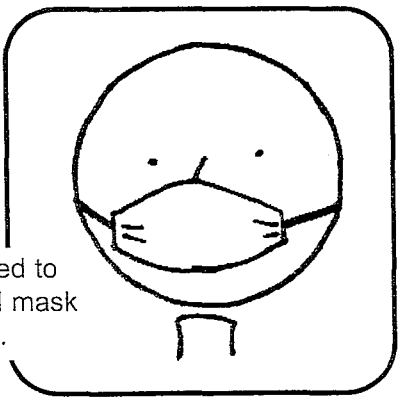
or

cough or sneeze into your upper sleeve, not your hands.





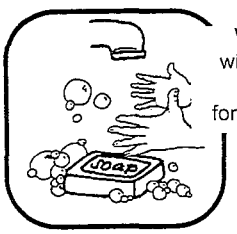
Put your used tissue in the waste basket.



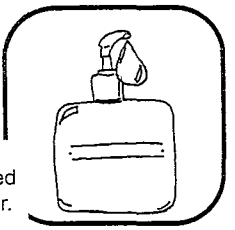
You may be asked to put on a surgical mask to protect others.

Clean your Hands

after coughing or sneezing.



Wash hands with soap and warm water for 20 seconds *or*



clean with alcohol-based hand cleaner.

CDC SAFER·HEALTHIER·PEOPLE™

MINNESOTA MDH DEPARTMENT of HEALTH
Minnesota Department of Health
717 SE Delaware Street
Minneapolis, MN 55414
612-676-5414 or 1-877-676-5414
www.health.state.mn.us

STOP
Minnesota Antibiotic Resistance Collaborative

APIC

Preventing Infections

Universal Precautions refers to the practice, in medicine, of avoiding contact with patients' bodily fluids by means of the wearing of nonporous articles such as medical gloves, goggles, and face shields.

Under ***Universal Precautions*** all patients are considered to be possible carriers of blood-borne pathogens. ***Universal Precautions*** are designed for doctors, nurses, patients, and health care support workers who are required to come into contact with patients or bodily fluids.

- ❑ Hand washing before and after each procedure
- ❑ No needle recapping (to avoid needle stick injury)
- ❑ Safe collection and immediate disposal of sharps
- ❑ Keep the sharps container away from children and untrained persons
- ❑ Gloves for contact with body fluids, non-intact skin and mucous membranes
- ❑ Wearing a mask, eye protection and a gown if blood or other body fluids might splash
- ❑ Covering cuts and abrasions
- ❑ Cleaning up spills of blood and other body fluids
- ❑ Using a safe system for health care waste management and disposal

To help reduce the risk of infection to you and/or your caregiver, please follow these steps:

- ✓ Wash hands before and after each procedure.
- ✓ Always wear gloves when handling blood or body fluid, or when in contact with mucous membranes or open cuts.
- ✓ Caregivers should wear protective gown, mask and gloves where contact with patient blood or body fluids is likely.
- ✓ Never re-cap needles. Always dispose of needles in a safety container. Use only disposable razors for shaving.
- ✓ Only one person should use the thermometer.
- ✓ Stay away from others who are sick
- ✓ Avoid contact with those who have colds or other infectious diseases. If caregiver has a cold or flu symptoms, a mask should be worn.
- ✓ Cover minor cuts and abrasions with a bandage
- ✓ Change dressings and perform catheter care on schedule as directed.
- ✓ Patients on home infusion therapy should have limited contact with pets.
- ✓ Wash surfaces or equipment contaminated with blood or other body fluids with a solution of detergent, water and household bleach.
- ✓ Maintain good oral hygiene
- ✓ Daily personal cleanliness is encouraged

Important Health Information

Preventing Falls

Begin a regular exercise program

Exercise is one of the most important ways to lower your chances of falling. It makes you stronger and helps you feel better. Exercises that improve balance and coordination (like Tai Chi) are the most helpful. Lack of exercise leads to weakness and increases your chances of falling. Ask your doctor or health care provider about the best type of exercise program for you.

Have your health care provider review your medicines

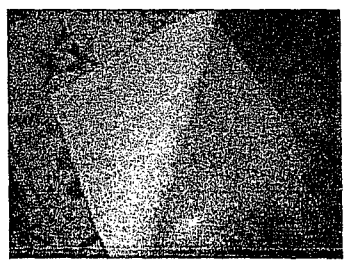
Have your doctor or pharmacist review all the medicines you take, even over-the-counter medicines. As you get older, the way medicines work in your body can change. Some medicines, or combinations of medicines, can make you sleepy or dizzy, and can cause you to fall.

Have your vision checked

Have your eyes checked by an eye doctor at least once a year. You may be wearing the wrong glasses or have a condition like glaucoma or cataracts that limits your vision. Poor vision can increase your chances of falling.

Make your home safer

About half of all falls happen at home. To make your home safer:



- ✓ Remove things you can trip over (like papers, books, clothes and shoes) from stairs and places where you walk.
- ✓ Remove small throw rugs or use double-sided tape/rug grippers to keep the rugs from slipping.
- ✓ Keep items you use often in cabinets you can reach easily without using a step stool.
- ✓ Have grab bars put in next to your toilet and in the tub or shower.
- ✓ Use non-slip mats in the bathtub and on shower floors.
- ✓ Improve the lighting in your home. As you get older, you need brighter lights to see well. Hang lightweight curtains or shades to reduce glare.
- ✓ Have handrails and lights put in on all staircases.
- ✓ Wear shoes both inside and outside the house. Avoid going barefoot or wearing slippers.

Call 911 if you have fallen and have severe pain

Medication Safety

1. Do not take medications that are prescribed for someone else.
2. Write down all of your medications (including prescription, over-the- counter, vitamins, herbals) and show the list to your doctor or pharmacist to keep from combining drugs inappropriately. If there are any changes, add them to the list immediately.
3. Know the name of each of your medicines; why you are taking it, how to take it.
4. Report medication allergies and any medication side effects to your healthcare providers.
5. Take medications exactly as instructed. If the medication looks different than you expected, ask your health care provider or pharmacist about it. Drug names can look alike or sound alike. To avoid errors, check with your health care provider if you have any questions.
6. Do not stop or change medicines without your doctor's approval, even if you are feeling better.
7. Consider a chart or container system to help you remember what kind, how much and when to take medicine.
8. Read medicine labels carefully and keep medicines in their original containers.
9. Store medications safely in a cool/dry place according to the instructions on the label of the medication.
10. If you miss a dose, do not double the next dose later. Check with your doctor or pharmacist before taking any action.
11. Dispose of old medications safely by flushing them down the toilet or as directed.
12. Keep medicines away from children.

Home Safety Guidelines

Hazardous Items and Poisons

- ❑ Know how to contact your poison control center.
- ❑ Use care in storing hazardous items. Only store hazardous items in their original containers.
- ❑ Do not mix products that contain chlorine or bleach with other chemicals. Understand the risk of insecticides.
- ❑ Keep hazardous items, cleaners and chemicals out of reach of children and confused or impaired adults.
- ❑ Dispose of household trash in a covered waste receptacle outside the home.

Fire Safety / Burn Precautions

- All family members and caregivers should be familiar with emergency/911 procedures.
- Notify the fire department if a disabled person is in the home.
- Do not smoke in bed. Never leave burning cigarettes unattended. Do not empty smoldering ashes in a trash can. Keep ashtrays away from upholstered furniture and curtains.
- Do not smoke where oxygen equipment is being used.
- Install smoke alarms on every floor of your home, including the basement.
- Place smoke alarms near rooms where people sleep. Test smoke alarms every six months to make sure they are working properly.
- Install new smoke alarm batteries at least twice a year.
- Make a family fire escape plan and practice it every 6 months. At least 2 different escape routes are planned from each room for each family member.
- If you live in an apartment building, know where the exit stairs are located.
- Do not use an elevator during a fire emergency.
- Designate a safe place building for family members to meet after escaping a fire.
- If your fire escape is cut off, remain calm. Close the door and seal cracks to hold back smoke. Signal for help at the window.
- If attempting to exit through a closed door, place your hand on the door to ensure it is not hot indicating that there is no fire on the other side.

Fire Safety / Burn Precautions (continued)

- Remember, life safety is first, but if the fire is contained and small, you may be able to use your fire extinguisher until the fire department arrives.
- Have your heating system checked and cleaned regularly by someone qualified to do maintenance.
- Wood burning stoves/fireplaces are properly installed; chimney is inspected and cleaned by a professional.
- Make sure appliances and cords are clean, in good condition and not exposed to liquids.
- Portable heaters (electric or kerosene) are placed out of the path of traffic and is operated at least 3 feet away from upholstered furniture, drapes, bedding and other combustible materials. Use on the floor and turn off when family members leave the house or are sleeping.
- Electrical outlets are grounded.
- Do not leave stove unattended when cooking.
- Keep cooking areas free of flammable objects.
- Turn pan handles away from burners and the edge of the stove.
- Keep electrical appliances away from the bathtub or shower area.
- Set water heater thermostat below 120 to prevent accidental scalding.
- Store flammable liquids in properly labeled, tightly closed, non-glass containers. Store away from heaters, furnaces, and other appliances.

Emergency or Disaster Preparedness

If you are Involved in a Natural Disaster such as a Hurricane, Tornado, Winter Weather, Excessive Prolonged Heat, Flood, Earthquake, or Fire, Please Follow these Instructions:

- ✓ If you must leave your home, please call your home infusion pharmacy to arrange for delivery of your supplies. Be ready to give your new address and phone number where you can be reached.
- ✓ If your area is involved in a disaster and you decide to stay home, please let your home infusion pharmacy know if your home can be reached by delivery truck. If not, your pharmacy can help you arrange for delivery of your therapy supplies.
- ✓ If you need emergency medical care or medical supplies, go to a local hospital in the nearest unaffected area.
- ✓ If your water is contaminated, you and/or your caregiver can wash your hands with alcohol (rubbing alcohol or isopropyl alcohol) or hydrogen peroxide prior to performing any sterile procedures. Do not expose your catheter or catheter site to any unclean water.
- ✓ Keep a battery-operated radio tuned in to a local station during conditions that you suspect may lead to a disaster warning.
- ✓ Have on hand these emergency items:
  - Flashlight
  - Medicines and medical supplies
  - First aid supplies
  - Portable radio
  - Backup batteries
  - Canned foods and water
  - Blankets
- ✓ You are strongly urged to follow the local disaster advisories for your area.
- ✓ If a planned or unplanned evacuation is necessary, the following is advised:
  - Go to the hospital if you cannot manage your therapy safely
  - Take your medications, equipment and supplies with you
  - Notify your branch pharmacy when you plan to return home.

Under disaster conditions, your home infusion representative at the pharmacy will try to contact you. Calling into an area that has been involved in a natural disaster, however, can be difficult, and telephone lines are typically jammed. Therefore, please try to call out and establish contact with your pharmacy. They will then make plans based on your specific emergency needs.

Resources related to emergency preparedness

There are many resources in and around your community that you can connect with:

- State Homeland Security and Emergency Services. Links to homeland security and public safety Web sites from the states and the District of Columbia.
- Locate In-Person Services Near You. www.USA.gov has an extensive list of resources to help you find government offices and services near you, in your local community or state.
- American Hometowns – cities, Counties and Towns. www.USA.gov has a list of localities that you can use to find local resources.
- State and Local Agencies and Offices, by Topic. www.USA.gov has a list of state and local agencies and offices.
- National Mail Service Updates. Change your address online and find current service disruptions from the U.S. Postal Service.
- Emergency Watershed Protection Program. The Emergency Watershed Protection Program was set up by Congress to respond to emergencies created by natural disasters. It is designed to relieve imminent hazards to life and property caused by floods, fires, windstorms, and other natural occurrences. You may qualify through your community.
- Community Development Resources. Rural community development resources compiled by the U.S. Department of Agriculture.

Additional Resources

- www.CDC.gov – information available for preparedness for all hazards
- www.RedCross.org – information available for preparedness
- www.noaa.gov – information available for weather preparedness
- www.osha.gov – information available for workplace preparedness

Determining Your Nutritional Health

The warning signs of poor nutritional health are often overlooked. Use this checklist to find out if you or someone you know is at nutritional risk.

Read the statements below. Circle the number in the "yes" column for those that apply to you or someone you know. For each "yes" answer, score the number in the box. Total your nutritional score.

	Yes
I have an illness or condition that made me change the kind and/or amount of food I eat	2
I eat fewer than 2 meals per day	3
I eat few fruits or vegetables or milk products	2
I have 3 or more drinks of beer, liquor or wine almost every day	2
I have tooth or mouth problems that make it hard for me to eat	2
I don't always have enough money to buy the food I need	4
I eat alone most of the time	1
I take 3 or more different prescribed or over-the-counter drugs a day	1
Without wanting to, I have lost or gained 10 pounds in the last 6 months	2
I am not always physically able to shop, cook and/or feed myself	2
Total	

Total your Nutritional Score. If it is -

0-2	Good! Recheck your nutritional score in 6 months
3-5	You are at moderate nutritional risk. See what can be done to improve your eating habits and lifestyle. Your local office on aging, senior nutrition program, senior citizens center or health department can help. Recheck your nutritional score in 3 months.
6 or more	You are at high nutritional risks. Bring this checklist the next time you see your doctor, dietitian or other qualified health or social service professional. Talk with them about any problems you may have. Ask for help to improve your nutritional health.

Remember the Warning Signs suggest risk, but do not represent a diagnosis of any condition.

These materials were developed by the Nutrition Screening Initiative, a project of: American Academy of Physicians, The American Dietetic Association, The National Council on the Aging, Inc.

Managing Your Pain

One of the most important things we do is help you make a comfort goal. Your nurse will discuss with you a level of comfort that allows you to continue to enjoy many activities.

Acute pain – which is brief in duration and subsides with healing.

Chronic pain – which is recurrent pain over a long period of time and can be disabling.

Pain can alter your ability to sleep, walk, read, concentrate or breathe. It is important that you try to identify all areas of your life that are affected by pain and seek relief through an effective treatment plan.

The following six tools may help you in describing your pain to us.

0
No Hurt
Smiling
Moves easily
Positive outlook

2
Hurts Little Bit
Neutral
Whimper, moans
Rubbing, shifting

4
Hurts Little More
Neutral/Frown
Pacing, restless
Increased heart rate

6
Hurts Even More
Grimacing
Rocking, crying
Agitation

8
Hurts Whole Lot
Clenched, tense
Screaming
Not moving

10
Hurts Worst
Withdrawn
Rigid posture
Shallow, rapid respirations

1. Report your pain

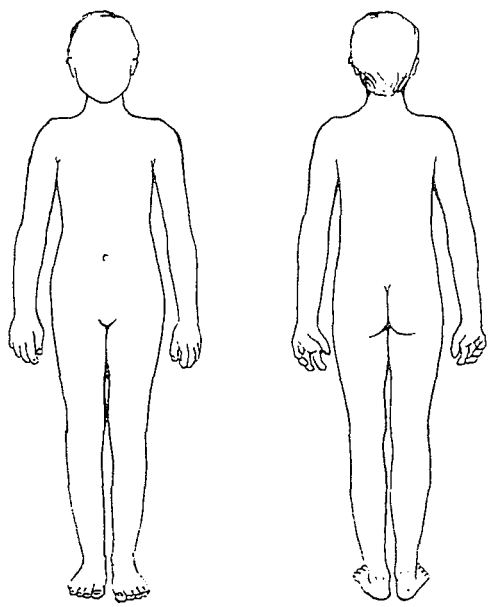
   Below are some words that may help you describe the type of pain you are feeling. Use them to describe your pain to us or your doctor.

Dull ache	Shooting	Crushing
Squeezing	Sharp	Nagging
Pressing	Pinching	Cutting
Stinging	Stabbing	Flickering
Pulsing	Tingling	Pricking
Burning	Itching	Cramping

2. Identify your acceptable level of pain-comfort goal

   Using a scale of 1 to 10, with zero being no pain and 10 being severe, what is your level of pain?

3. Report the location of your pain



4. Report when pain begins

   For example, do you notice the pain:

   - Following certain activity
   - During certain activities
   - At certain times of the day
   - 3 hours after medications are taken

5. Report how long pain is present

   For example, does the pain last until:

   - You sit or lie down
   - Stop activity
   - Close eyes or fall asleep
   - Take medication

6. If pain continues, discuss this with your nurse or physician

Financial Responsibility

General information is provided to inform you of the charges that will be billed to Medicare or your health plan. Depending on your insurance coverage, you may be responsible for all or some portion of these charges. The rates do not reflect any payment adjustments that Medicare, Medicaid or Managed Care Plans may make.

To assist you, AxelaCare will contact your health plan to verify your insurance coverage for the services ordered by your doctor.

Home Care – Insurance Coverage Highlights

Medicare Part B:

- Home medical equipment, enteral and parenteral nutrition, certain I.V. infusion medications, pain management, chemotherapy and possibly other services are covered at 80% of Medicare's allowable charge when Medicare's requirements are met. You are responsible for the remaining 20% and any deductible.
- Any service not covered by Medicare will be billed to you or any other insurance that you have.
- If Medicare's requirements are not met of if your requested an upgrade to a piece of equipment, you will be required to sign a Medicare Advanced Beneficiary Notice (ABN).
- Convenience and comfort items (i.e. bath aides) and most drugs are not covered under Part B.

Medicare Part D:

Part D may cover medications not covered under Part B. Each policy is different and benefits vary. You will receive information specific to your coverage as needed.

Your Medicare rights:

OMB Approval No. 0938-0975
Form CMS -10147

You have the right to request a coverage determination from your Medicare drug plan if you disagree with information provided by the pharmacy. You also have the right to request a special type of coverage determination called an "exception" if you believe:

- you need a drug that is not on your drug plan's list of covered drugs. The list of covered drugs is called a "formulary;"
- a coverage rule (such as prior authorization or a quantity limit) should not apply to you for medical reasons; or
- you need to take a non-preferred drug and you want the plan to cover the drug at the preferred drug price.

What you need to do:

You or your prescriber can contact your Medicare drug plan to ask for a coverage determination by calling the plan's toll-free phone number on the back of your plan membership card, or by going to your plan's website. You or your prescriber can request an expedited (24 hour) decision if your health could be seriously harmed by waiting up to 72 hours for a decision. Be ready to tell your Medicare drug plan:

1. The name of the prescription drug that was not filled. Include the dose and strength, if known.
2. The name of the pharmacy that attempted to fill your prescription.
3. The date you attempted to fill your prescription.
4. If you ask for an exception, your prescriber will need to provide your drug plan with a statement explaining why you need the off-formulary or non-preferred drug or why a coverage rule should not apply to you.

Your Medicare drug plan will provide you with a written decision. If coverage is not approved, the plan's notice will explain why coverage was denied and how to request an appeal if you disagree with the plan's decision.

Refer to your plan materials or call 1-800-Medicare for more information.

Medicaid:

Coverage guidelines are similar to Medicare. Covered services will be billed to the appropriate state department and are generally paid at 100% of allowable charges. Services that are not covered or services provided during a spend-down period (prior to eligibility) will be billed to you.

Medicaid Pending:

Once approved for Medicaid, it is your responsibility to call us with your eligibility information. Medicaid must be billed within 3 months of service. If your case is not approved, services provided will be billed to you.

Commercial Insurance:

All services will be billed to your insurance plan. Non-covered charges, co-insurance, co-payments and deductibles will be billed to you. Refer to your insurance plan's handbook for specific coverage information. Some plans have limitations for home care services.

Managed Care:

Many managed care plans use preferred provider networks and require pre-certification of services, we may or may not be contracted with your plan. We will contact your health plan to determine home care benefits, authorization requirements and preferred providers. All services will be billed to your insurance plan. Non-covered charges, co-insurance, co-payments and deductibles will be billed to you.

Self Pay:

Services provided will be billed directly to you. Payment arrangements are available and must be agreed to in advance. Payment is due within 30 days of receipt of bill. We accept MasterCard, Visa, Discover and American Express.

Identity Theft Prevention, Insurance Verification and Patient Agreement

Identify Theft Prevention:

Medical identity theft is when a person seeks health care using someone else's name or insurance information. As a health care provider, we are required by the Federal Trade Commission (FTC) to have a program to spot warning signs or "red flags" of identity theft. We may ask you to produce insurance cards or photo ID to protect you against payment denials and identity theft.

Insurance Verification:

You will need to show us your insurance cards. Please locate your Medicare, Medicaid or commercial insurance or supplemental insurance cards. Always keep your insurance cards together and in a safe place in your home or wallet. You may also want to keep a copy of them somewhere in the event they are lost or misplaced.

Home Care Patient Agreement:

In the front pocket of this admission pocket is a home care patient agreement or consent form that will be completed by your home care representative and a copy will be supplied to you. This form simply states that you have:

- Agreed to treatment,
- Agreed to the release of certain health and insurance information
- Assignment of benefits; and
- Been informed of your rights and responsibilities and the use and availability of Advanced Directives and received a written copy

Disclaimers and Details

Notice of Privacy Practices

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

I. Who We Are

This Notice describes the privacy practices of AxelaCare ("we" or "us"), including:

All employees and other health care professionals when they provide our services with access to your medical or billing records or health information about you ("**Protected Health Information**").

II. Our Privacy Obligations

We understand that your health information is personal and we are committed to protecting your privacy. In addition, we are required by law to maintain the privacy of your Protected Health Information, to provide you with this Notice of our legal duties and privacy practices with respect to your Protected Health Information, and to notify you in the event of a breach of your unsecured Protected Health Information. When we use or disclose your Protected Health Information, we are required to abide by the terms of this Notice (or other notice in effect at the time of the use or disclosure).

III. Permissible Uses and Disclosures without Your Written Authorization

In certain situations, which we will describe in Section IV below, we must obtain your written authorization in order to use and/or disclose your Protected Health Information. However, unless the Protected Health Information is Highly Confidential Information (as defined in Section IV.B below) and the applicable law regulating such information imposes special restrictions on us, we may use and disclose your Protected Health Information without your written authorization for the following purposes:

A. Treatment. We use and disclose your Protected Health Information to provide treatment and other services to you--for example, to provide our services or to consult with your physician about your healthcare. We may use your information to direct or recommend alternative treatments, therapies, health care providers, or settings of care to you or to describe a health-related product or service. We may also disclose Protected Health Information to other providers involved in your treatment.

B. Payment. We may use and disclose your Protected Health Information to obtain payment for health care services that we provide to you--for example, disclosures to claim and obtain payment from Medicare, Medicaid, your health insurer, HMO, or other company or program that arranges or pays the cost of your health care ("**Your Payor**") to verify that Your Payor will pay for the health care. We may also disclose Protected Health Information to your other health care providers when such Protected Health Information is required for them to receive payment for services they render to you.

C. Health Care Operations. We may use and disclose your Protected Health Information for our health care operations, which include internal administration and planning and various activities that improve the quality and cost effectiveness of the care that we deliver to you. For example, we may use Protected Health Information to evaluate the quality and competence of our services and other health care professionals. We may disclose Protected Health Information to our performance improvement team in order to resolve any complaints you may have and ensure that you our satisfied with our services.

D. Disclosure to Relatives, Close Friends and Other Caregivers. We may use or disclose your Protected Health Information to a family member, other relative, a close personal friend or any other person identified by you when you are present for, or otherwise available prior to, the disclosure, if: (1) we obtain your agreement or provide you with the opportunity to object to the disclosure and you do not object; or (2) we reasonably infer that you do not object to the disclosure.
If you are not present for or unavailable prior to a disclosure (e.g., when we receive a telephone call from a family member or other caregiver), we may exercise our professional judgment to determine whether a disclosure is in your best interests. If we disclose information under such circumstances, we would disclose only information that is directly relevant to the person's involvement with your care.

E. As Required by Law. We may use and disclose your Protected Health Information when required to do so by any applicable federal, state or local law.

F. Public Health Activities. We may disclose your Protected Health Information: (1) to report health information to public health authorities for the purpose of preventing or controlling disease, injury or disability; (2) to report child abuse and neglect to a government authority authorized by law to receive such reports; (3) to report information about products under the jurisdiction of the U.S. Food and Drug Administration; (4) to alert a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition; and (5) to report information to your employer as required under laws addressing work-related illnesses and injuries or workplace medical surveillance.

G. Victims of Abuse, Neglect or Domestic Violence. We may disclose your Protected Health Information if we reasonably believe you are a victim of abuse, neglect or domestic violence to a government authority authorized by law to receive reports of such abuse, neglect, or domestic violence.

H. Health Oversight Activities. We may disclose your Protected Health Information to an agency that oversees the health care system and is charged with responsibility for ensuring compliance with the rules of government health programs such as Medicare or Medicaid.

I. Judicial and Administrative Proceedings. We may disclose your Protected Health Information in the course of a judicial or administrative proceeding in response to a legal order or other lawful process.

J. Law Enforcement Officials. We may disclose your Protected Health Information to the police or other law enforcement officials as required by law or in compliance with a court order.

K. Decedents. We may disclose your Protected Health Information to a coroner or medical examiner as authorized by law.

L. Organ and Tissue Procurement. We may disclose your Protected Health Information to organizations that facilitate organ, eye or tissue procurement, banking or transplantation.

M. Clinical Trials and Other Research Activities. We may use and disclose your Protected Health Information for research purposes pursuant to a valid authorization from you or when an institutional review board or privacy board has waived the authorization requirement. Under certain circumstances, your Protected Health Information may be disclosed without your authorization to researchers preparing to conduct a research project, for research or decedents or as part of a data set that omits your name and other information that can directly identify you.

N. Health or Safety. We may use or disclose your Protected Health Information to prevent or lessen a serious and imminent threat to a person's or the public's health or safety.

O. Specialized Government Functions. We may use and disclose your Protected Health Information to units of the government with special functions, such as the U.S. military or the U.S. Department of State under certain circumstances.

P. Workers' Compensation. We may disclose your Protected Health Information as authorized by and to the extent necessary to comply with state law relating to workers' compensation or other similar programs.

IV. Uses and Disclosures Requiring Your Written Authorization

For any purpose other than the ones described above in Section III, we only use or disclose your Protected Health Information when you give us your written authorization.

A. Marketing. We must obtain your written authorization prior to using your Protected Health Information for purposes that are marketing under the HIPAA privacy rules. For example, we will not accept any payments from other organizations or individuals in exchange for making communications to you about treatments, therapies, health care providers, settings of care, case management, care coordination, products or services unless you have given us your authorization to do so or the communication is permitted by law.

We may provide refill reminders or communicate with you about a drug or biologic that is currently prescribed to you so long as any payment we receive for making the communication is reasonably related to our cost of making the communication. In addition, we may market to you in a face-to-face encounter and give you promotional gifts of nominal value without obtaining your written authorization.

B. Sale of Protected Health Information. We will not make any disclosure of Protected Health Information that is a sale of Protected Health Information without your written authorization.

C. Uses and Disclosures of Your Highly Confidential Information. Federal and state law requires special privacy protections for certain health information about you ("**Highly Confidential Information**"), including Alcohol and Drug Abuse Treatment Program records and other health information that is given special privacy protection under state or federal laws other than HIPAA. We generally do not maintain any Highly Confidential Information. However, in order for us to disclose any Highly Confidential Information for a purpose other than those permitted by law, we must obtain your authorization.

D. Revocation of Your Authorization. You may revoke your authorization, except to the extent that we have taken action in reliance upon it, by delivering a written revocation statement to the Privacy Office identified below.

VI. Your Individual Rights

A. For Further Information; Complaints. If you desire further information about your privacy rights, are concerned that we have violated your privacy rights or disagree with a decision that we made about access to your Protected Health Information, you may contact our Privacy Office. You may also file written complaints with the Office for Civil Rights of the U.S. Department of Health and Human Services. Upon request, the Privacy Office will provide you with the correct address for the Director. We will not retaliate against you if you file a complaint with us or the Director.

B. Right to Request Additional Restrictions. You may request restrictions on our use and disclosure of your Protected Health Information (1) for treatment, payment and health care operations, (2) to individuals (such as a family member, other relative, close personal friend or any other person identified by you) involved with your care or with payment related to your care, or (3)

to notify or assist in the notification of such individuals regarding your location and general condition. While we will consider all requests for additional restrictions carefully, we are not required to agree to a requested restriction unless the request is to restrict our disclosure to a health plan for purposes of carrying out payment or health care operations, the disclosure is not required by law and the information pertains solely to a health care item or service for which you (or someone on your behalf other than the health plan) have paid us out of pocket in full. If you wish to request additional restrictions, please obtain a request form from our Privacy Office and submit the completed form to the Privacy Office. We will send you a written response.

C. Right to Receive Communications by Alternative Means or at Alternative Locations. You may request, and we will accommodate, any reasonable written request for you to receive your Protected Health Information by alternative means of communication or at alternative locations.

D. Right to Inspect and Copy Your Health Information. You may request access to your medical record file and billing records maintained by us in order to inspect and request copies of the records. Under limited circumstances, we may deny you access to a portion of your records. If you desire access to your records, please obtain a record request form from the Privacy Office and submit the completed form to the Privacy Office. If you request copies, we may charge you a reasonable copy fee.

E. Right to Amend Your Records. You have the right to request that we amend your Protected Health Information maintained in your medical record file or billing records. If you desire to amend your records, please obtain an amendment request form from the Privacy Office and submit the completed form to the Privacy Office. We will comply with your request unless we believe that the information that would be amended is accurate and complete or other special circumstances apply.

F. Right to Receive An Accounting of Disclosures. Upon request, you may obtain an accounting of certain disclosures of your Protected Health Information made by us during any period of time prior to the date of your request provided such period does not exceed six years. If you request an accounting more than once during a twelve (12) month period, we may charge you a reasonable fee for the accounting statement.

G. Right to Receive Paper Copy of this Notice. Upon request, you may obtain a paper copy of this Notice, even if you agreed to receive such notice electronically.

VII. Effective Date and Duration of This Notice

A. Effective Date. This Notice is effective on September 23, 2013.

B. Right to Change Terms of this Notice. We may change the terms of this Notice at any time. If we change this Notice, we may make the new notice terms effective for all your Protected Health Information that we maintain, including any information created or received prior to issuing the new notice. If we change this Notice, we will post the new notice in our waiting room and on our Internet site at **www.Axelacare.com**. You also may obtain any new notice by contacting the Privacy Office.

VIII. Privacy Officer

You may contact the Privacy Office at:

Privacy Office
AxelaCare
15529 College Boulevard
Lenexa, KS 66219
Telephone Number: (877) 342-9352

Medicare DMEPOS Supplier Standards

Note: This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.

2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.

3. A supplier must have an authorized individual (whose signature is binding) sign the enrollment application for billing privileges.

4. A supplier must fill orders from its own inventory, or contract with other companies for the purchase of items necessary to fill orders. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or any other Federal procurement or non-procurement programs.

5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.

6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.

7. A supplier must maintain a physical facility on an appropriate site and must maintain a visible sign with posted hours of operation. The location must be accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.

8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards.

9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted hours is prohibited.

10. A supplier must have comprehensive liability insurance in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.

11. A supplier is prohibited from direct solicitations to Medicare beneficiaries. For complete details on this prohibition see 42 CFR § 424.57 (c) (11)

12. A supplier is responsible for delivery of and must instruct beneficiaries on use of Medicare covered items, and maintain proof of delivery and beneficiary instruction.

13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.

14. A supplier must maintain and replace at no charge or repair cost either directly, or through a service contract with another company, any Medicare-covered items it has rented to beneficiaries.

15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.

16. A supplier must disclose these standards to each beneficiary to whom it supplies a Medicare-covered item.

17. A supplier must disclose any person having ownership, financial, or control interest in the supplier.

18. A supplier must not convey or reassign a supplier number, i.e., the supplier may not sell or allow another entity to use its Medicare billing number

19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.

20. Complaint records must include: the name, address, telephone number, and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.

21. A supplier must agree to furnish CMS any information required by the Medicare statute and regulations.

22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services (except for certain exempt pharmaceuticals).

23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.

24. All supplier locations, whether owned or subcontracted, just meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.

25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.

26. A supplier must meet the surety bond requirements specified in 42 CFR § 424.57(d).

27. A supplier must obtain oxygen from a state-licensed oxygen supplier.

28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 CFR § 424.516(f).

29. A supplier is prohibited from sharing a practice location with other Medicare providers and suppliers.

30. A supplier must remain open to the public for a minimum of 30 hours per week except physicians (as defined in section 1848(j) (3) of the Act) or physical and occupational therapists or a DMEPOS supplier working with custom made orthotics and prosthetics.

Effective July 2013

Medicare Information

NOTICE TO MEDICARE BENEFICIARIES: All medical equipment rented by our company is protected under warranty. The Company notifies all Medicare beneficiaries of this warranty coverage and honors all warranties under law. The Company will repair or replace Medicare-covered equipment, free of charge. An owner's manual for the Medicare-covered equipment will be provided to the beneficiary, where a manual is available.

Medicare Prescription Drug Coverage and Your Rights

Your Medicare rights

You **have the right to request a coverage determination** from your Medicare drug plan if you disagree with information provided by the pharmacy. You also **have the right to request a special type of coverage determination called an "exception"** if you believe:

- you need a drug that is not on your drug plan's list of covered drugs. The list of covered drugs is called a "formulary;"
- a coverage rule (such as prior authorization or a quantity limit) should not apply to you for medical reasons; or
- you need to take a non-preferred drug and you want the plan to cover the drug at the preferred drug price.

What you need to do

You or your prescriber can contact your Medicare drug plan to ask for a coverage determination by calling the plan's toll-free phone number on the back of your plan membership card, or by going to your plan's website. You or your prescriber can request an expedited (24 hour) decision if your health could be seriously harmed by waiting up to 72 hours for a decision. Be ready to tell your Medicare drug plan:

1. The name of the prescription drug that was not filled. Include the dose and strength, if known.
2. The name of the pharmacy that attempted to fill your prescription.
3. The date you attempted to fill your prescription.
4. If you ask for an exception, your prescriber will need to provide your drug plan with a statement explaining why you need the off-formulary or non-preferred drug or why a coverage rule should not apply to you.

Your Medicare drug plan will provide you with a written decision. If coverage is not approved, the plan's notice will explain why coverage was denied and how to request an appeal if you disagree with the plan's decision.

Refer to your plan materials or call 1-800-Medicare for more information.

Your Rights and Responsibilities

As a home infusion patient, you have the RIGHT…..

1. To be fully informed in advance about service/care to be provided, including the disciplines that furnish care and the frequency of visits as well as any modification to the service/care plan
2. To participate in the development and periodic revision of the plan of service/care.
3. To be informed consent and refusal of service/care or treatment after the consequences of refusing service/care of treatment are fully presented.
4. To be informed both orally and in writing, in advance, of service/care being provided, of the charges, including payment for service/care expected from third parties and any charges for which the client/patient will be responsible.
5. To have one's property and person treated with respect, consideration and recognition of dignity and individuality.
6. To be able to identify visiting staff members through proper identification.
7. To voice your grievances/complaints regarding treatment of care lack of respect of property or recommend changes in policy, staff, or service/care without restrain, interference, coercion discrimination, or reprisal.
8. To have grievances/complaints regarding treatment of care that is (or fails to be) furnished or lack of respect of property investigated.
9. To place a complaint with your State Department of Health regarding treatment or care furnished by AxelaCare or subsidiaries. This includes the right to place a complaint with the state health department at any time, even without first complaining to the agency.
10. Choose a health care provider.
11. To have confidentiality and privacy of all information contained in the client/patient record and of Protected Health Information.
12. To be advised on the agency's policies and procedures regarding the disclosure of clinical records.
13. To receive appropriate service/care without discrimination in accordance with physician orders.
14. To be informed of any financial benefits when referred to an organization.
15. To be fully informed of one's responsibilities.
16. To be informed of provider service/care limitations.

17. To receive, upon request, a written notice in advance of care or during the initial evaluation visit before the initiation of treatment, listing of all individuals or other legal entities who have an ownership or control interest in AxelaCare.

18. To be informed of client/patient rights under state law to formulate advanced directives.

19. To be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client/patient property.

As a home infusion patient, you have the RESPONSIBILITY....

1. To provide to the best of your knowledge, accurate and complete information.

2. To follow the plan of care or service recommended by your physician. To care for, use as instructed and return rental equipment in good condition, normal wear and tear expected.

3. To pay for the replacement costs of any equipment damaged, destroyed or lost due to misuse, abuse or neglect.

4. To notify the pharmacy of any equipment malfunction or defective, and allow company technicians to enter the premises to repair, relocate or provide substitute equipment.

5. To be responsible for any payment not paid by your insurance company, except for where not allowed by law.

6. To make it known that you clearly understand the equipment and services being provided.

7. To advise AxelaCare or subsidiary of any changes in your status including address, medical condition, etc.

Complaint or Grievance Policy

In order to achieve our mission to be our customer's choice for comprehensive infusion services, we strive to provide services that meet or exceed our customers' expectations. In the event that we do not meet your expectations, we would like the opportunity to resolve any concerns you have.

If you have questions, concerns or complaints about the care or services you received from AxelaCare, we invite you to call us so we can correct the problem.

A patient or caregiver will receive an acknowledgement (phone, e-mail, fax, or in person) of the complaint within 5 business days and the complaint is being investigated.

The branch manager or regional nurse manager will investigate the complaint or grievance and provide WRITTEN notification to the patient or caregiver of the results of the investigation no later than (14) working days of the complaint.

Access I.V. Branch
AxelaCare Health Solutions, LLC
4610 Northgate Boulevard
Suite 130
Sacramento, CA 95834

Phone: 916.648.0124
Fax: 916.648-0128

Corporate Headquarters
AxelaCare Health Solutions, LLC
15529 College Blvd.
Lenexa, Kansas 66219

Toll Free: 844.902..9352 or
compliance at 877.352.3957
Email: compliance@axelacare.com
Fax (Toll Free): 877.542.9352

In addition, if there are any patient concerns, your State Department of Health or Accrediting Body may be notified at any time. To place a complaint with your State Department of Health or Accrediting Body use the contact information (phone, fax, or email) for your State and/or Accrediting Body, this is provided in the Community Resources section of this patient handbook. If you have any difficulties contacting them or questions about which organization to contact, feel free to call our corporate offices (toll free) at 877.342.9352 or email us at compliance@axelacare.com.

The Joint Commission on Accreditation of Health Care Organizations accredits AxelaCare . This internationally recognized program evaluates the quality of health care. As part of our on-going accreditation with Joint Commission, you have additional resources available for you to report your concerns. The public may contact the Joint Commission's Office of Quality Monitoring to report any concerns or register complaints about a Joint Commission-accredited health care organization by either calling 1-800-994-6610 or e-mailing complaint@jointcommission.org

Advance Directives: Your Right To Decide

The purpose of this brochure is to inform you of ways that you can direct your medical care and treatment in the event that you are unable to communicate for yourself.

The importance of advance directives

Each time you visit your physician, you make decisions regarding your personal health care. You tell your doctor (generally referred to as a "physician") about your medical problems. Your physician makes a diagnosis and informs you about available medical treatment. You then decide what treatment to accept. That process works until you are unable to decide what treatments to accept or become unable to communicate your decisions. Diseases common to aging such as dementia or Alzheimer's disease may take away your ability to decide and communicate your health care wishes. Even young people can have strokes or accidents that may keep them from making their own health care decisions. Advance directives are a way to manage your future health care when you cannot speak for yourself.

What is an advance directive?

"Advance directive" is a term that refers to your spoken and written instructions about your future medical care and treatment. By stating your health care choices in an advance directive, you help your family and physician understand your wishes about your medical care. Some State's laws pay special attention to advance directives.

Advance directives are normally one or more documents that list your health care instructions. An advance directive may name a person of your choice to make health care choices for you when you cannot make the choices for yourself. If you want, you may use an advance directive to prevent certain people from making health care decisions on your behalf.

Your advance directives will not take away your right to decide your current health care. As long as you are able to decide and express your own decisions, your advance directives will not be used. This is true even under the most serious medical conditions. Your advance directive will only be used when you are unable to communicate or when your physician decides that you no longer have the mental competence to make your own choices.

Are advance directives required?

Advance directives are not required. Your physician or hospital cannot require you to make an advance directive if you do not want one. No one may discriminate against you if you do not sign one. Physicians and hospitals often encourage patients to complete advance directive documents. The purpose of the advance directive is for your physician to gain information about your health care choices so that your wishes can be followed. While completing an advance directive provides guidance to your physician in the event that you are unable to communicate for yourself, you are not required to have an advance directive.

What happens if you do not have an advance directive?

If you do not have an advance directive and are unable to choose medical care or treatment, state law decides who can do this for you. If you cannot communicate and do not have an advance directive, your physician will try to contact a member of your immediate family. Your health care choices will be made by the family member that your physician is able to contact.

What types of advance directives may be recognized?

- Talking directly to your physician and family
- Organ and tissue donation
- Health care representative
- Psychiatric advance directives
- Living Will Declaration or Life-Prolonging Procedures Declaration
- Power of Attorney
- Out of Hospital Do Not Resuscitate Declaration and Order
- Physician Orders for Scope of Treatment (POST)

Talking to your physician and family

One of the most important things to do is to talk about your health care wishes with your physician. Your physician can follow your wishes only if he or she knows what your wishes are. You do not have to write down your health care wishes in an advance directive. By discussing your wishes with your physician, your physician will record your choices in your medical chart so that there is a record available for future reference. Your physician will follow your verbal instructions even if you do not complete a written advance directive. Solely discussing your wishes with your physician, however, does not cover all situations. Your physician may not be available when choices need to be made. Other health care providers would not have a copy of the medical records maintained by your physician and therefore would not know about any verbal instructions given by you to your physician. In addition, spoken instructions provide no written evidence and carry less weight than written instructions if there is a disagreement over your care. Writing down your health care choices in an advance directive document makes your wishes clear and may be necessary to fulfill legal requirements.

If you have written advance directives, it is important that you give a copy to your physician. He or she will keep it in your medical chart. If you are admitted to a hospital or health facility, your physician will write orders in your medical chart based on your written advance directives or your spoken instructions. For instance, if you have a fatal disease and do not want cardiopulmonary resuscitation (CPR), your physician will need to write a "do not resuscitate" (DNR) order in your chart. The order makes the hospital staff aware of your wishes. Because most people have several health care providers, you should discuss your wishes with all of your providers and give each provider a copy of your advance directives.

It is difficult to talk with family about dying or being unable to communicate. However, it is important to talk with your family about your wishes and ask them to follow your wishes. You do not always know when or where an illness or accident will occur. It is likely that your family would be the first ones called in an emergency. They are the best source of providing advance directives to a health care provider.

Organ and Tissue Donation

Increasing the quality of life for another person is the ultimate gift. Donating your organs is a way to help others. Making your wishes concerning organ donation clear to your physician and family is an important first step. This lets them know that you wish to be an organ donor. A person that wants to donate organs may include their choice in their will, living will, on a card, or other document. If you do not have a written document for organ donation, someone else will make the choice for you. A common method used to show that you are an organ donor is making the choice on your driver's license. When you get a new or renewed license, you can ask the license branch to mark your license showing you are an organ donor.

Health care representative

A "health care representative" is a person you choose to receive health care information and make health care decisions for you when you cannot. To choose a health care representative, you must fill out an appointment of health care representative document that names the person you choose to act for you. Your health care representative may agree to or refuse medical care and treatments when you are unable to do so. Your representative will make these choices based on your advance directive. If you want, in certain cases and in consultation with your physician, your health care representative may decide if food, water, or respiration should be given artificially as part of your medical treatment.

The advance directive naming a health care representative must be in writing, signed by you, and witnessed by another adult. Because these are serious decisions, your health care representative must make them in your best interest. Courts have made it clear that decisions made for you by your health care representative should be honored.

Living will

A "living will" is a written document that puts into words your wishes in the event that you become terminally ill and unable to communicate. A living will is an advance directive that lists the specific care or treatment you want or do not want during a terminal illness. A living will often includes directions for CPR, artificial nutrition, maintenance on a respirator, and blood transfusions.

Living Will Declaration: This document is used to tell your physician and family that life-prolonging treatments should not be used so that you are allowed to die naturally. Your living will does not have to prohibit all life-prolonging treatments. Your living will should list your specific choices. For example, your living will may state that you do not want to be placed on a respirator but that you want a feeding tube for nutrition. You may even specify that someone else should make the decision for you.

Life-Prolonging Procedures Declaration: This document is the opposite of a living will. You can use this document if you want all life-prolonging medical treatments used to extend your life.

Both of these documents can be canceled orally, in writing, or by destroying the declaration yourself. The cancellation takes effect only when you tell your physician. For either of these documents to be used, there must be two adult witnesses and the document must be in writing and signed by you or someone that has permission to sign your name in your presence.

Psychiatric advance directive

Any person may make a psychiatric advance directive if he/she has legal capacity. This written document expresses your preferences and consent to treatment measures for a specific diagnosis. The directive sets forth the care and treatment of a mental illness during periods of incapacity. This directive requires certain items in order for the directive to be valid.

Out of hospital do not resuscitate declaration and order

In a hospital, if you have a terminal condition and you do not want CPR, your physician will write a "do not resuscitate" order in your medical chart. If you are not in a hospital when an emergency occurs, the emergency medical personnel or the hospital where you are sent likely would not have a physician's order to implement your directives. For situations outside of a hospital, the Out of Hospital Do Not Resuscitate Declaration and Order is used to state your wishes.

The law allows a qualified person to say they do not want CPR given if the heart or lungs stop working in a location that is not a hospital. This declaration may override other advance directives. The declaration may be canceled by you at any time by a signed and dated writing, by destroying or canceling the document, or by communicating to health care providers at the scene your desire to cancel the order. Emergency Medical Services (EMS) may have procedures in place for marking your home so they know you have an order. You should contact your local EMS provider to find out their procedures.

Physician orders for scope of treatment (post)

A "Physician Orders for Scope of Treatment" (also referred to as a POST form) is a direct physician order for a person with at least one of the following:

1. An advanced chronic progressive illness.
2. An advanced chronic progressive frailty.
3. A condition caused by injury, disease, or illness from which, to a reasonable degree of medical certainty there can be no recovery and death will occur from the condition within a short period without the provision of life prolonging procedures.
4. A medical condition that, if the person were to suffer cardiac or pulmonary failure, resuscitation would be unsuccessful or within a short period the person would experience repeated cardiac or pulmonary failure resulting in death.

In consultation with you or your legal representative, your physician will write orders that reflect your wishes with regards to cardiopulmonary resuscitation (CPR), medical interventions (comfort measures, limited additional interventions, or full treatment), antibiotics and artificially administered nutrition. You additionally have the option on the POST form to designate a "Health Care Representative" [see the section "Health Care Representative" above for additional information]. Note that if you have previously designated a health care representative and you name a different person on your POST form, the person designated on the POST form replaces (revokes) the person named in the previous health care representative advance directive.

The POST form must be signed and dated by you (or your legal representative) and your physician to be valid. The original form is your personal property and you should keep it. Paper, facsimile (fax), or electronic copies of a valid POST form are as valid as the original. Your physician is required to keep a copy of your POST form in your medical record or; if the POST form is executed in a health facility, the facility must maintain a copy of the form in the medical record. The POST form may be used in any health care setting

Executed POST forms may be revoked at any time by any of the following:

1. A signed and dated writing by you or your legal representative.
2. Physical cancellation of destruction of the POST form by you or your legal representative.
3. Another individual at the direction of you or your legal representative.
4. An oral expression by you or your legal representative of intent to revoke the POST form. The revocation is effective upon communication of the revocation to a health care provider.

Power of attorney

A "power of attorney" (also referred to as a "durable power of attorney") is another kind of advance directive. This document is used to grant another person say-so over your affairs. Your power of attorney document may cover financial matters, give health care authority, or both. By giving this power to another person, you give this person your power of attorney. The legal term for the person you choose is "attorney in fact." Your attorney in fact does not have to be an attorney. Your attorney in fact can be any adult you trust. Your attorney in fact is given the power to act for you only in the ways that you list in the document. The document must:

1. Name the person you want as your attorney in fact;
2. List the situations which give the attorney in fact the power to act;
3. List the powers you want to give; and
4. List the powers you do not want to give.

The person you name as your power of attorney is not required to accept the responsibility. Prior to executing a power of attorney document, you should talk with the person to ensure that he or she is willing to serve. A power of attorney document may be used to designate a health care representative. Health care powers are granted in the power of attorney document by naming your attorney in fact as your health care representative under the Health Care Consent Act or by referring to the Living Will Act. When a power of attorney document is used to name a health care representative, this person is referred to as your health care power of attorney. A health care power of attorney generally serves the same role as a health care representative in a health care representative advance directive. Including health care powers could allow your attorney in fact to:

1. Make choices about your health care;
2. Sign health care contracts for you;
3. Admit or release you from hospitals or other health facilities;
4. Look at or get copies of your medical records; and
5. Do a number of other things in your name.

Your power of attorney document must be in writing and signed in the presence of a notary public. You can cancel a power of attorney at any time but only by signing a written cancellation and having the cancellation delivered to your attorney in fact.

Which advance directive or directives should be used?

The choice of advance directives depends on what you are trying to do. The advance directives listed above may be used alone or together. Although an attorney is not required, you may want to talk with one before you sign an advance directive. The laws are complex and it is always wise to talk to an attorney about questions and your legal choices. An attorney is often helpful in advising you on complex family matters and making sure that your documents are correctly done under your State's law. An attorney may be helpful if you live in more than one state during the year. An attorney can advise you whether advance directives completed in another state are recognized in your State.

Can I change my mind after I write an advance directive?

It is important to discuss your advance directives with your family and health care providers. Your health care wishes cannot be followed unless someone knows your wishes. You may change or cancel your advance directives at any time as long as you are of sound mind. If you change your mind, you need to tell your family, health care representative, power of attorney, and health care providers. You might have to cancel your decision in writing for it to become effective. Always be sure to talk directly with your physician and tell him or her your exact wishes.

Are there forms to help in writing these documents?

Advance directive forms are available from many sources. Most physicians, hospitals, health facilities, or senior citizen groups can provide you with forms or refer you to a source. These groups often have the information on their web sites. You should be aware that forms may not do everything you want done. Forms may need to be changed to meet your needs. Although advance directives do not require an attorney, you may wish to consult with one before you try to write one of the more complex legal documents listed above.

What should I do with my advance directive if I choose to have one?

Make sure that your health care representative, immediate family members, physician, attorney, and other health care providers know that you have an advance directive. Be sure to tell them where it is located. You should ask your physician and other health care providers to make your advance directives part of your permanent medical chart. If you have a power of attorney, you should give a copy of your advance directives to your attorney in fact. You may wish to keep a small card in your purse or wallet that states that you have an advance directive, where it is located, and who to contact for your attorney in fact or health care representative, if you have named one.

Summary of advance directives

You have the right to choose the medical care and treatment you receive. Advance directives help make sure you have a say in your future health care and treatment if you become unable to communicate.

Even if you do not have written advance directives, it is important to make sure your physician and family are aware of your health care wishes.

No one can discriminate against you for signing, or not signing, an advance directive. An advance directive is, however, your way to control your future medical treatment.

Additional Instructions

May Include Specific Information on...

- ❑ Access
- ❑ Pump/Device
- ❑ Therapy
- ❑ Drug
- ❑ Condition/Disease
- ❑ Other _____
- ❑ Other _____
- ❑ Other _____

AXELA

Experience. The Difference.

Patient Infusion Teaching / Safety Form

Patient: **DOB:** **Physician:**

Date: **Agency:**

Purpose of Visit: ❑ Initial Teach ❑ Follow-up Teach ❑ Hospital Teach ❑ Home Teach

Information & Procedures (How, When, & Why)	N/A	RN Initial & Date When Instructed	Patient/PCG Verbalizes Understanding	Patient/PCG Returns Demo
Policies and Procedures				
Waste disposal, return equipment, defective equipment				
Signature of forms, consent, bill of rights				
Delivery of supplies, inventory				
On-call afterhours system				
Grievances/Incident Report				
Nurse/Pharmacy Responsibilities				
Frequency of Visits				
Patient's training literature and application				
Importance of following physician's orders & compliance				
Indwelling Catheters/Access Device				
Care of the access device (dressing change, proper handling, etc.) Care of entrance or exit site care and inspection. Type of Catheter/Access Device				
IV/access device dressing change frequency				
Showering, bathing, swimming & activities				
Access device care and cap replacement (if applicable)				
Saline and heparin flush (preparation and administration)				
Infusion Therapy/Solution Administration				
Inspection, labels, administration				
Purpose of therapy, method of administration, infusion equipment, pump, Preparation of infusion, adding meds. **Pump instruction manual provided.**				
Connecting of tubing/connecting to catheter/device				
"Purging" tubing of air (importance of prevention of air in system).				
Flow rate (gravity/pump) _____				
Set up, infusion admin, monitoring & discontinuing infusion.				
Side effects, complications and response from Pharmacist				

Information & Procedures (How, When, & Why)	N/A	RN Initial & Date When Instructed	Patient/PCG Verbalizes Understanding	Patient/PCG Returns Demo
Infection Control				
Aseptic techniques (hand washing, inspecting and storing solution and supplies, sterile supplies, selection of preparation area at home, proper handling, contamination, etc.)				
Safety				
Safety- physical layout, adequate lighting, physical storage of medication, hazardous waste disposal, fire and grounded electrical outlets has been discussed with patient.				
Patient has received information regarding fall prevention				
Patient has received hand washing/universal precautions/ infection prevention education.				
Medication is stored per manufacturer's guidelines.				
Patient is aware of proper disposal of unused medicines as per manufacturer's guidelines.				
Supplies are located in a dry, clean area and are identifiable.				
Sharps container is present and out of reach of young children.				
If using assistive device, able to access all rooms and gain entry to outside as appropriate.				
Patient has received a copy of the Home Safety Guidelines, provided in Welcome Folder, and has been instructed to seek needed resources, if applicable.				
Who is responsible for IV infusion?				
❑ Patient ❑ Caregiver ❑ Nurse				
Other/Comments				

Patient/Caregiver accepts responsibility for content marked as instructed

RN Signature Date Patient/Caregiver Signature Date

RN Print Date Patient/Caregiver Print Date

Subcutaneous Administration

Patient: **DOB:** **Physician:**

Date: **Agency:**

Information & Procedures (How, When, & Why)	N/A	RN Initial When Instructed	Patient/PCG Verbalizes Understanding	Patient/PCG Returns Demo
Patient Skills Reviewed – for Subcutaneous Administration				
Define subcutaneous administration				
Describe appropriate sites for SCIg catheter placement				
Describe signs/symptoms of subcutaneous needle complications				
Identify appropriate interventions for complications **Scenarios to be discussed:** ▪ Blood return in tubing upon pullback ▪ Pump malfunctions/alarms ▪ Site reactions ▪ Other adverse events: headache, rash				
Gather appropriate supplies for proper administration and aseptic technique				
Demonstrate proficiency in setting up (priming) tubing				
Demonstrate proficiency in inserting subcutaneous catheter and checking for blood return				
Demonstrate proficiency in discontinuing subcutaneous infusion				
Demonstrate proficiency in filling syringe or cassette				
Demonstrate understanding of storage and disposal of biological waste				
Demonstrate understanding of post-infusion site care				
Demonstrate understanding of care and maintenance of infusion pump				
Demonstrate understanding of appropriate use of EpiPen®				
Additional patient-specific tasks (if applicable)				
Patient discharge instruction sheet reviewed & explained to patient				

Information & Procedures (How, When, & Why)	N/A	RN Initial When Instructed	Patient/PCG Verbalizes Understanding	Patient/PCG Returns Demo
Who is responsible for Subcutaneous Infusion?				
❑ Patient ❑ Parent/Guardian ❑ Primary Care Partner ❑ Privately Employed Caregiver				
Additional Required Information for Subcutaneous Infusion				
Contact Information for medication, supplies, and pumps:				
Contact information for medical issues/urgent:				
Contact information for medical issues/non-urgent:f				
Other/Comments				

Patient/Caregiver accepts responsibility for content marked as instructed

RN Signature	Date	Patient/Caregiver Signature	Date
RN Print	Date	Patient/Caregiver Print	Date

❑ Drug Monographs / Medication Information

Additional Materials/Notes:

Attachment 4

REPRODUCTIVE HEALTH TECHNOLOGIES PROJECT

american society for emergency contraception (asec)

American College of Clinical Pharmacy
Women's Health
Practice & Research Network

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. Most levonorgestrel EC products are available over-the-counter (OTC) without age restrictions. (See reverse side for specific medication details.)
- EC pills that contain ulipristal acetate are available 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 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.

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.

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 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.

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.

REPRODUCTIVE HEALTH TECHNOLOGIES PROJECT

american society for emergency contraception asec

American College of Clinical Pharmacy
Women's Health
Practice & Research Network

FDA-Approved Emergency Contraceptive Pills as of June 2015

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

Medication	Information
Brand and Generic One-Pill Levonorgestrel EC Products	• **May be stocked on OTC shelves in stores.** • Label may indicate that the product is intended for use by women ages 17 and older, but ID check is not required. • Take as soon as possible; may be effective up to 5 days after unprotected sex. • 1 tablet (1.5 mg levonorgestrel)
Generic Two-Pill Levonorgestrel EC Product	• **Must be stocked behind the pharmacy counter.** • Prescription required for those 16 years and younger. Available for purchase over-the-counter for those 17 and older. • Only EC product that is currently "dual labeled" for prescription and OTC usage. • Take both pills together as soon as possible; may be effective up to 5 days after unprotected sex. • 2 tablets (each 0.75 mg levonorgestrel)
Ulipristal acetate	• **Must be stocked in the pharmacy as a prescription-only drug.** • Available for purchase by prescription at the pharmacy. • Only EC product labeled for prescription use only. • Take as soon as possible; effective up to 5 days after unprotected sex. • 1 tablet (30 mg ulipristal acetate)

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

Learn more about EC at www.not-2-late.com and www.rhtp.org.

asec
american society for emergency contraception

REPRODUCTIVE HEALTH TECHNOLOGIES PROJECT

American College of Clinical Pharmacy
Women's Health
Practice & Research Network

January 6, 2016

To: State Boards of Pharmacy
Pharmacy Professional Associations
Pharmacy Corporations

Re: Emergency Contraception Guide for Pharmacies

As advocates for direct pharmacy access and over the counter access to emergency contraception (EC), the undersigned organizations encourage state boards of pharmacy, professional pharmacy associations, and pharmacy corporations to facilitate access by disseminating resources to pharmacists, pharmacy staff, and the public. States with pharmacist EC protocols in place have an additional opportunity to ensure timely access to this medication.

In the past several years, there have been numerous new EC products and changes in regulations, such as restricting access based on age or checking identification. As a result, pharmacies are often unable to keep up with the latest products and changes. This has led to misinformation to the public and refusals by community pharmacies, most commonly related to presumed age or gender restrictions.

Some key findings from recent studies of pharmacy access to EC:

- 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].

To address the knowledge and awareness deficits among pharmacists, pharmacy staff, and consumers alike, we encourage boards of pharmacy, professional pharmacy associations, and pharmacy corporations to make accurate information available to public consumers, as well as their licensees, members, and employees. Suggested resources include a pharmacy guide to the various EC products, EC locator tools, and patient education materials and websites.

A concise and comprehensive guide on EC product availability and access has been developed to serve as an easy reference to stay current on access issues and available products. This guide is intended for use as a reference for pharmacists, as well as pharmacy or store management and staff.

The guide is updated as needed and can be found on the American Society for Emergency Contraception (ASEC) website: http://americansocietyforec.org/uploads/3/2/7/0/3270267/pharmacy_ec_access_overview.pdf.
The guide is also available in Spanish: http://americansocietyforec.org/uploads/3/2/7/0/3270267/pharmacy_ec_access_overview_spanish.pdf
This guide was developed by ASEC in collaboration with the American College of Clinical Pharmacy Women's Health Practice and Research Network and the Reproductive Health Technologies Project. Organizations are welcome to adapt this guide to meet their needs.

Pharmacies are encouraged to stock EC products and make them available on the over-the-counter shelves as well, in order to minimize barriers to access. Pharmacists can help provide evidence-based counseling on medications, in addition to referrals for more effective methods of contraception and sexually transmitted infection screening/treatment. Please refer to specific state laws regarding refusals for personal objections.

Sincerely,

Kelly Cleland, MPA MPH
Executive Director
American Society for Emergency Contraception

Jessica Arons
President & CEO
Reproductive Health Technologies Project

Brooke Griffin, PharmD, BCACP
Chair
American College of Clinical Pharmacy Women's Health Practice & Research Network

Attachment 5

Draft Letter of Support for NABP's .Pharmacy Top-Level Domain (TLD) Initiative

To the National Association of Boards of Pharmacy (NABP):

On behalf of the California State Board of Pharmacy, I write to express the board's endorsement and support for NABP's .pharmacy Top-Level Domain (TLD) initiative. The board believes the .pharmacy TLD, as operated by NABP, fully represents the board's vision of healthy Californians through safe, quality pharmacists care.

The California State Board of Pharmacy is responsible for actively licensing and regulating the businesses and individuals involved in the distribution and dispensing of medications, from the time the product leaves the site of manufacture until it reaches the consumer. The board licenses over 139,000 licensees in 23 licensing categories including but not limited to pharmacists, pharmacy technicians, pharmacies, wholesale distributors, and other drug distribution outlets in California and those entities that ship pharmaceuticals into California.

The Internet has become an invaluable resource for communication, education, and commerce. At the same time, however, it is too often used by cybercriminals to defraud consumers. Such threats make it difficult for consumers to utilize this resource safely. The board believes that the .pharmacy TLD, as operated by NABP, will help to ensure public health and safety.

For this reason, the board fully supports NABP in its role as registry operator for the .pharmacy TLD. NABP has a respected history of promoting safe access to medicine online and developing uniform standards to protect public health in the United States. The board is confident that NABP is currently operating and will continue to operate the .pharmacy TLD in a safe and effective manner.

Please accept this letter of endorsement and support for NABP's .Pharmacy TLD Program. The California State Board of Pharmacy applauds this initiative and its mission to protect the public health.

About Us

.Pharmacy and the Global Pharmacy Community

The National Association of Boards of Pharmacy (http://www.nabp.net)® (NABP®), the impartial professional organization that supports the state boards of pharmacy in protecting public health, is spearheading the .pharmacy initiative. To ensure the program operates in a manner consistent with international laws and standards, a global coalition of pharmacy community stakeholders provides guidance to the .Pharmacy TLD Program (http://www.safe.pharmacy). In addition, the program:

- Establishes partnerships with regulators in each jurisdiction where the .pharmacy domain names are available,
- Coordinates with the appropriate national regulatory bodies when reviewing .Pharmacy applications to ensure compliance with applicable laws, and
- Maintains the highest program standards through participation in global forums to gather input from international pharmacy community stakeholders.

The program's financial supporters include the following organizations:

- Eli Lilly and Company
- Merck & Co, Inc
- Pfizer Inc

The following organizations provided invaluable non-financial support:

- Amgen Inc
- Alliance for Safe Online Pharmacies
- British Brands Group
- Boehringer Ingelheim
- Drugsdepot.com
- DrugSource, Inc
- EnforceTheAct.org
- European Alliance for Access to Safe Medicines
- Indiana Board of Pharmacy
- International Pharmaceutical Federation
- Ipsen Pharma
- LegitScript
- National Association of Pharmacy Regulatory Authorities
- North Dakota State Board of Pharmacy
- Novo Nordisk, Inc
- Rx Direct, Inc
- Sanofi

For more information on how your organization can support NABP's .pharmacy initiative, email info@safe.pharmacy (mailto:info@safe.pharmacy).

Program Standards

The .pharmacy TLD will be available to pharmacies and other entities offering prescription drugs or prescription drug-related products, services, or information via the Internet, subject to their completion of the registrant application and approval process to establish compliance with all applicable laws and .pharmacy program standards.

The application and approval process includes vetting by NABP prior to registration to ensure that they meet all applicable regulatory standards, including those addressing pharmacy licensure and valid prescription requirements. Eligible registrants will demonstrate good standing and compliance with the laws of the jurisdiction in which they are based, as well as in all jurisdictions in which they conduct business, including without limitation dispensing or shipping prescription medications in or to a jurisdiction.

The core standards that must be met to be eligible to register a .pharmacy domain name follow:

1. **Licensure.** An applicant, as well as community members to which the applicant site links or with which it is affiliated, must possess all necessary licenses, registrations, or permits to practice in all required jurisdictions. This includes not only the jurisdiction where the entity is located, but also any jurisdiction where its patients or customers reside. All such licenses, registrations, or permits must be in good standing.
2. **Prior discipline.** An applicant, as well as any community members to which the applicant site links or with which it is affiliated, must not have been subject to significant recent and/or repeated disciplinary sanctions.
3. **Location.** An applicant, as well as community members to which the applicant site links or with which it is affiliated, must be domiciled in the US or in a country with a .pharmacy National Standard Setting Committee, or in a country that has established an understanding with NABP that will allow non-US .pharmacy applicant evaluations to be performed by NABP.
4. **Validity of prescription.** A pharmacy shall dispense or offer to dispense prescription drugs only upon receipt of a valid prescription, as defined by the applicable jurisdictions. A valid prescription is one issued pursuant to a legitimate patient-prescriber relationship, as defined by the applicable jurisdictions.
5. **Legal compliance.** An applicant, as well as community members to which the applicant site links or with which it is affiliated, must comply with all provisions of jurisdictional law, including laws addressing regulatory agency approval of prescription medication.
6. **Privacy.** If the applicant website, or any site to which the applicant site links or with which it is affiliated, maintains or transmits patient health information, the information must be maintained or transmitted in accordance with jurisdictional patient information privacy and security laws, including those addressing notice to patients regarding privacy and security of such information.
7. **Patient services.** An applicant pharmacy, medical or veterinary practice, medical or veterinary practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, must provide on the website an accurate street address of the dispensing pharmacy, medical practice, medical practitioner, or corporate headquarters. The applicant pharmacy, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, 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 or

medical practitioner regarding complaints or concerns or in the event of a possible adverse event involving their medication.

8. **Website transparency.** An applicant, as well as community members to which the applicant site links or with which it is affiliated, must not engage in practices or extend offers on its website that may deceive or defraud patients as to any material detail regarding the practice, its staff, prescription drugs, or financial transactions.
9. **Domain name registration.** The domain name registration information of the applicant website, or of any community member it promotes, must be accurate, and the domain name registrant must have a logical nexus to the dispensing pharmacy, medical or veterinary practice, or medical or veterinary practitioner. Applicant websites utilizing anonymous domain name registration services will not be eligible for approval.
10. **Affiliated websites.** The applicant website, any community member it promotes, its staff, domain name registrants, and any person or entity that exercises control over, or participates in the applicant business, must not be affiliated with or control any other website that violates these standards.

All .pharmacy registrants must meet these core standards. Registration within the .pharmacy gTLD is open to eligible entities in any country, subject to verification of compliance with .pharmacy standards. Additional jurisdiction-specific standards may apply to registrants based in or serving customers in other jurisdictions.

Registrant Eligibility

The following types of businesses are eligible to apply for approval to register a .pharmacy domain name.

1. Pharmacy
   a. Human Pharmacy
   b. Veterinary pharmacy
2. Pharmacy Benefit Management Company
3. School or College of Pharmacy
4. Continuing Pharmacy Education Provider
5. Wholesale Drug Distributor
6. Pharmaceutical Manufacturer
7. Resource
   a. Advocacy or Consumer Education Group
   b. Drug Information or Pharmacy Referral Site
   c. Pharmacy Association
8. Professional
   a. Medical Professionals Sites
   b. Pharmacy Consultant
9. Pharmacy Automation Distributors
10. Board of Pharmacy and Regulatory Agency

Authorized Usage Policy

This Authorized Usage Policy (AUP) governs how a registrant may use its registered domain name(s).

All .pharmacy domain names must be used to serve the needs of the .pharmacy TLD community and must continue to meet program standards for as long as they are held by the registrant.

Registrants are not permitted to prevent/block NABP access (virtual or physical) to their location(s).

By registering a name in this TLD, the registrant agrees to be bound by the terms of this AUP.

Registrants may not:

1. Use domain names for any purposes that are prohibited by the laws of the jurisdiction(s) in which registrant does business, or any other applicable law in jurisdictions in which its customers reside.
2. Use domain names for any purposes or in any manner that violates a statute, rule, or law governing use of the Internet and/or electronic commerce (specifically including, but not limited to, "phishing," "pharming," distributing malware, fast-flux hosting, botnet command and control and other destructive activities).
3. Use a domain name for the promotion of excessive, risky or inappropriate use of medication.
4. Use domain names for the following types of activity:
   i. Violation of the privacy or publicity rights of another member of the pharmacy community or any other person or entity, or breach of any duty of confidentiality that registrant owes to another member of the .pharmacy TLD community, or any other person or entity;
   ii. Promotion of or engagement in hate speech, hate crime, terrorism, violence against people, animals, or property, or intolerance of or against any protected class;
   iii. Promotion of or engagement in defamatory, harassing, abusive, or otherwise objectionable behavior;
   iv. Promotion of or engagement in child pornography or the exploitation of children;
   v. Promotion of or engagement in any spam or other unsolicited bulk e-mail, or computer or network hacking or cracking;
   vi. Infringement on the intellectual property rights of another member of the .pharmacy TLD community, or any other person or entity;
   vii. Engagement in activities designed to impersonate any third party or create a likelihood of confusion in sponsorship;
   viii. Interference with the operation of the .pharmacy TLD or services offered by NABP;
   ix. Installation of any viruses, worms, bugs, Trojan horses, or other code, files, or programs designed to, or capable of, disrupting, damaging, or limiting the functionality of any software or hardware; or distributing false or deceptive language, or unsubstantiated or comparative claims, regarding NABP;
   x. Registration of .pharmacy domain names for the purpose of reselling or transferring those domain names;
   xi. Linking to other websites that are not .pharmacy, for the purpose of transferring business to an unsafe source of products or services or for the purpose of misleading the public;
   xii. Affiliating or linking with other organizations that do not support the safe, legal and ethical practices of .pharmacy.

Terms and Conditions

Download the Terms and Conditions (/system/rich/rich_files/rich_files/000/000/229/original/-pharmacytermsconditionsjuly2015.pdf) (PDF).

.pharmacy Terms and Conditions

Please read these terms and conditions (T&C) carefully. The T&C describe the rights and obligations of the National Association of Boards of Pharmacy® ("NABP"®) and 1) the applicant submitting a .pharmacy domain application to NABP ("Applicant"); and 2) the Applicant if its .pharmacy application is approved by NABP or Applicant, or a third party such as an assignee, if it acquires a .pharmacy domain name registration (collectively "Registrant"). Applicant and Registrant may be collectively referred to as "Customer." NABP, Applicant, Registrant, or Customer are each a "Party" and collectively are "Parties." By submitting an application for a .pharmacy domain or acquiring a .pharmacy domain name, Customer agrees to comply with these T&C.

NABP is approved by the Internet Corporation for Assigned Names and Numbers ("ICANN") as the registry for .pharmacy. NABP is a 501(c)(3) nonprofit corporation located at 1600 Feehanville Drive, Mount Prospect, IL 60056, United States of America. NABP operates the .pharmacy Top-Level Domain (TLD) Program in furtherance of its mission to support its member boards of pharmacy in protecting public health.

Now, therefore, in consideration of the promises and covenants herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the Parties, NABP and Customer agree to the following terms:

1. INFORMATION & MONITORING

1.1 NABP reserves the right to review any and all information available to it to determine whether Applicant complies with the T&C, Registrant Eligibility requirements, Program Standards, the Authorized Usage Policy, and .pharmacy TLD Program requirements published on www.safe.pharmacy or its successor site (s) (collectively "Standards"). Information that NABP may review about Customer includes, but is not limited to, the information provided in the application, information provided to NABP by Applicant or that NABP obtains or receives, whether through the .pharmacy TLD Program, one or more accreditation programs, or any other NABP program, publicly available information, information available through proprietary sources, and information that NABP learns from its own investigations. For all applications, NABP reserves the right to request additional information or documentation from the Customer. Such information shall not be disclosed by NABP unless: (a) the information is publicly available; (b) the information is legally required to be disclosed; (c) NABP, its employees, or contractors believe in good faith that a Customer, its owners, or its affiliates engaged in or are engaging in conduct that violates these T&C, state, federal, country, or regional law, or ICANN requirements; or (d) as otherwise permitted under these T&C or required for NABP to perform its obligations under these T&C or as a registry for the .pharmacy domain. If NABP notifies its member boards of pharmacy or appropriate state, federal, country, or regional regulatory or law enforcement authorities, or ICANN, NABP agrees to notify Customer to the extent permitted by law. Please note that notwithstanding anything to the contrary in the T&C, NABP may utilize contractors or agents to perform any of its activities or obligations under these T&C.

1.2 If NABP approves the .pharmacy domain application, Registrant agrees to notify NABP of any changes to the information provided to NABP via the .pharmacy application or other NABP-designated document including, but not limited to, change in pharmacist-in-charge, change in ownership, change in facility name, change in facility location, or the filing or disposition of any disciplinary action.

1.3 By receiving NABP approval for a .pharmacy domain, Registrant understands that it may be, and agrees to be, subject to regular monitoring for compliance with the Standards.

2. .pharmacy REGISTRANT ELIGIBILITY STANDARDS, AUTHORIZED USAGE POLICY AND PROGRAM REQUIREMENTS, AND WITHDRAWAL

Customer agrees to comply with the .pharmacy Registrant Eligibility Requirements and Program Standards (collectively, "RES"), the .pharmacy Authorized Usage Policy ("AUP"), and program requirements published at the www.safe.pharmacy site or its successor site(s), which are hereby incorporated into the T&C by reference. Customer agrees that NABP may, at its sole discretion, amend the RES, AUP, or program requirements. If NABP amends the RES, AUP, or program requirements, NABP will notify Customer by sending a notification to the contact e-mail account provided by Customer in its .pharmacy domain application. NABP will allow a reasonable amount of time to comply with the amended RES, AUP, or program requirements, unless the amendment pertains to an ICANN requirement, law, or regulation that requires Customer's immediate compliance. Customer may elect to withdraw the .pharmacy domain application, decline to register the NABP-approved .pharmacy domain, or discontinue using the .pharmacy domain that it registered (collectively "Withdrawal"). In any case of Withdrawal, Customer agrees to provide written notice of Withdrawal to NABP and the applicable Registrar. Following receipt of the notice of Withdrawal, NABP shall delete the .pharmacy domain no later than thirty (30) days after receipt of the notice of Withdrawal, unless, in the case of discontinuation of use of a .pharmacy domain, NABP and Registrant agree in writing to a different date of deletion for the .pharmacy domain. Customer agrees to discontinue use of the .pharmacy domain for which it submitted the notice of Withdrawal. The T&C will terminate on the date that NABP deletes the .pharmacy domain. NABP will return the .pharmacy domain name, which was the basis for Customer's application, to the general pool of .pharmacy domains.

3. APPLICATION DENIAL OR CLOSURE

3.1 NABP reserves the right to refuse to consider any domain application on the basis that the requested domain is the subject of a previous application, in NABP's sole discretion. Pursuant to the United States Anticybersquatting Consumer Protection Act of 1999 or other applicable laws or ICANN requirements, NABP may deny an application or delete, remove, transfer, disable, forfeit, or cancel a domain if the domain name is identical to, confusingly similar to, or dilutive of another's trademark.

3.2 Upon Applicant's submission of a complete, accurate, and truthful .pharmacy application and payment of the then-current application fee, NABP and/or one of its contractors will review the application to assess Applicant's compliance with the Standards. If NABP obtains information indicating that Applicant violated or does not comply with the Standards, NABP will send Applicant a written notice of intent to deny the application to register the .pharmacy domain ("Notice of Intent to Deny") and the reason(s) therefor. The Applicant shall have thirty (30) days from the date of the Notice of Intent to Deny to respond. If Applicant does not timely respond, then NABP will send written notification to Applicant that its .pharmacy application is denied ("Denial Notice"). If Applicant responds, NABP will review Applicant's response and any additional relevant information that the Applicant provides in response to the Notice of Intent to Deny. After its review, if NABP determines that Applicant did not violate and is in compliance with the Standards, then NABP will rescind the Notice of Intent to Deny by approving Applicant to register the .pharmacy domain for which Applicant applied and issuing Applicant a registration token. After its review, if NABP determines that

Applicant violated the Standards or is not in compliance with the Standards, NABP will send Applicant a Denial Notice. Denial Notices and NABP's decision to deny the .pharmacy application are final and NABP will not reconsider any of its decisions. The T&C terminate effective on the date of the Denial Notice. Following the Denial Notice, NABP will return the .pharmacy domain name for which the Applicant had applied to the general pool of .pharmacy domains. If Applicant reapplies, it must correct all non-compliances described in Notice of Intent to Deny and meet all then-applicable Standards. If Applicant reapplies for the same or a different .pharmacy domain, NABP cannot guarantee the availability of the .pharmacy domain that was the basis of the previous application.

3.3 If NABP has questions about an application or needs additional information, then NABP may send a written request to the Applicant identifying the specific questions or information requested. The Applicant shall have thirty (30) days to respond to the NABP request. If Applicant does not respond to the request for information, then NABP shall close the application and send a "Notice of Application File Closure," and the .pharmacy domain will be placed in the general pool of .pharmacy domains. If Applicant responds, NABP will review Applicant's response and any additional relevant information that the Applicant provides in response to the NABP request. After its review, if NABP determines that Applicant meets the Standards, then NABP will approve Applicant's .pharmacy domain application and issue a registration token. After its review, if NABP determines that Applicant does not meet the Standards, then NABP will send Applicant a Notice of Application File Closure. Notices of Application File Closure and NABP's decision to close Applicant's .pharmacy application file are final and NABP will not reconsider any of its decisions. The T&C terminate effective the date of the Notice of Application File Closure. A refund will be issued only per the Refund Policy in these T&C. Following the Notice of Application File Closure, NABP will return the .pharmacy domain name to the general pool of .pharmacy domains. If Applicant reapplies, it must answer all NABP questions or provide the information that NABP requested in connection with the Applicant's previous .pharmacy application and meet all current Standards. Applicant may reapply for the same or a different .pharmacy domain, but NABP cannot guarantee the availability of the .pharmacy domain that was the basis of the previous application.

3.4 If NABP receives two or more complete applications for the same domain from different Applicants, and the completed application received first in time is approved, the application(s) received subsequently will be closed by NABP. NABP shall send a "Notice of Application Closure" to the Applicant. A refund will be issued only per the Refund Policy in these T&C. Applicant may reapply for a different domain.

4. REGISTRATION & REGISTRATION TOKEN

Upon approval of a .pharmacy domain, NABP will provide Registrant with an electronic registration token. Using the electronic registration token, Registrant must register the .pharmacy domain requested, within sixty (60) days of approval, with an authorized .pharmacy registrar ("Registrar"). A list of authorized .pharmacy Registrars may be found at www.safe.pharmacy or successor site(s). If Registrant fails to register the .pharmacy domain within sixty (60) days of being approved, the Registrant will forfeit that .pharmacy domain, and it will be placed in the general pool of .pharmacy domains. If the prior Registrant wishes to register that .pharmacy domain at a later time when that domain is still available, it must reapply including paying the then-current .pharmacy application fee.

5. DOMAIN TRANSFER

Registrant is prohibited from transferring, sublicensing, or assigning a .pharmacy domain to another registrant by any means, except with NABP's prior written consent. Registrant is prohibited from transferring the registration of a .pharmacy domain from one Registrar to a different Registrar except with NABP's prior written consent.

6. OWNERSHIP, LICENSE, & RESTRICTIONS ON USE

6.1 All rights, title, and interest in .pharmacy (including all copyrights, trademarks, and other intellectual property rights) are the property of NABP or its ICANN-approved affiliates or successors. Except as expressly provided below, nothing contained herein shall be construed as conferring to any Customer or its successors any license or right, by implication, estoppel, or otherwise to claim, exercise, or exploit any copyright or other intellectual property rights.

6.2 Customer agrees that acceptance or approval of a .pharmacy application or acquisition of a .pharmacy domain name does not constitute a warranty or an endorsement by NABP of Customer's products or services, or Customer's compliance with any law or regulation. Customer may not sublicense, transfer, or assign a .pharmacy domain name without prior written approval of NABP.

7. REFUND POLICY

Customer agrees that there are no refunds of application or registration fees, except if the .pharmacy domain applied for has been approved by NABP for a different applicant. Such refund will be made in the same manner that the fee was paid to NABP.

8. SUNRISE DISPUTE RESOLUTION POLICY AND OTHER DOMAIN DISPUTE DECISIONS

8.1 Through the National Arbitration Forum or any successor organization, NABP provides a mechanism to resolve disputes in connection with Sunrise registrations. NABP's Sunrise Dispute Resolution Policy, available at www.safe.pharmacy/standards-policies, describes the process and requirements for challenging .pharmacy domain names registered during the Sunrise period. NABP and Customer each agree to abide by the decision made by National Arbitration Forum. In the event that the National Arbitration Forum decision calls for the transfer of the domain, the designated domain recipient must first be approved by NABP as compliant with the then-applicable .pharmacy Standards.

8.2 In the event that a court of competent jurisdiction or an ICANN-recognized arbitration organization issues a decision calling for the transfer of a .pharmacy domain name, the designated domain recipient must first be approved by NABP in writing as compliant with the then-applicable .pharmacy Standards.

9. DOMAIN DISCONTINUATION BY REGISTRANT & DELETION, SUSPENSION, OR TERMINATION BY NABP

9.1 Following receipt of written notice that Registrant will discontinue seeking to register a .pharmacy domain name or wishes to discontinue using a registered .pharmacy domain, NABP will delete the domain name no later than thirty (30) days after receipt of the written notice unless, in the case of discontinuation of use of a .pharmacy domain, NABP and Registrant agree in writing to a different date of deletion for the .pharmacy domain. The T&C will automatically terminate on the date that NABP deletes the .pharmacy domain name. NABP will not issue a refund if Registrant discontinues seeking to register or using a .pharmacy domain.

9.2 If NABP obtains information indicating the Registrant violated or is not in compliance with the Standards, NABP will send Registrant a notice of intent to terminate NABP's approval of the .pharmacy application or delete the .pharmacy domain registration ("Notice of Intent to Delete") and the reason(s) therefor. Registrant shall have thirty (30) days from the date of the Notice of Intent to Delete to respond. If Registrant does not timely respond, then NABP will send written notification to Registrant that NABP's approval of the .pharmacy application is terminated or that it will delete Registrant's domain registration, as applicable ("Deletion Notice"). If Registrant timely responds, NABP will review Registrant's response and

any additional relevant information that the Registrant provides in response to the Notice of Intent to Delete. After its review, if NABP determines that Registrant did not violate and is in compliance with the Standards, then NABP will rescind the Notice of Intent to Delete and will approve Registrant to register the .pharmacy domain or continue to use the .pharmacy domain name registration, as applicable. After its review, if NABP determines that Registrant violated the Standards or is not in compliance with the Standards, NABP will send a Deletion Notice. The T&C terminate effective on the date of the Deletion Notice. All Deletion Notices and NABP's decision to terminate its approval for the .pharmacy domain or to delete the .pharmacy domain name registration are final and NABP will not consider any internal appeal of its decisions. Following the Deletion Notice, NABP will return the .pharmacy domain name that was the basis for the Customer's application to the general pool of .pharmacy domains. If Registrant reapplies, it must correct all non-compliances with the Standards described in Notice of Intent to Delete and meet all then-applicable Standards. Registrant may reapply for the same or a different .pharmacy domain, but NABP cannot guarantee the availability of the .pharmacy domain that was the basis of the previous application.

9.3 NABP reserves the right, in its sole discretion, to immediately suspend Registrant's .pharmacy domain or NABP's approval of Registrant's .pharmacy domain application if NABP obtains information indicating that Registrant is violating, or within the previous 12 months violated without disclosing to NABP, any criminal, fraud, pharmaceutical, pharmacy-related, patient safety-related, or Internet-related law or regulation or ICANN requirement, is engaging in abusive activities in connection with the Internet or its governance, threatens or its activities threaten the security or stability of the Internet or of the .pharmacy namespace, or Registrant is likely to cause direct and material harm to others ("Violation"). NABP shall provide a written notice to the Registrant of the suspension ("Suspension Notice"), the reason for the suspension, notify Registrant of NABP's intent to delete Registrant's domain, and provide Registrant with the opportunity to respond. Within 30 days of the date of the Suspension Notice, Registrant may submit a response to NABP, including any available documentation to substantiate Registrant's response. If Registrant does not timely respond, then NABP will send written notification to Registrant that NABP's approval of the .pharmacy domain application is terminated or that it deleted Registrant's .pharmacy domain registration ("Deletion Notice"). If Registrant timely responds, NABP will review Registrant's response and any relevant information that the Registrant provides in response to the Suspension Notice. After its review, if NABP determines that Registrant did not engage in any Violation and is compliant with the Standards, then NABP will rescind the Suspension Notice and will confirm its approval for Registrant to register the requested .pharmacy domain or reinstate Registrant's .pharmacy domain name registration, as applicable. After its review, if NABP in its sole discretion determines that Registrant engaged in a Violation, NABP will send a Deletion Notice. The T&C terminate effective on the date of the Deletion Notice. All Suspension and Deletion Notices and NABP's decisions to suspend Registrant's .pharmacy domain, suspend its approval of Registrant's .pharmacy domain, or to delete Registrant's .pharmacy domain name registration are final and NABP will not reconsider any of its decisions. Following the Deletion Notice, NABP will return the .pharmacy domain name that was the basis for the Registrant's application to the general pool of .pharmacy domains. If Registrant reapplies after receiving a Deletion Notice, it must correct all Violations described in Suspension Notice and meet all then-applicable Standards. Registrant may reapply for the same or a different .pharmacy domain, but NABP cannot guarantee the availability of the .pharmacy domain that was the basis of the previous application.

9.4. If Customer fails to pay the application or registration fees when due, NABP will send Customer written notification of impending termination of NABP's consideration of the application, approval of the .pharmacy domain, or deletion of Registrant's .pharmacy domain name registration. If Customer does not timely pay all applicable fees within thirty (30) days of the date of such notification, NABP will terminate its consideration of the application, its approval of the .pharmacy domain or delete the .pharmacy domain

name registration, as applicable. NABP will return the .pharmacy domain, which was the basis for the .pharmacy application, to the general pool of .pharmacy domains, and will send written notification thereof to Registrant. The T&C terminate effective on the date of the written notification. Registrant may reapply for the same or a different .pharmacy domain, but NABP cannot guarantee the availability of the .pharmacy domain that was the basis of the previous application.

9.5 NABP will send Registrant a Deletion Notice if Registrant does not timely respond to any NABP request for information or if Registrant does not provide all NABP-requested documentation within 30 days of the date of a Notice of Intent to Delete. NABP will terminate its approval of the .pharmacy domain or delete Registrant's .pharmacy domain name registration, as applicable, and NABP will return the .pharmacy domain, which was the basis for the .pharmacy application, to the general pool of .pharmacy domains. The T&C terminate effective on the date of the Deletion Notice. If Registrant reapplies, it must correct all non-compliances with the Standards described in Notice of Intent to Delete and meet all then-applicable Standards. Registrant may reapply for the same or a different .pharmacy domain, but NABP cannot guarantee the availability of the .pharmacy domain that was the basis of the previous application.

9.6 If Customer applies for or is accredited or approved by NABP through one or more current or future NABP accreditation or approval programs including, without limitation, the Verified-Accredited Wholesale Distributors® (VAWD®), Verified Internet Pharmacy Practice Sites® (VIPPS®), or Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS), and its application is denied or Customer is disqualified from one of the NABP accreditation or approval programs, Customer hereby agrees that the application denial or disqualification is grounds for denial of Customer's .pharmacy application or temporary suspension, termination of approval, or deletion of Customer's .pharmacy domain and that NABP may deny, temporarily suspend, terminate its approval, or delete Customer's .pharmacy domain pursuant to the requirements of the T&C. NABP will return any denied or deleted domain name(s) to the general pool of .pharmacy domains. If Customer reapplies, it must correct all non-compliances described in the applicable notice, including the Notice of Intent to Deny or Notice of Deletion, and meet all then-applicable Standards. If Customer's application for a .pharmacy domain name is denied or its .pharmacy domain name(s) are deleted or NABP terminates its approval of Customer's .pharmacy domain name(s), then Customer hereby agrees that the denial of the .pharmacy application or deletion or termination of approval of its .pharmacy domain name(s) is grounds for loss of qualification under the accreditation or approval program letter of agreement (LOA) and NABP may suspend or disqualify Customer from one or more NABP accreditation or approval programs pursuant to the terms and conditions of the applicable LOA(s).

9.7 Customer must notify NABP in writing of any change in its ownership, including if Customer is merged, acquired by, or consolidated with another organization within 30 days of any such change. In such circumstance, NABP may, in its sole reasonable discretion, require Customer to reapply for approval of a .pharmacy domain. In such circumstance, NABP shall send a written notice advising the Customer that it must complete the .pharmacy application, submit the then-applicable payment, and meet the then-applicable Standards. In the case of a Registrant, its .pharmacy domain will remain active for 30 days, while the Registrant prepares its .pharmacy application for submission. If Registrant fails to reapply within those 30 days, then NABP will send Registrant a Deletion Notice. If Registrant timely applies and NABP determines that Registrant meets the then-applicable Standards, then Registrant's .pharmacy domain will remain active for the remaining balance of the 12-month term, and NABP will send Registrant written notification thereof. If Registrant timely applies and NABP has questions about the application or needs information, then NABP shall send a written request to the Registrant identifying the specific questions or information requested. The Registrant shall have 30 days to respond to the NABP request. If Registrant does not timely respond to the NABP request, the application will be closed and NABP will send Registrant notification that its application file was closed and the Registrant's domain will be deleted. Thereafter, the .pharmacy domain will be placed in the general pool of .pharmacy domains. If Registrant timely

responds, NABP will review Registrant's response and any additional relevant information that the Registrant provides in response to the NABP request. After its review, if NABP determines that Registrant meets the Standards, then Registrant's .pharmacy domain will remain active for the remaining balance of the 12-month term, and NABP will send Registrant written notification thereof. After its review, if NABP determines that Registrant does not meet the Standards, the application will be closed, NABP will send Registrant notification that its application file was closed and Registrant's domain will be deleted. Thereafter the .pharmacy domain will be placed in the general pool of .pharmacy domains. NABP's decisions to close Registrant's .pharmacy application and delete its .pharmacy domain registration are final and NABP will not reconsider any of its decisions. The T&C terminate effective on the date of the Deletion Notice. A refund will be issued only in accordance with the Refund Policy in these T&C. If Registrant reapplies, it must answer all NABP questions or provide the information that NABP requested in connection with the previous .pharmacy application and meet all then-applicable Standards. Registrant may reapply for the same or a different .pharmacy domain, but NABP cannot guarantee the availability of the .pharmacy domain that was the basis of the previous application.

10. RIGHT OF PUBLICITY

Customer grants NABP a nonexclusive, transferrable (except for the logo), royalty-free worldwide license to publish and use in .pharmacy materials, Customer's name, logo, address, website address, and its date of approval of the .pharmacy domain application, along with other information required by ICANN.

11. TERM

The term of a domain name is twelve (12) months, which begins upon the date the domain name is registered with a Registrar. The Registrant must reapply annually to maintain the .pharmacy domain name. NABP reserves the right to suspend or delete a domain name during the term, consistent with these T&C. Termination of Customer's registration or deletion of Customer's .pharmacy domain does not relieve Customer of liability for obligations that relate to activities occurring before such termination or deletion.

12. RENEWAL

One hundred twenty (120) days prior to the anniversary of the domain name registration date ("120-Day Notice"), each successive year during which the domain name is active, Registrar will advise Registrant to complete the annual .pharmacy TLD Program application form (found at www.safe.pharmacy/ apply, or successor site(s)) to reapply for the domain name. Registrar will send a reapplication notice to the Registrant thirty (30) days after the date of the 120-Day Notice. If Registrant has not reapplied within sixty (60) days of the anniversary of the domain name registration date, Registrar will advise Registrant that if the reapplication is not processed prior to the anniversary date, the domain name may be suspended and ultimately deleted. If the Registrant has not reapplied within thirty (30) days of the anniversary of the domain name registration date, Registrar will advise Registrant that the domain name is at risk of being suspended and ultimately deleted. If the Registrant reapplies within five (5) days of the anniversary of the domain name registration date, NABP cannot guarantee that it will be able to review and, if Registrant meets all Standards, approve the domain renewal request prior to the anniversary date. If by the anniversary date NABP has not completed its review of the application that Customer submitted within five (5) days of the anniversary date, NABP may, in its sole discretion, suspend the domain name pending NABP's review and approval of Customer's application. If NABP decides to suspend the domain name, NABP will notify the Registrar regarding the domain suspension and will send a notice to the Customer that is domain is suspended pending NABP's review and approval of Customer's application. If the Customer has not reapplied as of the anniversary date, NABP will notify the Registrar to suspend the domain name and send a notice to the Customer that its domain is suspended pending NABP's review and approval of

Customer's application. A Customer that has not submitted its application prior to the anniversary date shall be given thirty (30) additional days to reapply ("Redemption Grace Period") during which time the domain will remain suspended. After the expiration of the Redemption Grace Period, if the Customer has not timely reapplied, the domain name will be deleted by NABP and placed into the general pool of .pharmacy domains. Customer may reapply for the same or a different .pharmacy domain, but NABP cannot guarantee the availability of the .pharmacy domain that was the basis of the previous application.

If NABP approves the renewal of the domain name, Customer may register the domain name for another year. Registrar will collect the applicable registration fee. NABP and Customer agree that review and handling of Customer's .pharmacy TLD Program application for renewal of its .pharmacy domain will be handled in accordance with the then-current terms and conditions for the .pharmacy TLD Program.

13. INDEMNIFICATION AND LIMITATION OF LIABILITY

Customer agrees to indemnify and hold harmless NABP, its employees, agents, contractors, officers, and directors against all third-party claims, losses, lawsuits, damages, and expenses, including, without limitation, reasonable attorneys' fees arising out of:

a. Any failure on the part of Customer or its employees, agents, contractors, officers, and directors to comply with these T&C;
b. Any use of a .pharmacy domain, including content in any advertisement, brochure, or other publication released to the public by Customer or its agents or contractors, and any content on any Internet site substantially owned or controlled by or affiliated with Customer including, but not limited to, any claim related to infringement, misappropriation or other violation of a right of another person (including, without limitation, copyright, right of privacy or publicity, or trade secret), or a claim for defamation or obscenity;
c. The sale, offer to sell, or provision of any product or service of or by Customer or any other entity substantially owned or controlled by or affiliated with Customer; or
d. The negligence, gross negligence, misconduct, or intentional tort of Customer or its employees, agents, contractors, officers, or directors.

WITH THE EXCEPTION OF CUSTOMER'S INDEMNIFICATION OF NABP AS DESCRIBED IN THIS SECTION, NEITHER NABP NOR CUSTOMER SHALL BE LIABLE TO THE OTHER OR ANY THIRD PARTY FOR ANY INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGE OR DAMAGES FROM LOST PROFITS OR LOST USE. THE MAXIMUM AGGREGATE LIABILITY OF NABP FOR ALL CLAIMS ARISING OUT OF OR RELATING TO THESE T&C, REGARDLESS OF THE FORM OR CAUSE ACTION, SHALL BE THE TOTAL FEES PAID BY CUSTOMER TO NABP FOR THE .PHARMACY DOMAIN NAME DURING THE TERM OF THE T&C.

14. ZONE FILE AND/OR WHOIS DATA ACCESS

NABP, its employees, agents, contractors, officers, and directors shall not be liable to Registrant for a) any access, use, or modification (whether or not permitted) of the Zone File or WHOIS data, without limitation; b) the unauthorized, improper, or illegal access or use of the Zone File or WHOIS data, without limitation; or c) any negligent act or omission or willful misconduct in the access or use of the Zone File or WHOIS data, without limitation.

15. MISCELLANEOUS

15.1 Customer will notify NABP in writing if Customer, its pharmacy, owners, or affiliates become the subject of an investigation, indictment, prosecution, conviction, or disciplinary order within thirty (30) days of learning of such investigation, indictment, prosecution, conviction, or disciplinary order.

15.2 Customer represents and warrants that the information it submits in its .pharmacy application and in any other document submitted in connection with its .pharmacy application or domain is complete, accurate, and truthful to the best of Customer's knowledge. Customer further represents that the person or entity submitting the application for the .pharmacy domain and all documents in connection with the .pharmacy application or domain is fully authorized to submit the application and bind Customer to the T&C.

15.2.1 NABP and Customer further represent and warrant that they are duly organized, validly existing, and in good standing under the laws of their respective jurisdictions of organization, they have full corporate power to conduct their respective business and perform all of their respective obligations under the T&C, and they are operating in compliance with all applicable laws, rules, and regulations, and ICANN requirements.

15.2.2 NABP DISCLAIMS ALL WARRANTIES AND GUARANTEES TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW.

15.3 The T&C are not assignable by Customer without the prior written consent of NABP.

15.4 The headings contained in the T&C are for the purposes of convenience only and are not intended to define or limit the contents of the provisions contained therein.

15.5 The failure of NABP to exercise any of its rights regarding a breach of these T&C shall not be deemed to be a waiver of such rights nor shall the same be deemed to be a waiver of any subsequent breach.

15.6 The T&C constitute the entire agreement between the Parties relating to the subject matter hereof and supersede all prior and contemporaneous oral and written negotiations, commitments, and understandings of the parties with respect to the same subject matter.

15.7 The validity, interpretation, and performance of the T&C shall be controlled and construed under the laws of the state of Illinois, United States of America without reference to any conflict of laws principles. The state courts located in Cook County, IL, United States of America shall have jurisdiction over any dispute regarding the T&C or in connection with the NABP .pharmacyTLD Program. All provisions contained in the T&C shall extend to and are binding on Customer and its respective successors and assigns. Customer expressly waives all objection to the choice of law or personal jurisdiction of these courts and shall not contest the choice of law or venue chosen for the hearing of the case.

15.8 Provisions 3, 6, 7, 8, 9, 10, 11, 12, 13, 14, and 15 of the T&C shall survive the termination of the T&C or any termination or deletion of the .pharmacy domain name.

15.9 Any act or omission of any of the affiliates of the Customer that is contrary to the T&C shall be deemed the act or omission of the Customer.

15.10 The provisions of the T&C are severable. If any provision is determined by a court of competent jurisdiction or a governmental regulatory entity to be invalid or unenforceable, in whole or in part, that provision shall be construed or limited in such a way as to make it enforceable and consistent with the manifest intentions of the Parties. If such construction or limitation is impossible, the unenforceable provision will be stricken, and the remaining provisions of the T&C will remain valid and enforceable.

15.11 NABP retains all rights, immunities, and protections that are available to it under applicable law.

15.12 NABP cannot and will not guarantee that Applicant's .pharmacy domain application will be approved, and Applicant acknowledges the same by submitting its .pharmacy domain application.

15.13 Customer hereby agrees that NABP may send all notices, communications, and notifications under the T&C to the contact e-mail account provided by Customer in its .pharmacy application. Customer agrees to maintain the valid operation of and regularly check this e-mail account for purpose of receiving such notices and complying with the T&C.

15.14 No formal or informal hearing, whether in-person, in writing or otherwise, is permitted under the T&C.

15.15 The T&C constitutes the entire agreement between the Parties relating to this .pharmacy domain application, or any acquisition or use of a .pharmacy domain in connection with this application, and supersedes all prior and contemporaneous oral and written negotiations, commitments, and understandings of the Parties with respect to this application.

By submitting this application or acquiring a .pharmacy domain name, Customer hereby authorizes release of any and all information from regulatory agencies to NABP and its contractors for the purpose of verifying information regarding the Customer and/or evaluating any noncompliance with the T&C, applicable laws, or disciplinary actions involving any person or entity associated with the Customer or its affiliates in the practice of pharmacy, wholesale drug distribution, pharmaceutical manufacturing, or the provision of pharmacy-related services or products. Customer further authorizes NABP to release to regulatory agencies information NABP receives or obtains related to Customer, or when such information leads NABP to believe in good faith that the Customer or its staff are engaging in or engaged in conduct that violates state, federal, national, or regional laws or regulations.

By submitting this application or acquiring a .pharmacy domain name, Customer hereby accepts and agrees to be bound by the T&C without modification except as provided in section 2.

Version 4.0; 14July2015

Refund Policy

Customer agrees that there are no refunds of the application fee or the registration fee, except if the .pharmacy domain applied for has been approved by NABP for a different applicant. Such refund will be made in the same manner that the fee was paid to NABP.

Apply

Interested in obtaining a .pharmacy domain name for your organization? Here's the process in three basic steps:

1. First, apply to NABP for approval to register the domain name(s).
2. NABP reviews your application, required supplemental documentation, and proposed website content, and processes fees. The application review process is expected to take 60 days in most instances. A couple of items of note:
   A. Before beginning your application, review the program standards and read the application instructions. Understanding these documents will help ensure a smooth application process.
   B. All applicants seeking .pharmacy domains must be able to provide the content of the proposed .pharmacy site either via a site that is currently live or a staged site.
   C. NABP is in the process of creating relationships with regulatory agencies outside of the US. If a relationship has not been established in the country where your organization is located, NABP will contact you immediately to discuss how this may delay approval of your application.
3. If your organization meets the program standards (http://www.safe.pharmacy/standards-and-policies/program-standards), NABP will grant your organization a secure, electronic token of approval. You will need to submit the token to one of NABP's approved registrars to register the domain.
4. Organizations that have been granted a .pharmacy domain must re-apply with NABP and re-register with one of NABP's approved registrars annually. All relevant fees will be charged to applicants seeking renewal.

Learn more about the benefits (/system/rich/rich_files/rich_files/000/000/230/original/benefitsdotpharmacy7-7-15.pdf) (PDF) of obtaining a .pharmacy URL for your organization's pharmacy or pharmacy-related website.

Attachment 6

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

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

NEWS RELEASE
February 10, 2016

CONTACT: Debbie Damoth
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Translations on Prescription Drug Labels

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

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

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

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

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

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

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

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

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Junta de Farmacias del Estado
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BUSINESS, CONSUMER SERVICES and HOUSING AGENCY
DEPARTAMENTO DE ASUNTOS DEL CONSUMIDOR
GOBERNADOR EDMUND G. BROWN JR.

COMUNICADO DE PRENSA
10 de febrero de 2016

CONTACTO: Debbie Damoth
(916) 574-7935
Debbie.Damoth@dca.ca.gov

Traducción de las etiquetas de medicamentos con receta

Los pacientes ahora pueden solicitar la traducción de las instrucciones de uso de ciertos medicamentos con receta

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

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

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

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

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

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

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

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加州藥劑局
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商業, 消費者服務及住家中介單位
消費者服務部門
EDMUND G. BROWN JR. 州长

新聞稿
二零一六年二月三日

聯絡人: Debbie Damoth
(916) 574-7935
Debbie.Damoth@dca.ca.gov

處方藥標籤翻譯
患者即起可要求特定處方藥標籤中的使用說明翻譯

擁有閱讀處方藥標籤的能力是了解正確用藥方式的重要一環。

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

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

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

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

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

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

###

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THÔNG CÁO BÁO CHÍ
10 Tháng Hai, 2016

LIÊN HỆ: Debbie Damoth
(916) 574-7935
Debbie.Damoth@dca.ca.gov

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

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

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

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

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

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

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

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

###

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산업, 소비자 서비스 및 주택청
소비자부
GOVERNOR EDMUND G. BROWN JR.

보도 자료
2016 년 2 월 3 일

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처방약 라벨에 대한 번역

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

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

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

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

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

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약사법 개정안과 더불어 이 새로운 법률에 대한 추가적인 정보를 원하시면 다음 링크를 통해서 위원회의 웹싸이트에서 찾아보실 수 있습니다- - http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf

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

###

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АГЕНТСТВО ПО ВЕДЕНИЮ БИЗНЕСА, ОБСЛУЖИВАНИЮ ПОТРЕБИТЕЛЕЙ И НЕДВИЖИМОСТИ
УПРАВЛЕНИЕ ПО ДЕЛАМ ПОТРЕБИТЕЛЕЙ
УПРАВЛЯЮЩИЙ ЭДМУНД Г. БРАУН МЛ.

ПРЕСС-РЕЛИЗ
от 10 февраля 2016 года

КОНТАКТНОЕ ЛИЦО: Дебби Дамос
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Перевод инструкций по применению лекарственных препаратов, отпускаемых по рецепту

Теперь пациенты могут запросить перевод инструкций по применению определенных лекарственных средств рецептурного отпуска

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

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

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

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

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

Более подробно о новом Законе, а также законодательных изменениях в фармацевтической области, можно прочитать на сайте Управления по адресу:
http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf

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

###

Attachment 7

I. Update on Media Activity

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

- **The Daily Beast,** October 6, 2015: M.L. Nestel, prescriptions with an alias
- **Enterprise Record,** October 8, 2015: Ryan Olson, cease and desist order
- **ProPublica,** October 16, 2015: Charlie Ornstein, Valeant
- **Reuters,** October 21, 2015: Deena Beasley, Philidor Rx Services
- **Wall Street Journal,** October 23, 2015: Jeanne Whalen, Philidor Rx Services and R&O Pharmacy
- **Bloomberg,** October 26, 2015: Robert Langreth, Philidor Rx Services
- **Bloomberg News,** October 29/30, 2015: Carolyn Chen, specialty pharmacies
- **California Health Line,** October 30/31, 2015: George Lauer, drug take back regulations
- **Thomson-Reuter's LA Bureau,** November 2, 2015: Tim Reid, Philidor/Valeant
- **ABC Channel 7, Albuquerque, NM,** November 3/4,2015: Megan Cruz, Naloxone
- **San Diego Union Tribune,** November 20, 2015: Kristina Davis, drug diversion
- **Sacramento Bee,** November 20, 2015: Margie Lundstrom, disciplinary case
- **CBS 13 News,** November 23, 2015: Adrienne Moore, birth control and naloxone
- **New York Times,** November 25, 2015: Anna North, SB 493
- **LA Times,** December 1, 2015: Soumya Karlamangla, self-administered contraceptives provided by pharmacists
- **Medical Marketing & Media,** December 2/3, 2015: Jaimy Lee, disciplinary case
- **CBS News,** December 3, 2015: Chris Weicher, San Bernardino shooting incident
- **STAT,** December 4, 2015: David Armstrong, drug thefts from supply chain
- **Wall Street Journal,** December 4, 2015: Jeanne Whalen, San Bernardino shooting incident
- **Orange County Register,** December 4, 2015: Jenna Chandler, naloxone
- **Sacramento Bee,** December 8, 2015: Shawn Hubler, SB 493 implementation
- **Sacramento Bee,** December 9, 2015: Shawn Hubler, SB 493 implementation-continued
- **NBC Bay Area,** December 9, 2015: Kevin Nious, lost/stolen prescription drug information
- **NY Times,** December 10, 2015: Paula Span, patient-centered labels
- **Wall Street Journal,** December 15, 2015: Emily Rand, licensure status of an applicant
- **RV Traveler,** December 16, 2015: Russ Demaris, dispensing prescription written in a foreign country – spoke with Supervising Inspector Janice Dang
- **LA Magazine,** December 17, 2015: Jeff Gottleib, disciplinary case – spoke with Assistant Executive Officer Anne Sodergren
- **KQED,** December 29, 2015: April Dembosky, CURES 2.0
- **CBS 13 News,** January 4, 2016: Adrienne Moore, hormonal contraception including on camera interview
- **CNN,** January 14, 2016: Heather Kelly, smart phone app for doctor consultation
- **Capitol Morning Report,** January 14, 2016: Lauralynne Powell, drug take back regulations
- **Orange County Register,** January 20, 2016: Jenna Chandler, SB 493 implementation
- **Orange County Register,** January 22, 2016: Jenna Chandler, Follow up questions on SB 493 implementation
- **Kaiser Healthnews,** January 28, 2016: Chad Terhune, Disciplinary action against a licensee, IV Solutions
- **KOVR Channel 13 Sacramento,** February 8-9, 2016: Tamara Christian, Sudafed sales
- **KOVR Channel 13 Sacramento,** February 10, 2016: Tamara Christian, Sudafed sales
- **KOVR Channel 13 Sacramento,** February 11, 2016: Tamara Christian, Sudafed sales and
- prescriptions with on camera interview
- **KALX 90.7FM Berkeley**, February 16, 2016: Charlotte Jachquemart, hormonal contraception protocol
- **Orange County Register,** February 16, 2016: Jenna Chandler, drug take back regulation

Attachment 8

m. Update on Public Outreach Activities Conducted by the Board

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

- August 29: Supervising Inspector Janice Dang participated as a panel speaker at the Napa Pain Conference.
- September 11: Supervising Inspector Tony Ngondara provided information about being a pharmacist-in-charge and pharmacy operations for CPhA CE.
- September 12: Inspector Suzy Patell provided information about the board and staffed an information booth at the Indian Pharmacists Association annual meeting in Orange County.
- September 18: Supervising Inspector Christine Acosta presented to Tenet Healthcare on sterile compounding regulations and board expectations on sterile compounding regulations.
- September 30: Supervising Inspector Bill Young presented at Keck Graduate Institute.
- October 3: Executive Officer Virginia Herold presented at a joint board/DEA forum on prescription drug abuse and corresponding responsibility.
- October 13 & 14: Executive Officer Herold attended the NABP's Executive Officer Forum in Chicago, where she provided a presentation about the board's wholesaler and 3PL licensure programs.
- October 19: Executive Officer Herold provide information about implementation of SB 493 to the pharmacy department at UCSD's Hillcrest Hospital.
- October 24: Supervising Inspector Tony Ngondara provided information about prescription drug abuse at a seminar at Henry Mayo Hospital in Los Angeles.
- November 4: Inspector Manisha Shafir participated in a telephone conference presentation to the San Diego Pharmacist Association about Surviving as a Pharmacist-in-Charge.
- November 16-18: Executive Officer attended FDA's Interactive Forum on DSQA. She provide two presentations, one on outsourcing facilities and one on licensure components for wholesalers and third partly logistics providers.
- December 4: Executive Officer Herold provided a presentation on pending drug-take back regulations under development with the board to the CDPH state workgroup on opioid abuse.
- February 16: Executive Officer Herold provided a presentation on California's naloxone protocol to the Department of Health Care Services Drug Utilization Review Board.

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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:	January 20, 2016
Location:	Department of Consumer Affairs 1625 N. Market Blvd., El Dorado Room 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
Committee Members Not Present:	Ricardo Sanchez, Public Member
Board Members Present in the Audience:	Amy Gutierrez, PharmD, President
Staff Present:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Laura Hendricks, Staff Analyst Debbie Damoth, Staff Services Manager

Board members present: Debbie Veale and Ramón Castellblanch.

Note: Lavanza Butler arrived at 10:41 am and Ryan Brooks arrived 10:43 am.
Board members not present: Ricardo Sanchez.

The meeting was called to order at 10:30 a.m. Chairperson Debbie Veale welcomed those in attendance. Chairperson Veale announced that as two board members were on their way to the meeting, items on the agenda would be taken out of order. Ms. Veale began the meeting with Agenda Item 8.

Item 8 - Final Report on the Prescription Drug Abuse Subcommittee

Prescription Drug Abuse Subcommittee Chair Castellblanch provided the final report on the subcommittee's work to the committee. Dr. Castellblanch provided an overview of the mission of the subcommittee and the frequency of the meetings. Dr. Castellblanch also provided an overview of the groups the subcommittee received testimony; education tools made available on the board's website; professional educational information available about pain killers; public education on pain killers; and CURES 2.0.

Chairperson Veale thanked Dr. Castellblanch for his work on the subcommittee and encouraged Dr. Castellblanch to continue pursuit these items through his continued participation and involvement on the Communication and Public Education Committee.

Chairperson Veale conducted another roll call. Committee members present: Lavanza Butler, Ramón Castellblanch, Debbie Veale, and Ryan Brooks.

Fred Mayer on behalf of Pharmacy Planning Services, Inc. (PPSI), CARA, and RX Safe from Marin County provided handouts to the committee. Mr. Mayer encouraged the committee keep the subcommittee. Chairperson Veale explained by keeping prescription drug abuse as a focus of the Communication and Public Education Committee the issue will be addressed in a more efficient manner.

Item 5 - Update on Information on the Board's Website Regarding the State's Emergency Contraception Protocol

Chairperson Veale welcomed to the committee via telephone conference Dr. Sally Rafie, BCPS, from UCSD's School of Pharmacy. At the October 2015 committee meeting, Dr. Rafie requested that the committee reevaluate the emergency contraception information provided on the board's website. The committee requested Dr. Rafie provide letters of endorsements from reproductive organizations supporting her position that posting such information on the board's website would assist in public education. Additionally, the committee asked Dr. Rafie to provide the educational materials without reference to brand names, so as not to confuse the posting on the board's website with an endorsement for a particular brand of emergency contraception.

Dr. Rafie presented the letter of support from Executive Director Kelly Cleland, MPA MPH of the American Society for Emergency Contraception (ASEC); President and CEO Jessica Arons of the Reproductive Health Technologies Project (RHTP); and Chair Brooke Griffin, PharmD, BCACP of the American College of Clinical Pharmacy Women's Health Practice & Research Network as well as updated educational material for the board's website without brand name identification or pricing information. Chairperson Veale thanked Dr. Rafie for the letter of support validating the information provided.

Chairperson Veale called for questions from the committee and public. There were no questions for Dr. Rafie.

Motion: Recommend to post information provided by Dr. Rafie on the board's website.

M/S: Brooks/Butler

Chairperson Veale called for comment from the board and public. There was none.

Support: 4 Oppose: 0 Abstain: 0

Item 1 – Presentation by Department of Health Care Services Pharmacist James Gasper Promoting Naloxone and Buprenorphine Access and Subsequent Discussion

Chairperson Veale reviewed Assembly Bill 1535 (Chapter 326, Statutes of 2014), which allows pharmacists to furnish naloxone without a prescription under a protocol developed by the Medical Board and the Board of Pharmacy.

The board promulgated emergency regulations to establish a protocol for pharmacists furnishing naloxone hydrochloride. The emergency regulation was approved by the Office of Administrative Law and became effective 4/10/15. The board readopted the emergency regulation with an expiration date of 4/6/16 while the board sought to establish the non-emergency regulation through the normal regulatory process. The non-emergency regulation was noticed on 5/22/15 for a 45-day comment period and a subsequent 15-day comment period on 9/5/15. [Note: The non-emergency regulation was recently approved on 1/27/16.]

Chairperson Veale introduced Dr. James Gasper, BCPP, Psychiatric and Substance Use Disorder Pharmacist, Pharmacy Benefits Division, California Department of Health Care Services. Dr. Gasper provided a presentation on the current state of opioid addiction and opioid overdose deaths both in California and nationally. Dr. Gasper discussed potential interventions that pharmacists can make today to reduce opioid overdoses by providing patients with the opioid overdose antidote naloxone and other forms such as buprenorphine.

Dr. Gasper highlighted the fact that there has been an increase in drug overdose deaths in the US including prescription opioids and heroin. Dr. Gasper explained that when opioids are being restricted without offering treatment alternatives, there is an addiction that exists which is left without direction. Often times, people turn to heroin in these cases because it is cheaper than prescription opioids.

Dr. Gasper reported that in California, the counties with the highest overdose death rates are in the rural northern counties. The data provided by Dr. Gasper was from 2012, he indicated that

the 2013 data was similar and the 2014 data is currently being compiled. According to his data the average statewide overdose death rate is 4.9 overdose deaths per 100,000 from opioids and heroin in California. However, in the northern rural counties, the averages range from 11 to 23.9 deaths per 100,000. This pattern emerges due to the fact that there is no infrastructure for treatment and providers in these rural counties.

Committee member Ryan Brooks inquired if the prescription data in CURES reflects these statistics. Dr. Gasper noted that CURES data does indicate an elevated opioid prescription volume in these areas. Dr. Gasper indicated the difficulty is in identifying the legitimate prescriptions for opioids. He added that pharmacist often struggle to identify when a prescription if for a legitimate medical purpose. Dr. Castellblanch noted that a pharmacist may believe they are filling a legitimate prescription, when in fact the prescriber is overprescribing opioids to their patient.

Mr. Brooks asked if the board investigates more licensees in these identified counties. Executive Officer Virginia Herold indicated that most investigations are initiated based on complaints received by the board. She added that complaints may be generated by someone who sees a family member being overprescribed opioids or suspects they may be selling their opioid medications. Ms. Herold also reported that the board also conducts proactive prescription drug abuse investigations by using data from CURES. Ms. Herold stated that the board can analyze CURES data by county, but staff will also look statewide.

Mr. Brooks noted that the board should continue to investigate through the complaint process as well as identify areas statewide with high opioid overdose deaths per capita. Chairperson Veale added that the committee can assist with communication and education. Dr. Gasper added that many communities do not have the resources to help people with opioid addictions.

Chairperson Veale indicated pharmacists are receiving new legitimate prescriptions for pain; however, they are unable to take on the new patient because of limitations on opioids drugs. Ms. Herold explained that pharmacists are having difficulties obtaining opioids from wholesalers because many are being investigated by the DEA.

Ms. Herold noted that it is important to remember that people need treatment for their legitimate pain. Dr. Gasper added that because the opioid supply is sequestered some end-of-life patients do not receive pain treatment, which is a tragedy.

Committee member Lavanza Butler recalled that at a Prescription Drug Abuse Subcommittee meeting there had been a presentation by a group of attorneys who were filing a lawsuit based on deceptive marketing practices by pharmaceutical companies. The lawsuit alleged that doctors are prescribing opioids for chronic pain, rather than acute pain (for which opioids are

intended) because the pharmaceutical representatives are falsely stating that opioid use for chronic pain is appropriate.

Dr. Gasper provided a map of California which illustrated that methadone clinics are not available in over 20 rural counties. Chairperson Veale asked why a county would not have a methadone clinic. Dr. Gasper indicated the county board of supervisors may not approve it or there may not be a "business need" to open the treatment program.

Dr. Gasper explained that buprenorphine was the first drug that could be used outside a methadone clinic to treat an opioid addiction. It has been on the market for 13 years.

Dr. Gasper noted the solutions to the opioid epidemic include safe prescribing practices, naloxone distribution, and increasing access to treatment for opioid addiction. He noted the barriers for naloxone include knowledge of training available for providers, adoption of pharmacies' policies and procedures, and proactive patient selection by pharmacists. Dr. Gasper recommended a compendium of Naloxone courses acceptable by the board would be helpful. Ms. Herold stated the board would be happy to post this information on the board's website. A representative from CPhA offered to provide information to the board about their Naloxone training. It was noted that Rx Consultant also has training available.

President Amy Gutierrez added from the audience, that the White House Office of National Drug Control Policy issued a statement saying public agencies (including state and counties) can get the Narcan nasal spray at 40% discount.

Dr. Gasper noted that opioid addiction is not comfortable topic for many pharmacists; educational literature is a first step. Dr. Gasper reported that patient behavior changes when naloxone is received with opioids, because they realize that their opioid prescription needs to be used with caution and monitored. Dr. Gasper added pharmacists are the front line in identifying what patient may need naloxone. Dr. Castellblanch noted this assessment could be part of the red flag process.

Dr. Steve Gray of Kaiser noted a point of confusion for pharmacists is whether or not naloxone is covered if it is dispensed by a pharmacist rather than prescribed by a prescriber. The other point of confusion is if naloxone is covered by the purchaser's insurance if it is for another person who may be at risk for overdose. Staff noted that this information is not available and needs to be clarified at a future meeting.

Dr. Gray further noted that under the protocol, if a pharmacist provided Naloxone to a patient, that information cannot be communication to the physician without explicit consent from the patient. For organizations that share information across medical records this would require some pharmacies to undergo significant modification of dispensing systems.

Dr. Gasper stated that one of the reasons naloxone has not been as well received is the affordable version of naloxone requires an atomizer that does not have an NDC. This atomizer can't be paid for by health plans and historically, pharmacies were unable to obtain atomizers. He noted that if there is one product that is both affordable and available, it will help pharmacies provide Naloxone to more patients.

Dr. Gasper continued that there has been a lot of confusion on who is the prescriber of record. Ms. Herold explained that pharmacists are able to furnish Naloxone. Dr. Gasper added that should be clarified that the prescriber on record is the pharmacist.

Ms. Herold, Ms. Sodergren and Dr. Gutierrez left the meeting at approximately 10:47 a.m.

Dr. Gasper stated that having written information available on the furnishing of Naloxone would be helpful to pharmacists and healthcare providers. Chairperson Veale added that a Naloxone Frequently Asked Questions (FAQs) section of the board's website would be helpful.

Dr. Gasper provided that buprenorphine is a long acting opioid and partial agonist which means there is a limit to the opioid effect it has; treats withdrawal; and, stops the patient from using opioids. It is not constrained to the methadone clinic. Chairperson Veale added the limiting factor is the prescription from a prescriber that is required.

Dr. Castellblanch asked what the board could do to promote this. Dr. Gasper added pharmacists in these communities need education and make them the proponents. Chairperson Veale added pharmacists need to be comfortable discussing addictions, naloxone and drug treatment programs. The committee discussed possible options including a roadshow in these counties.

Dr. Gasper continued pharmacies may be methadone dispensaries in collaboration with the prescribing physicians. This is a way to get the methadone maintenance to the outlying counties. Mr. Brooks added the methadone registration will be the most difficult part. Local board of supervisors or councils need to be educated.

Chairperson Veale thanked Dr. Gasper for his presentation and asked for public comment.

2. Discussion on Development of Regulations to Allow for the Waiver of Patient-Centered Label Requirements (Business and Professions Code Section 4076.5(d))

Chairperson Veale reviewed the requirements for the waiver of patient-centered labels pursuant to Business and Professions Code section 4073.5(d). Currently, the process for a licensee requesting the waiver is to come before the committee and full board. The development of the proposed regulation would allow for this decision to be made at the staff

level, provided the licensee has demonstrated meeting the required elements of section 4073.5(d).

Dr. Gray discussed possible issues with the accrediting requirement as there are accreditations agencies other than the Joint Commission.

Dr. Gray also stated that there may be a problem with the use of the word "parenteral" included in (g)(2). He explained that "parenteral" is defined as medication administered in a manner other than through the digestive tract. He also noted that the compounding regulation now includes eye drops, ear drop, or vaginal suppository.

Chairperson Veale asked that board staff modify the proposed language in response to the issued raised by Dr. Gray before the next board meeting.

Motion: Recommend to the full board:

(1) Add language to the appropriate subsection of section 1707.5 to allow waiver requests to be submitted to board staff for review and approval;
(2) Incorporate the definition of parenteral;
(3) Add "include other accrediting agencies"; and,
(4) Provide the Executive Officer and board staff the authority to sign off on waivers.

M/S: Brooks/Castellblanch

Chairperson Veale called for comment from the board and public. There was none.

Support: 4 Oppose: 0 Abstain: 0

3. Consideration of Request for Waiver of Requirements for Patient-Centered Labels as Provided in California Business and Professions Code section 4076.5(d) from Access IV

Ramona Moenter, R.Ph., MBA, of Access IV presented the request for waiver of requirements for patient-centered labels as provided in California Business and Professions Code section 4076.5(d). Pharmacist Moenter confirmed that Access IV meets the requirements for exemption as outlined in section 4076.5(d).

Pharmacist Moenter reported that the directions provided in 12 point font are currently being cut off because they are too long to fit on the label. To remedy this staff manually truncate the directions for use so that they will fit on the label, this results in unclear directions for the patient. Ms. Moenter stated Access IV would go back to the original size font of 10 point if the waiver is approved. Access IV services agreed to be in compliance with the patient-centered labels and translation requirements.

Motion: Recommend to the board that Access IV be granted a two-year conditional waiver and require Access IV to self-report complaints to the board.

M/S: Brooks/Butler

Chairperson Veale called for comment from the board and public. Steve Gray requested clarification on if the waiver would be granted for a specific site or it would be an enterprise wide approval. Chairperson Veale confirmed an approved waiver would be site specific to the four sites listed in the request from Access IV.

Support: 4 Oppose: 0 Abstain: 0

4. Consideration of Issuing a Revised Patient Consultation Survey Questionnaire

At the July 2015 Board Meeting, the board reviewed the results of a short questionnaire made available to licensees via Survey Monkey regarding patient consultation. At the October 2015 board meeting, President Gutierrez asked the committee to develop a broader survey on patient consultation.

The committee determined Dr. Castellblanch to be the point of contact for quality control. The committee discussed options within the Department of Consumer Affairs, schools of pharmacies, and associations for the survey to pharmacists.

Steve Gray of Kaiser mentioned he had many contacts for survey formulation including the UCSB graduate school, Kaiser Family Foundation, and the USC School of Business. Chairperson Veale directed staff work with Dr. Castellblanch and research survey options with the entities Dr. Gray's mentioned.

6. Update on the Redesign of the Board's Website

Chairperson Veale provided that she and Dr. Castellblanch met with Webmaster Victor Perez. The new website design is scheduled for release in late spring 2016.

7. Discussion on .Pharmacy Domain

a. Options for the Board to Distribute Public Information via the Board's Website

Chairperson Veale deferred this item until the board's website has been updated.

b. Option of Sending a Letter of Support for .Pharmacy Domain

Chairperson Veale reported that board staff worked with NABP staff to draft a letter of support for the .Pharmacy program. She explained that if the committee approves the letter it will be forwarded to the full board for approval.

Fred Mayer of PPSI had to leave the meeting early and requested the issue of medical marijuana and the drug issue pertaining to pharmacy consultation be added to the next committee agenda.

The committee discussed the requirements for pharmacies who wish to participate in the .Pharmacy program. Chairperson Veale called for public comment.

Dr. Steve Gray indicated he has attended many meetings and believes the intent is good but didn't recall the criteria used by .Pharmacy. He recommended reviewing the criteria and then providing recommendation to the board.

Chairperson Veale researched online during the meeting and found information about the standards used by .Pharmacy. The non-recommended sites were found to have accepted non-valid prescriptions; issued prescriptions by online consultants or questionnaires only without a medical doctor involved; offered foreign or non-FDA approved medications and dispensed controlled drugs; and lacked a secure website. Chairperson Veale and the committee briefly reviewed the .Pharmacy standards.

A representative from CPhA added that they have received a lot of complaints of bad pharmacy websites and would support the idea of providing a letter of support to the .Pharmacy program.

Motion: Recommend to the board the letter of support be sent to NABP for their .pharmacy domain initiative.

M/S: Brooks/Butler

Support: 3 Oppose: 1 Abstain: 0

9. Discussion Regarding Prescription Label Translations of Directions for Use

Chairperson Veale reported that Assembly Bill 1073 was approved by the Governor on October 11, 2015. The bill requires a pharmacist to use professional judgment to provide a patient with directions for use of a prescription, consistent with the prescriber's instructions. AB 1073 also requires a prescriber to provide translated directions for use, if requested, and authorizes the dispenser to use the translations made available on the board's website to comply with the requirement. Dispensers are not required to provide translated directions for use beyond what the board has made available. However, the bill does authorize a dispenser to provide his or her own translated directions for use to comply with the requirement. Veterinarians are exempt from the requirement to provide translated directions for use. The provisions of the bill went into effect on January 1, 2016.

Ms. Sodergren returned to the meeting at 1:12 pm. Committee member Brooks left the meeting at 1:12 pm. The committee took a break at 1:13 pm and resumed at 1:25 pm.

Chairperson Veale posed the high level question as to what the committee thinks will be necessary to educate the public on translations. Dr. Castellblanch indicated a sign informing patients of their right to translations in the five languages identified would be helpful. The committee discussed other possible means of communication.

Ms. Sodergren offered various ideas such as a drafting a public service announcement, posting information on Facebook, Tweeting about the availability of translations, or developing a communication plan. Chairperson Veale asked staff to form a communication plan and bring it the next committee meeting for review and approval.

Ms. Sodergren offered a drafting and releasing a PSA in the interim while developing a communication plan and regulation. Chairperson Veale requested the PSA be released in advance of the committee meeting.

Kim Chen from CPEN indicated her willingness to partner with the board in educating licensees and the public about translation services. Ms. Chen indicated the "Point to your Language" poster is a place to start and recommended reaching out to Assembly member Ting's office for additional help in publicizing translation services.

Dr. Castellblanch thanked Ms. Chen for her assistance.

10. Report on Development of FAQs Received From ask.inspector@dca.ca.gov

Chairperson Veale reported the board has implemented a program which gives licensees the opportunity to call and ask general questions to one of the board's pharmacist inspectors. This call-in service is available Tuesdays and Thursdays from 8:00 am to 4:30 pm. In addition, licensees may submit an email request to a pharmacist inspector at ask.inspector@dca.ca.gov.

Ms. Sodergren reported the board is working on developing the FAQs for the licensees as well as consumers as both populations ask different types of questions. The board has developed the first FAQs for licensees and will be posting them to the board's web site as well as including them in the next newsletter.

Chairperson Veale indicated posting the FAQs on the website once approved would be acceptable. Ms. Veale asked for public comment. There was none.

11. CURES 2.0 Update on Communication to Licensees

Chairperson Veale reported that the Department of Justice (DOJ) recently announced another milestone in its conversion to CURES 2.0. Specifically, the DOJ announced that beginning January 8, 2016, the upgraded prescription drug monitoring program is available. As part of

this transition, on or after January 8, 2016, all current registrants are required to update their registration in the new 2.0 environment to ensure access to the system. This can be done electronically.

Ms. Veale stated that according to the DOJ, CURES 2.0 will be available to all registrants that use Microsoft Internet Explorer Version 11.0 or greater, Mozilla FireFox, Google Chrome, or Safari when accessing the system. Registrants that do not currently have access to one of those specified internet browsers will be able to continue to access the prior version of CURES until the legacy system's retirement, at that time the updated browser must be used.

Ms. Veale reminded the committee and public that all pharmacists are required to be registered to use CURES no later than July 1, 2016. On or after January 8, 2016, pharmacists can register using an automated system by visiting www.oag.ca.gov/cures and clicking on the Registration link and following the instructions.

Chairperson Veale reported the board is working with the DOJ to develop "Frequently Asked Questions" to assist registrants with understanding CURES 2.0. The board will send out updates via its subscriber alert system as it learns additional information from the DOJ. Questions regarding these changes should be directed to cures@doj.ca.gov .

Dr. Castellblanch asked if CURES was working. A representative of CPhA reported to the committee that at least 10 pharmacists are having issues logging in and added that CPhA has limited contact with DOJ. The representative explained that the pharmacists are prompted to enter a new password; however when they attempt to enter a new password there is an error screen. It was noted that some pharmacists were able to log-in after waiting 1-2 days after receiving the error message.

Ms. Sodergren provided that after January 8th, everyone has to re-register online in a streamlined fashion in CURES 2.0 environment. Ms. Sodergren asked CPhA for a screenshot of the error message their members are receiving. Ms. Sodergren reported that the board has requested that the DOJ produce a tutorial, however it is unclear if that occurred. She added that the DOJ has requested that all issues be addressed to DOJ via email. The board has requested a list of common issues from DOJ so that an FAQ can be developed to help direct people who are experiencing problems. Chairperson Veale asked for an update on CURES 2.0 at the next meeting.

Dr. Castellblanch asked for the status of the applications pending in the CURES 1.0 environment. Ms. Sodergren indicated she would find out the status of the applications and report back to the committee.

Dr. Castellblanch asked for CURES 2.0 issue to be earlier on the agenda at the next committee meeting.

12. Update on the Educational Information on Board's Website Regarding Opioids, Naloxone, Red Flags, Consumer Information, and Prescription Drug Abuse Prevention for 13/14/15 Year Olds, and UCSD/Consumer Reports

Dr. Castellblanch requested the information be posted on the website. Board staff Debbie Damoth indicated she would work on this request.

There were no comments from the committee or from the public.

13. Update on *The Script* Newsletter

Chairperson Veale reported Board staff has written the Winter issue of *The Script* newsletter. The Winter issue is currently under legal review, and will be issued soon.

Dr. Castellblanch requested an article in the next issue about the CDC report on opioid related deaths. Ms. Veale asked Dr. James Gasper to write an article on the opioid epidemic for the next newsletter.

14. Update on Media Activity

Chairperson Veale reported on the media activity for the board.

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

Chairperson Veal requested agenda item #16 – Review and Discussion of News or Journal Articles be postponed to the next meeting. Dr. Castellblanch requested articles from the New York Times about opioid abuse be included for discussion at the next committee meeting.

Chairperson Veale recapped requests for future agenda items provided throughout the meeting.

Steve Gray requested the Department of Consumer Affairs' publication entitled "*Consumer's Guide to Healthcare Providers"* be updated to include pharmacists as pharmacists are now considered healthcare providers with the enactment of SB 493.

Fred Mayer of PPSI requested the issue of medical marijuana and the drug issue pertaining to pharmacy consultation be added to the next committee agenda.

Ms. Veale adjourned the meeting was adjourned at 1:52 pm.