California State Board of Pharmacy
1625 N. Market Blvd, Suite 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.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Debbie Veale, Chair
Ramon Castellblanch, PhD, Vice Chair, Public Member
Lavanza Butler, Professional Member
Ricardo Sanchez, Public Member
Rosalyn Hackworth, Public Member
Ryan Brooks, Public Member

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

Attachments 1 and 2

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

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

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

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

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

Waivers have been requested by:

a. Coram CVS/Specialty Infusion Services - **Attachment 1** contains the request from Coram/CVS Specialty Infusion Service

b. BioRx, LLC - **Attachment 2** contains the request from BioRx LLC

2. Discussion of the Patient Consultation Survey Questionnaire Released in July 2015 for Possible Revision and Future Use

Attachment 3

At the July Board Meeting, the board reviewed the results of a short questionnaire made available to the public via Survey Monkey regarding patient consultation. Over 1,000 individuals responded to this survey. A copy of the results is provided in **Attachment 3.**

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

During this part of the meeting, the committee will have a chance to review the questionnaire.

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

Attachment 4

For a number of years, California has had a protocol that allows pharmacists to provide emergency contraception to patients who request it. The protocol was developed by a group of sponsors for the enabling legislation, vetted and approved by the board and the Medical Board. **Attachment 4** contains a copy of the protocol.

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

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

Attachment 4 also contains the information Dr. Rafie submitted for the committee's review.

4. Discussion Surrounding that October is "Talk About Prescriptions Month"

Attachment 5

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

The goal is to "focus attention on the value that better medicine communication can play in promoting better medicine use and better health outcomes." **Attachment 5** contains some of the materials developed by NCPIE for this promotion.

In their press release, NCPIE states:

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

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

5. Update on the Redesign of the Board's Website in 2015

Board Webmaster Victor Perez continues his work on redesigning the board's website to make it more user-friendly. A snapshot of the new design was provided at the July Board Meeting.

Mr. Perez plans to complete the redesign by the end of the year.

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

Attachment 6

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

One component of the .pharmacy system is the offering to state boards of pharmacy the opportunity to establish .pharmacy websites for their use. Our .pharmacy website is www.CAboard.pharmacy, which currently links to our www.pharmacy.ca.gov website.

Attachment 6 provides a report of NABP's problem identification with Internet Websites. More information will be provided at the committee's meeting.

7. **Discussion on Development of a Report on the Activities of the Prescription Drug Abuse Subcommittee**

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

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

The committee looks forward to Dr. Castellblanch's report.

8. **Presentation on Prescription Drug Abuse Activities in Northern California Counties**

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

9. **Update on *the Script***

The board will release the Fall issue shortly, perhaps before this meeting. Work has begun on the Winter issue which we have out before the end of the year.

10. **Public Outreach Activities Conducted by the Board**

A list of major public outreach activities provided by the board's staff will be distributed at the committee meeting.

11. **Review and Discussion of Articles on Issues of Interest**

Attachment 7

Attachment 7 contains several items of potential issues of interest for this committee.

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

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

Attachment 1

CVSHealth

April 21, 2015

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

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

Dear Executive Officer Herold:

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

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

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

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

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

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

CVSHealth

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

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

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

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

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

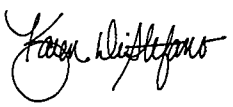
Development of the plan of care by Coram nursing or a contracted home health agency with ongoing patient monitoring is initiated at time of admission and continued until therapy is completed.

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

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

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

Sincerely,



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

Example

12310 World Trade Drive Suite 100
San Diego, CA 92128-3793
CORAM. DEA# BC4458368 FAX: (858) 618-2482
(858) 576-6969 / (800) 540-7897

Coram Alternate Site Services, Inc.

Patient: [redacted] RX#: [redacted]

Patient ID: [redacted] Prescriber: [redacted]

TOTAL VOLUME: 1800 ml (EXCLUDES ANY OVERFILL)

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

ADDITIVES ARE LISTED PER BAG:

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

ADMINISTRATION DIRECTIONS:

INFUSE 1800 ML OVER 9 HOURS INTRAVENOUSLY via CURLIN pump in TPN mode infuse bag Three times WEEKLY, Pump will TAPER UP 1 HOUR AND TAPER DOWN 1 HOUR. Bag volume: 1850 ml; Volume to be infused: 1800 ml; Inf rate: 225ml/hr; Up Ramp: 1 hr; Down Ramp: 1 hr; Total Inf Time: 9hrs; KVO: 0ml/hr; Lock ivl: 2
ADD TO TPN BAG JUST PRIOR TO INFUSION:
MVI 13 10 ml
Bag Contains Overfill
Allow drug to reach ROOM TEMPERATURE before administration.
Compounded by Coram Pharmacy
ORIGINAL FILL: 02-27-2015 STORAGE: REFRIGERATED
DATE PREPARED: 02-27-2015 Days Supply: 7 Quantity: 3
DISCARD AFTER: 03-20-2015 RPh: LUNDBERG

CORAM.

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

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

Coram Healthcare Corporation of Northern California

Sacramento, CA

has been Accredited by

The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Home Care Accreditation Program

March 1, 2014

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD
Chair, Board of Commissioners

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

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

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

This reproduction of the original accreditation certificate has been issued for use in regulatory/payer agency verification of accreditation by The Joint Commission. Please consult Quality Check on The Joint Commission's website to confirm the organization's current accreditation status and for a listing of the organization's locations of care.

Coram Alternate Site Services, Inc.

Bakersfield, CA

has been Accredited by

The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Home Care Accreditation Program

March 1, 2014

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD
Chair, Board of Commissioners

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

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

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Coram Healthcare Corporation of Northern California

Hayward, CA

has been Accredited by

The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Home Care Accreditation Program

March 1, 2014

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Rebecca J. Patchin, MD
Chair, Board of Commissioners

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

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Coram Alternate Site Services, Inc.

San Diego, CA

has been Accredited by

The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Home Care Accreditation Program

March 1, 2014

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD
Chair, Board of Commissioners

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

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

Los Angeles, CA

has been Accredited by

The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Home Care Accreditation Program

March 1, 2014

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD
Chair, Board of Commissioners

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

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

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Coram Healthcare Corporation of Southern California

Ontario, CA

has been Accredited by

The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Home Care Accreditation Program

March 1, 2014

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Rebecca J. Patchin, MD
Chair, Board of Commissioners

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

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Coram Healthcare Corporation of Southern California

Goleta, CA

has been Accredited by

The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Home Care Accreditation Program

March 1, 2014

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD
Chair, Board of Commissioners

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

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Coram Healthcare Corporation of Southern California

Tustin, CA

has been Accredited by

The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Home Care Accreditation Program

March 1, 2014

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD
Chair, Board of Commissioners

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

Mark R. Chassin, MD, FACP, MPP, MPH
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Attachment 2

BioRx, LLC
1819 Aston Ave., Ste.102; Carlsbad, CA 92008
Tel 866-827-0972 Fax 855-602-4679
dspoonhour@biorx.net

RECEIVED BY CALIF
BOARD OF PHARMACY
2015 AUG 10 AM 9:39

AUGUST 6, 2015

California State Board of Pharmacy
1625 N Market Blvd #N219
Sacramento, CA 95834

Dear Members of the Board,

I am writing to request an exemption from California Code Section 4076.5, specifically in regards to: font size Patient-centered labeling, patients with limited English proficiency and the specific needs of seniors. We are a Specialty Pharmacy, providing parenteral biopharmaceuticals and TPN to patients for administration in the convenience of their homes.

All of our patients receive intensive instruction and training by both Pharmacist's and RN's upon admission to our service. We have RN's who either go out to infuse each and every ordered dose (e.g. IVIG, Glassia) or, if requested and safety allows, will teach the patient and/or family member(s) how to administer the product and properly utilize any necessary equipment and/or monitoring devices (e.g. spirometer, infusion pump, dynamometer).

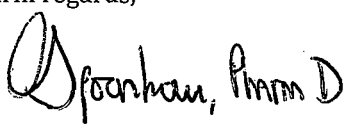
We have a variety of proprietary monitoring programs and tools that are used to track patient progress as well as to assess for potential and/or actual adverse events. Some of these programs utilize phone or in-person interviews with the patient after each infusion and some are tools such as logs in which patient's track their dosing and progress to share with their RN, Pharmacist and M.D. as needed. We also provide educational fliers and disease state specific booklets as well as a variety of webinars that are offered by our clinical staff. Education is a priority and is on-going.

We have patient advocates assigned to every patient. The advocates help them to navigate their way through the medical system and are an important asset when it comes to helping patients understand the insurance process. We also have Physical Therapists and Registered Dieticians on staff who step in and educate, counsel and advise as needed. Our pharmacists are in weekly contact with our TPN patients, monitoring progress, compliance, lab results and inventory prior to shipping. It is primarily our nursing staff who has weekly contact with our bio patients unless they have any pharmacy questions or counseling that is needed. Otherwise our pharmacists follow up with them on a monthly basis.

We are very "high touch" with our patients and we have contact with them via phone, e-mail, fax or text messaging based on their preference. We are ACHC and URAC accredited. I believe this fulfills the requirements needed to request an exemption. Our greatest need is in regards to labeling our TPN products. We've had instances where we have had to use 3 labels to fit the list of ingredients along with the pump settings, patient additives and infusion instructions. The appearance of these bags defies the "pharmaceutically elegant" clause that we are taught in pharmacy school.

Thank you for your consideration of my request.

Warm regards,



Deb Spoonhour, Pharm.D.

Clinical Pharmacist

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DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

August 19, 2015

Deb Spoonhour, PharmD
Clinical Pharmacist
BioRx, LLC
1819 Aston Avenuse, Suite 102
Carlsbad, CA 92008

RE: Request for Exemption from Business & Professions Code Section 4076.5
Patient- Centered Labeling Requirements

Dear Dr. Spoonhour:

This is to acknowledge your request for an exemption from California Business and Professions Code section 4076.5 with respect to patient-centered labeling.

This matter will be referred to the board's Communication and Public Education Committee. I believe there will be a meeting in early October where this matter will be placed on the agenda. Once we have established a meeting date, I will let you know where and when this meeting will be scheduled so that you may make your waiver request directly to the committee members. I expect that this meeting date should be set before the end of August.

Please do not hesitate to contact me with questions at 916-574-7911.

Sincerely,

Virginia Herold

VIRGINIA HEROLD
Executive Officer

Attachment 3

Survey for Pharmacists

Powered by SurveyMonkey

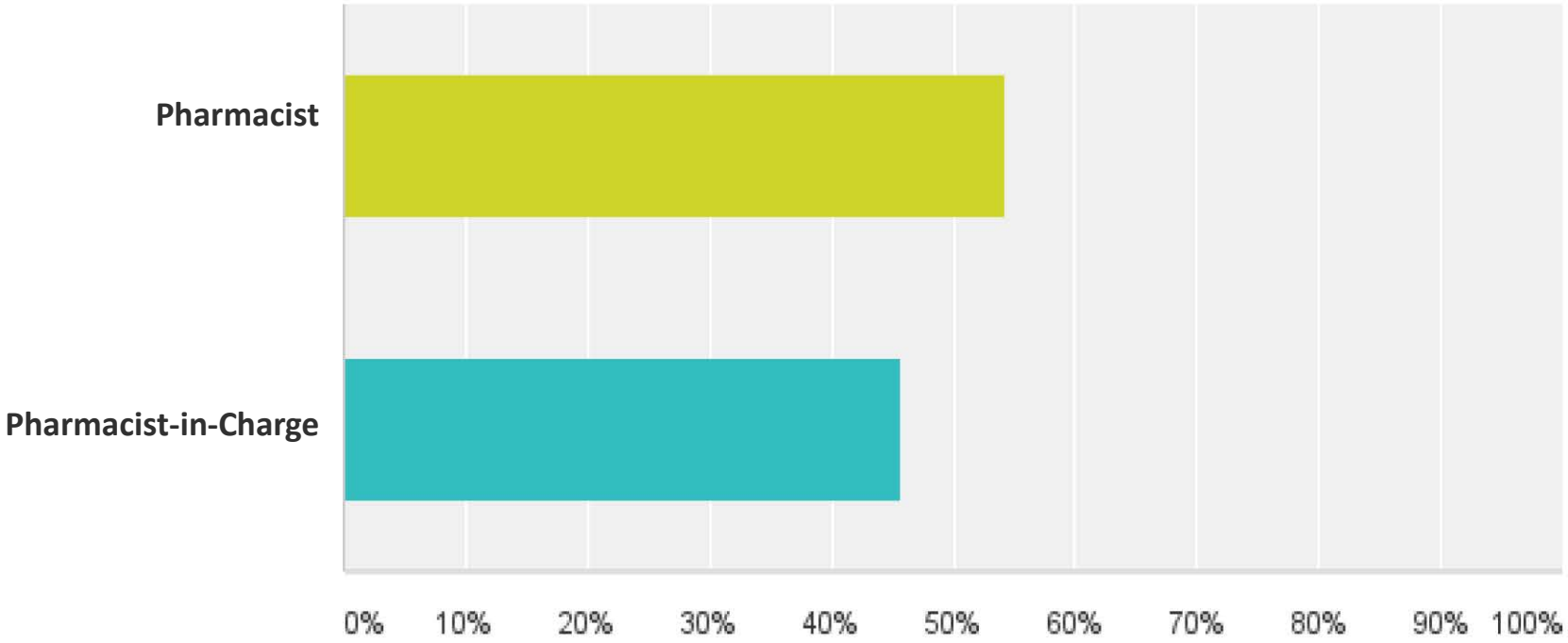
1,006 total responses

Survey Date: July 20-24, 2015

Powered by SurveyMonkey

Question 1: I am a licensed California_____.

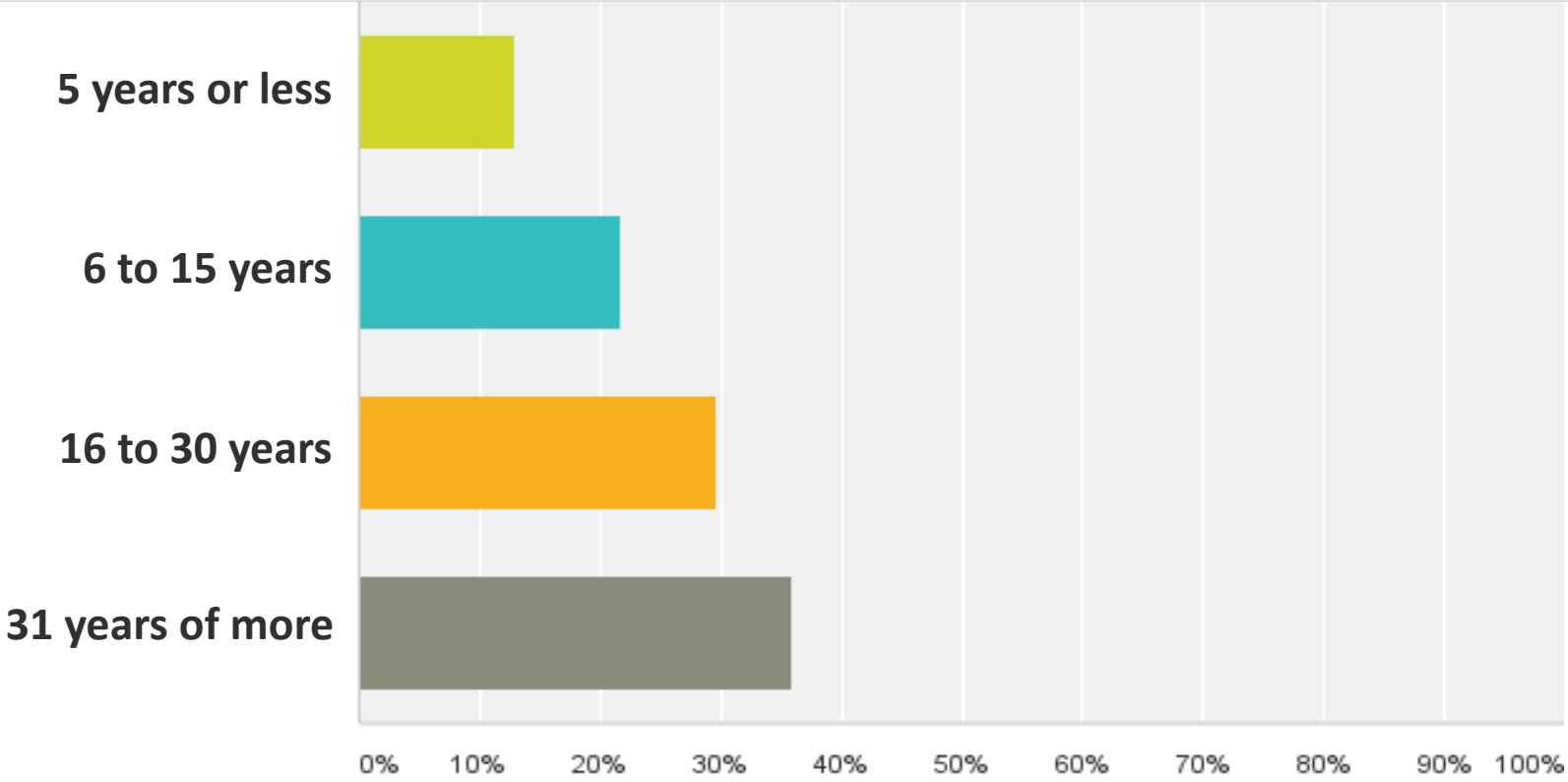
Answered: 998 Skipped: 8



Powered by SurveyMonkey

Question 2: How long have you been a pharmacist?

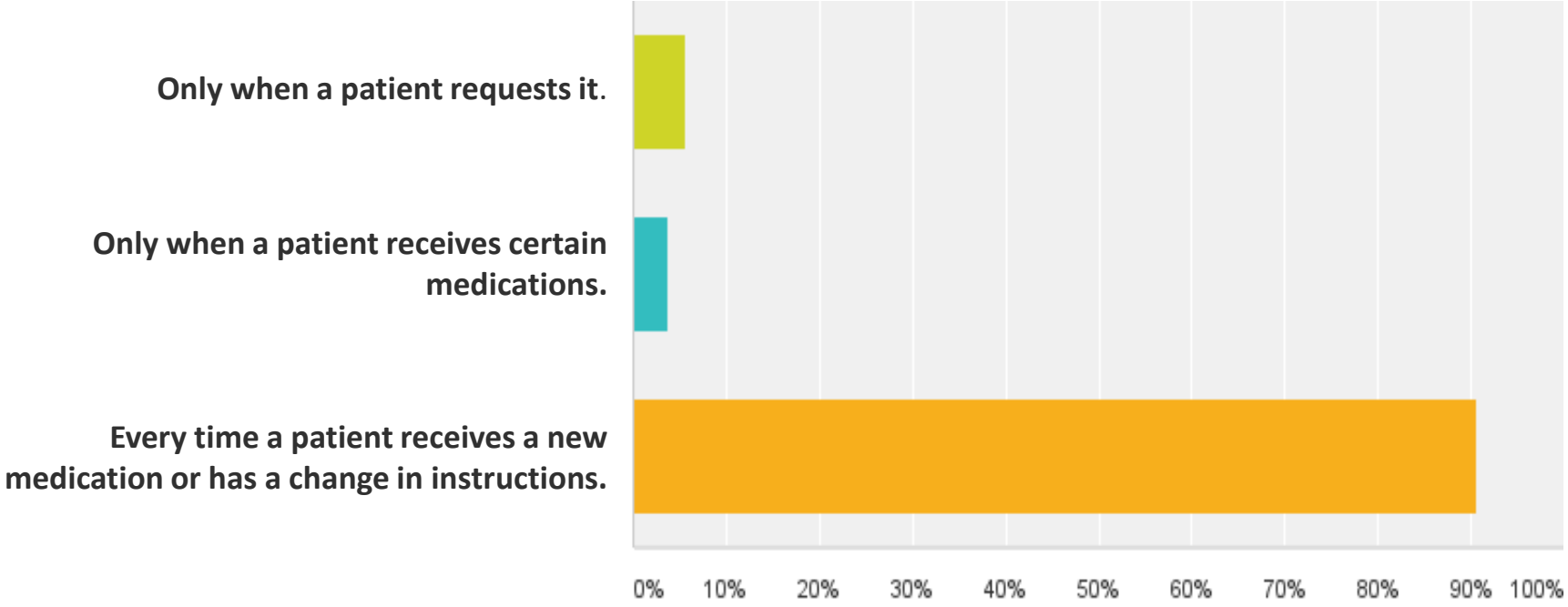
Answered: 1,004
Skipped: 2



Powered by SurveyMonkey

Question 3: I consult….

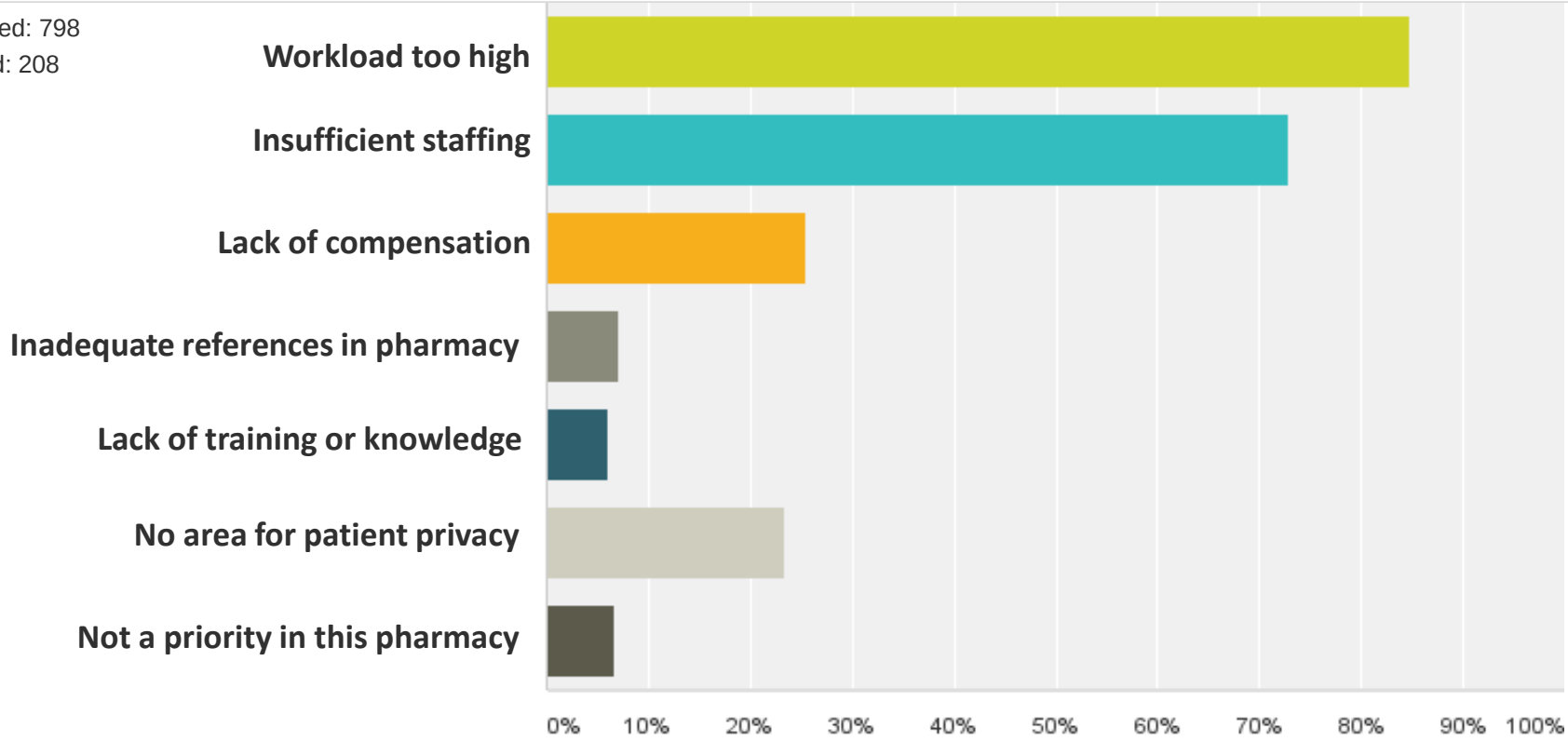
Answered: 897 Skipped: 109



Powered by SurveyMonkey

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

Answered: 798
Skipped: 208



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

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Attachment 4

CA State Board of Pharmacy Regulations:

(a) A pharmacist furnishing emergency contraception pursuant to Section 4052.3(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and communicate the following:

Are you allergic to any medications?

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

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

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

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

(4) The pharmacist shall provide a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations. Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

(11) Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception

		Ethinyl Estradiol Brand Dose	
per dose (mcg) One Tablet Regimens Plan B™ One-Step	1 tablet	0	1.5mg levonorgestrel
ella™	1 tablet	0	30mg ulipristal
Levonorgestrel	1 tablet	0	1.5mg levonorgestrel

Two Tablet Regimens

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

Oral Contraceptive Pills

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

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

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

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

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

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

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, including Plan B One-Step®, Take Action®, My Way®, Next Choice One-Dose®, and others. Most levonorgestrel EC products are available over-the-counter (OTC) without age restrictions. (See reverse side for specific product details.)
- EC pills that contain ulipristal acetate are available under the brand name ella® and are prescription only.
- All EC works best when taken as soon as possible after unprotected sex but may be effective up to 5 days after.
- EC is safe for women of all ages to use.

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

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

Where can EC be found within pharmacies and stores?

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

Why is it important to stock <u>one-pill LNG EC</u> on the shelf?

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

Can men purchase LNG EC?

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

What can I do if my store doesn't stock <u>one-pill LNG EC</u> 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 products listed below should be made available in the following ways:

Product	Information
Teva EC products (Plan B One-Step®, Take Action™, and Aftera™	• **May be stocked on OTC shelves in stores.** • Available for purchase over-the-counter for all ages –ID check is not required. • Take as soon as possible; may be effective up to 5 days after unprotected sex. • 1 tablet (1.5mg levonorgestrel) •
Other Generic One-Pill Levonorgestrel EC Products	• **May be stocked on OTC shelves in stores.** • Label indicates 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 (1.5mg levonorgestrel) • Additional generic one-pill LNG EC products not listed here may become available soon.
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 0.75mg levonorgestrel) •
ella®	• **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 (30mg 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.

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

Situation:

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

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

Background:

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

Assessment:

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

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

Prepared by Sally Rafie, PharmD, BCPS (srafie@ucsd.edu) on September 25, 2015

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

Recommendations:

Pharmacist Education:

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

Public/Consumer Education:

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

Prepared by Sally Rafie, PharmD, BCPS (srafie@ucsd.edu) on September 25, 2015

Attachment 5

October is NCPIE's 30th

"TALK ABOUT YOUR MEDICINES" Month

Safe use.
Safe storage.
Safe disposal.

learn more at: talkaboutrx.org

2015

Talk About Your Medicines Month

Have a conversation about: *Safe Medicine Use*

Can you answer these questions about the medicines you take?

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

talkaboutRx.org

Have a conversation about: *Safe Medicine Storage*

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

Are the medicines in your home stored safely?

talkaboutRx.org

FOR IMMEDIATE RELEASE
January 28, 2015

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

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

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

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

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

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

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

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

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

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

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

1. **Talk to your healthcare provider and ask questions about the benefits and potential risks of prescription medicines you take.**

2. **Tell your healthcare provider about *all* of the medicines you are taking—including over-the-counter medicines, vitamins, and dietary supplements.**

3. **Tell your healthcare provider about any allergies or sensitivities that you may have.**

4. **Read and follow the medicine label and directions.**

Visit TalkBeforeYouTake.org to learn more.

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

###

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

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

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

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

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

Communications Toolkit
October is Talk about Your Medicines Month:
Let's generate conversations about safe medicine use, safe storage and safe disposal.

Working Together to Increase Communications about Medicines

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

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

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

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

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

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

With thanks,

Ray Bullman
Executive Vice President,
National Council on Patient Information and Education

EDUCATE before YOU MEDICATE
The NCPIE Coalition-working together to promote safe medicine use
National Council on Patient Information and Education
www.talkaboutrx.org

TALK BEFORE YOU TAKE

Communications Toolkit: Talk About Your Medicines Month

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

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

Week 1 Focus: Introducing TAYMM	
Facebook:	• Good communication is at the heart of good medicine. October is Talk About Your Medicines Month, an annual opportunity to focus attention on the value that better medicine communications can play in promoting safe medicine use and better health outcomes. Tips, tools and handouts about safe medicine use, storage and disposal are available at www.TalkAboutRx.org. • Oct is Talk About Your Medicines Month. Arm your patients with the info to use, store and dispose of their medicines safely #TAYMM
Twitter:	• October is Talk About Your Medicines Month. Are you well informed about the meds you take? Use this list of questions http://bit.ly/TAYMM • Good communication is at the heart of good medicine. Kick start conversations with list helpful list of questions http://bit.ly/TAYMM • Talk About Your Medicines: safe use, safe storage & safe disposal. Informed = healthy. #TAYMM • Too many patients are unaware of potential medication risks/side effects. Oct is Talk About Medicine Month. Arm your patients with info.
Graphic#1:	Share "October is Talk About Your Medicines Month" **graphic #1**, provided as jpeg
Week 2 Focus: Safe Use	
Facebook:	• It's Talk About Your Medicines Month, and today we're talking about safe use. Always read the label and other accompanying information that accompanies your medicines. Whether you are taking prescription or an OTC product, the label contains important information about dosing, as well as any potential risks or side effects. Never take more than the label directs. Learn more safe use tips here (hyperlink: http://www.talkaboutrx.org/rxmonth2015.jsp) • When you have a visit with your healthcare providers, do you talk about the medicines you take? Good communications about your medicines can mean better health outcomes for you overall. October is Talk About Your Medicines Month. Use this list of recommended questions to discuss with your healthcare provider, in October – or any time of the year. [IMAGE]
Twitter:	• Ask your healthcare provider these questions before taking a new medicine http://bit.ly/TAYMM #TAYMM • Make sure you're using meds safely. Ask these questions at your next visit with your health provider http://bit.ly/TAYMM #TAYMM • If you can answer all the questions on this list, chances are you're using your medicines safely & responsibly. http://bit.ly/MedQs #TAYMM

	• If u can't answer these questions about your meds, then Talk About Your Medicines Month is time to find answers http://bit.ly/TAYMM #TAYMM • Good communication about medicine use can translate into better health outcomes for your patients http://bit.ly/TAYMM #TAYMM • What common questions do your patients ask @ the meds they take? Are these Qs on the list? If not they should be http://bit.ly/TAYMM #TAYMM
Graphic#2:	Share the **graphic #2**: ***Have a conversation about safe medicine use.*** Can you answer these questions about the medicines you take? 1. What specifically is the medicine for? 2. How and when do I take it, and for how long? 3. What side effects should I expect, and what should I do about them? 4. Should I take it on an empty stomach or with food? 5. Is it best to take it in the morning or evening? 6. Will it work safely with any other medicines I'm taking? 7. How should I store this medicine – room temperature, or in the refrigerator?
Week 3 Focus: Safe Storage	
Facebook:	• It's Talk About Your Medicines Month, and today we're talking about safe storage. If you are a parent with young children at home – or a grandparent who spends time with young grandchildren – make sure your medicines are stored up and away and out of reach and sight of curious young children. If you or your guests keep pills in purses or jacket pockets, make sure those are out of reach too. (hyperlink to: www.upandaway.com)
Twitter:	• Responsible use of medicines includes storing them securely. Keep all meds out of reach of curious youngsters. #TAYMM http://bit.ly/TAYMM • Got young children at home? Talk to houseguests about keeping their meds up and away to keep your kids safe. www.UpandAway.org #TAYMM • Responsible use of medicines includes storing them securely. Talk to your patients about safe storage. #TAYMM
Graphic#3:	Share **graphic #3**: ***Have a conversation about safe medicine storage*** Approximately 60,000 young children are brought to the emergency room each year because they got into medicines that were left within reach. Are the medicines in your home stored safely?

Week 4 Focus: Safe Disposal	
Facebook	• It's Talk About Your Medicines Month, and today we're talking about safe disposal. Can you take medicines that have expired? What is safe to throw in the trash, and what should you flush or return via a "take back" program at your local pharmacy? Use this helpful resource from the FDA. (hyperlink: http://1.usa.gov/1ILfaM2) • Don't keep unused or expired medicines sitting around. Dispose of them properly. For most medicines, the FDA recommends mixing them with something undesirable like used coffee grounds, sealing them in a ziplock bag and putting them in the household trash. For prescription vials, be sure peel or scratch off the label to remove your personal information. Learn more best practice disposal tips from FDA, and know the few meds they say should be flushed instead of trashed. (HYPERLINK: http://1.usa.gov/1ILfaM2)
Twitter	• When did you last clean out your household medicine cabinet? Toss expired & unused meds using these tips #TAYMM http://bit.ly/TAYMM • Responsible use of medicines includes disposing of them properly. Talk to your patients about safe disposal or take-back practices. #TAYMM
Graphic#4	Share the **graphic #4**: ***Have a conversation about safe medicine disposal.*** Most unused or expired medicines can be disposed of by following these 3 steps: 1. Mix medicines with an unpalatable substance such as kitty litter or used coffee grounds. 2. Place the mixture in a container or sealed plastic bag. 3. Throw the container in your household trash. There are some exceptions. Get more drug disposal info at www.talkaboutRx.org

Discuss the Benefits and Risks of Prescription Medicines

ABOUT NCPIE's *Talk Before You Take* CAMPAIGN

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

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

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

Discuss the Benefits and Risks of Prescription Medicines

TALK BEFORE YOU TAKE

HCP PROVIDERS > Talking Points

EDUCATE before YOU MEDICATE
National Council on Patient Information and Education
www.talkaboutrx.org

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

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

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

Facts

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

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

Talking Points

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

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

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

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

Discuss the Benefits and Risks of Prescription Medicines

TALK BEFORE YOU TAKE

EDUCATE before YOU MEDICATE
National Council on Patient Information and Education
www.talkaboutrx.org

PATIENTS > Talking Points

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

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

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

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

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

Questions to ask your Healthcare Provider

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

9.
10. **Is there** any additional written information I should read about the medicine?

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

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

Attachment 6

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Internet Drug Outlet Identification Program

Progress Report for State and Federal Regulators: April 2015

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nabp
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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM
PROGRESS REPORT: April 2015

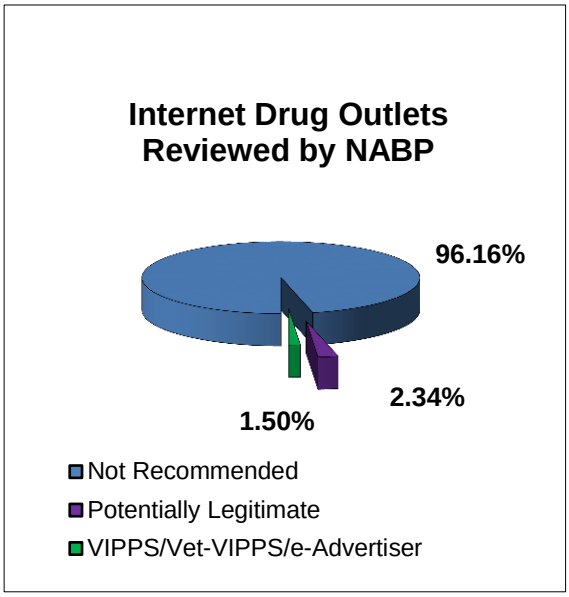
I. INTRODUCTION

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

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

II. RESULTS

A. Findings of Site Reviews to Date: As of March 31, 2015, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 10,965 Internet drug outlets selling prescription medications. Of these, 10,544 (96.16%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards. These sites are listed as Not Recommended in the "Buying Medicine Online" section under Consumers on the NABP website, as well as on NABP's AWARxE® Prescription Drug Safety website, *www.AWARErx.org*. Of the websites identified by NABP as Not Recommended, the majority were found to be dispensing prescription drugs without a valid prescription. In fact, for each of the past seven years that NABP has been reviewing rogue Internet drug outlets, this was by far the most common reason sites were listed as Not Recommended. These include sites dispensing drugs based solely on an online questionnaire, as well as those requiring no prescription at all. For most, dispensing without a valid prescription was one of several other concerning activities observed. Many also offer foreign and unapproved drugs. Both of these factors pose a public health risk that undermines the regulations put in place in the United States and other developed countries to set standards for the practice of pharmacy, standards for medication safety and efficacy, and regulations for safeguarding the medication supply chain from counterfeit drugs. Most sites selling drugs illegally online do not post any address, and nearly half register their domain names anonymously. The 10,544 Internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table below.[1]



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

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

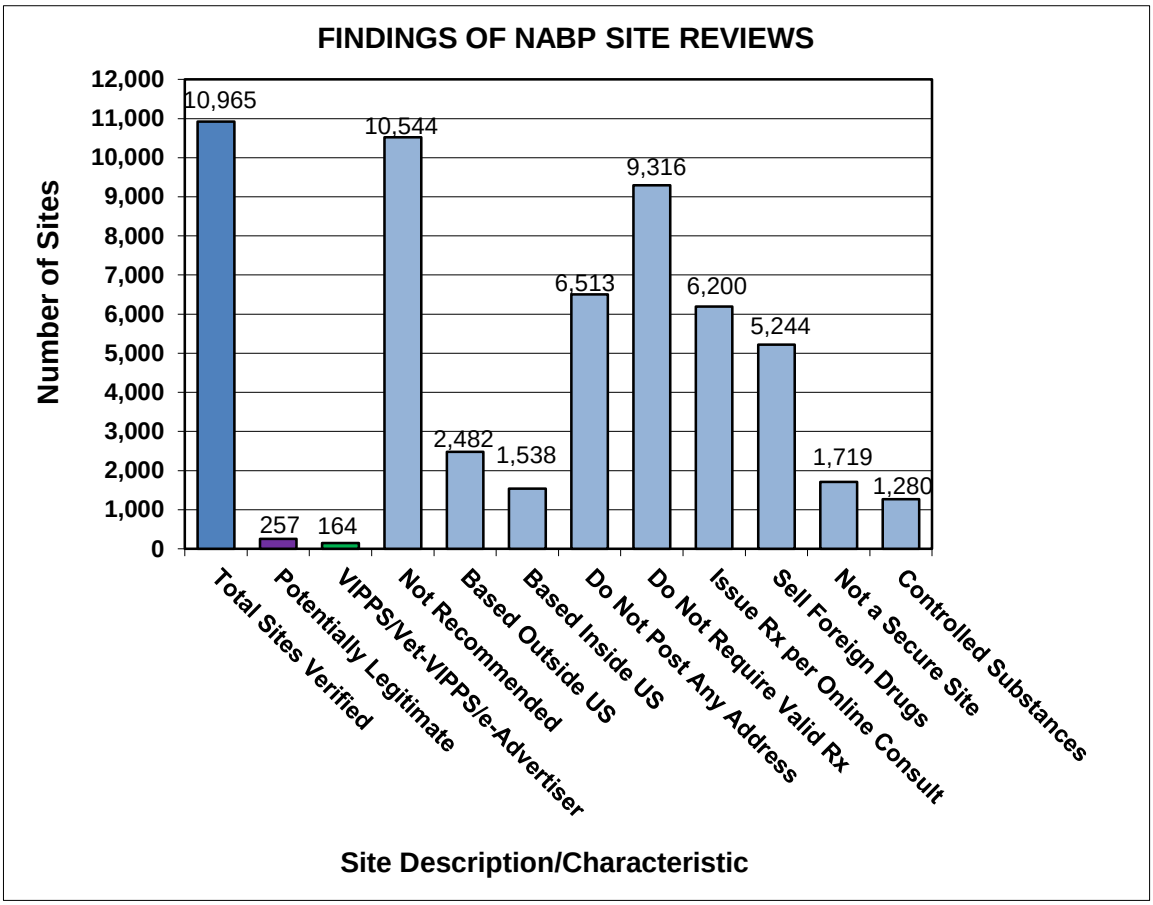
accredited through NABP's Verified Internet Pharmacy Practice Sites® (VIPPS®) or Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®) programs, or approved through the NABP e-Advertiser Approval℠ Program.

Not Recommended Sites

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

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

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



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

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

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

III. CONSUMER EDUCATION CAMPAIGN

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

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

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

The AWAR$_X$E Prescription Drug Safety Program is another avenue through which NABP provides authoritative resources about medication safety, prescription drug abuse, medication disposal, and safely buying medications on the Internet. This program provides consumers with medication safety information through the website, *WWW.AWARERX.ORG*, informational materials, PSAs, and social media. AWAR$_X$E has a YouTube page, *www.youtube.com/user/AWARxE*, where the above-referenced video can be viewed, and also has a Facebook page, *www.facebook.com/AWARxE*, and a Twitter profile.

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

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

Additional information about the .Pharmacy TLD Program, as well as information about buying medicine safely online is available at *www.safe.pharmacy*.

IV. DISCUSSION

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

V. APPENDIX

Internet Drug Outlet Identification Program Standards

1. **Pharmacy licensure.** The pharmacy must be licensed or registered in good standing to operate a pharmacy or engage in the practice of pharmacy in all required jurisdictions.

2. **DEA registration.** The pharmacy, if dispensing controlled substances, must be registered with the US Drug Enforcement Administration (DEA).

3. **Prior discipline.** The pharmacy and its pharmacist-in-charge must not have been subject to significant recent and/or repeated disciplinary sanctions.

4. **Pharmacy location.** The pharmacy must be domiciled in the United States.

5. **Validity of prescription.** The pharmacy shall dispense or offer to dispense prescription drugs only upon receipt of a valid prescription, as defined below, issued by a person authorized to prescribe under state law and, as applicable, federal law. The pharmacy must not distribute or offer to distribute prescriptions or prescription drugs solely on the basis of an online questionnaire or consultation without a preexisting patient-prescriber relationship that has included a face-to-face physical examination, except as explicitly permitted under state telemedicine laws or regulations.

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

6. **Legal compliance.** The pharmacy must comply with all provisions of federal and state law, including but not limited to the Federal Food, Drug, and Cosmetic Act and the Federal Controlled Substances Act (including the provisions of the Ryan Haight Online Pharmacy Consumer Protection Act, upon the effective date). The pharmacy must *not* dispense or offer to dispense medications that have not been approved by the US Food and Drug Administration.

7. **Privacy.** If the pharmacy website transmits information that would be considered Protected Health Information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CRF 164), the information must be transmitted in accordance with HIPAA requirements, including the use of Secure-Socket Layer or equivalent technology for the transmission of PHI, and the pharmacy must display its privacy policy that accords with the requirements of the HIPAA Privacy Rule.

8. **Patient services.** The pharmacy must provide on the website an accurate US street address of the dispensing pharmacy or corporate headquarters. The pharmacy must provide on the website an accurate, readily accessible and responsive phone number or secure mechanism via the website, allowing patients to contact or consult with a pharmacist regarding complaints or concerns or in the event of a possible adverse event involving their medication.

9. **Website transparency.** The pharmacy must not engage in practices or extend offers on its website that may deceive or defraud patients as to any material detail regarding the pharmacy, pharmacy staff, prescription drugs, or financial transactions.

10. **Domain name registration.** The domain name registration information of the pharmacy must be accurate, and the domain name registrant must have a logical nexus to the dispensing pharmacy. Absent extenuating circumstances, pharmacy websites utilizing anonymous domain name registration services will not be eligible for approval.

11. **Affiliated websites.** The pharmacy, website, pharmacy staff, domain name registrants, and any person or entity that exercises control over, or participates in, the pharmacy business must not be affiliated with or control any other website that violates these standards.

Attachment 7

When Drug Addicts Work in Hospitals, No One is Safe

BY KURT EICHENWALD / JUNE 18, 2015 6:07 AM EDT

NEWSWEEK
Filed Under: Tech & Science, Drugs, Hospitals

Updated | Gripping the drug-filled syringe, David Kwiatkowski furtively glanced around to confirm that none of his co-workers could see him. Then Kwiatkowski, a radiology technician at Arizona Heart Hospital, darted into an employee locker room, found an empty bathroom stall and locked himself inside. Sweat dripped from his face, and his stomach churned; he desperately needed a fix. Minutes earlier, he had snagged one of the syringes nurses preloaded with drugs before leaving them unattended in the operating room. It was labeled "fentanyl," an opiate many times more potent than heroin and Kwiatkowski's latest narcotic of choice.

It was about 3 o'clock in the afternoon on April 1, 2010, when Kwiatkowski screwed a hypodermic onto the syringe, placed the needle almost flat against his right arm and slid it into a vein. Slowly, he pushed the plunger, eagerly anticipating relief as the 50 micrograms of fentanyl bathed his brain.

Suddenly, he knew something had gone wrong. With only half the dose injected, Kwiatkowski felt a tingle in his feet, then in his hands. This wasn't fentanyl. The nurses had placed the wrong sticker on the syringe. As his muscles drooped, Kwiatkowski realized he had just injected succinylcholine, a powerful paralytic. That kind of labeling error could have killed a patient. Now, Kwiatkowski knew, he was the one who might die.

David Kwiatkowski, 35, a contract radiology technologist who worked at eighteen hospitals in seven states, was accused of infecting at least 45 people with hepatitis C at hospitals in New Hampshire, Kansas, Maryland and Pennsylvania. NEW HAMPSHIRE DEPARTMENT OF JUSTICE/REUTERS

He pulled the syringe out of his arm and dropped it in the toilet before falling face first into the stall's metal door. He hit the ground, and his head flopped out from under the partition. As the drug paralyzed more muscles, Kwiatkowski could no longer breathe, though he was fully conscious. Thirty seconds passed. A medical technician entered the room, saw Kwiatkowski and screamed for help. Just as the technician was preparing to perform CPR, the paralysis eased up. By stopping the injection halfway, Kwiatkowski had taken only a small dose. He took a breath. "Shit," he said. "Shit, I'm going to jail."

A few minutes later, Kwiatkowski sat up and flushed the toilet in hopes no one would find the syringe and suspect he had been using drugs. Junkie logic.

Then there was a blur of activity. A stretcher. The emergency room. The medical technician saw the syringe in the toilet with the fentanyl label still attached. A representative showed up from Springboard, the Phoenix agency that had placed Kwiatkowski at the hospital. Under questioning, Kwiatkowski spun a ridiculous story filled with lies. Someone called the police, but the hospital refused to cooperate—a good business decision, since an audit two months earlier revealed that a nurse there had been stealing narcotics, and Arizona Heart obviously had not yet fixed the problem. Kwiatkowski left with the Springboard representative, and they drove to a nearby bar.

Downing multiple glasses of Crown Royal whiskey, Kwiatkowski knew his time in Phoenix was over. Drugs and booze had cost him another job, but no matter; that's why he was "a traveler," a technician who agencies place on short-term contracts at hospitals around the country. He knew that, probably out of liability concerns, Arizona Heart would never file an official report that might cost him his radiology tech license; none of the hospitals ever did.

Kwiatkowski returned to his hotel, booted up his laptop and did a quick Internet search. A staffing agency had a listing for a job in Philadelphia. He filled out the online application and went to bed.

The next morning, the telephone rang in Kwiatkowski's hotel room. On the line was a representative from Advantage RN, who said, "Can you start Monday?"

Addicts in Lab Coats

And so it continued, month after month, year after year, as Kwiatkowski crisscrossed the United States, landing temporary jobs at hospitals that soon discovered his drug addictions, then quietly sent him on his way. But what makes this more than just another tale of medical irresponsibility and cover-ups is an alarming fact: Kwiatkowski was one of the 1.5 million intravenous drug users carrying the hepatitis C virus. So in his travels from state to state, he infected scores of people with this potentially fatal disease as syringes he borrowed for his narcotics injections were subsequently used on patients. This set off a national health crisis, with the Centers for Disease Control and Prevention (CDC) recommending that some 12,000 patients be tested because of their contact with Kwiatkowski's blood; in one of the biggest hepatitis outbreaks in decades, at least 45 people contracted the disease, including one who died.

Still, despite the enormous impact of his cross-country infection spree, Kwiatkowski is no anomaly. According to a recent study by the CDC, nearly 30,000 people may have been exposed to hepatitis C over the past decade by infected hospital employees using narcotics intended for patients. The disease is easy to transmit in a medical setting: Once a drop of blood carrying the hepatitis virus touches something, like a needle or plastic tubing, the organism is difficult to kill. So when an infected health worker steals opiates from patients—usually replacing the clear liquid drugs with saline—the pathogen can settle on any piece of the syringe or even in the liquid injected into the patient. And hepatitis is not the only danger. Last year, an outbreak of a serious bacterial infection that killed one patient at the University of Wisconsin Hospital and Clinics was traced to a nurse who stole opiates from syringes.

But infectious exposures are only part of the threat patients face from addicts in lab coats and nursing uniforms. Not all drug diverters—as they are known—carry hepatitis or other diseases. Federal researchers estimate that 100,000 health care workers in the United States are addicts, and their theft of narcotics from patients is believed to be widespread. That fear was reinforced when the University of Tennessee Medical Center cracked down with a tough program to detect drug diverters; in its early days, the effort caught three or four employees stealing narcotics each month. In December 2013, at the University of Michigan Health System, where Kwiatkowski had worked years earlier, a nurse and a doctor overdosed on the same day using pilfered injectable drugs. And for every health care worker replacing opiates with water or sucking fentanyl out of attachable patches, there are many patients suffering from pain they don't know is untreated.

PHOTOALTO/ALAMY

Yet no one has been able to provide a wide-scale inside look at this dirty secret within America's hospitals, primarily since no major drug diverter has ever granted a public interview. That is, until now. In a six-hour, face-to-face discussion and other lengthy communications with *Newsweek*, David Kwiatkowski laid out the scope of narcotics thefts and cover-ups he witnessed

during his nine years working at 19 hospitals in eight states. Thousands of pages of documents—including internal hospital records, correspondence and personnel files; notes of interviews by the FBI; state investigative reports; court filings; and an array of other evidence never before publicly disclosed—back up his account. Kwiatkowski—now serving a 39-year sentence at a maximum-security federal prison for his role in the hepatitis outbreak—told a horror story of addicted health workers wandering hospital wards while stealing drugs, a tale that perhaps only he has enough detailed personal knowledge to divulge.

Kwiatkowski has nothing to gain from his disclosures; the federal system has no parole. Indeed, both Kwiatkowski and prison officials fear this article might anger other inmates and place him in danger. But Kwiatkowski, who says he is sober for the first time in decades, is haunted by the knowledge that he hurt so many people and believes he needs to make amends by revealing the scope and methods of this medical crime that endangers an unknowing public.

"Somebody has to tell how it's done, how easy it is and how the structure of the hospitals isn't any good to stop it," he says of drug diversion. "And I guess the only guy who can really do that is me."

A Shot in the Butt

Early on, all Kwiatkowski wanted to do was play baseball. Born and raised in Michigan, he seemed a typical clean-cut boy attending public school. He avoided cigarettes and alcohol; baseball was too important to risk getting thrown off the team. That changed at the end of his junior year of high school. His friends started heading into the woods on weekends, building bonfires and staying out all night drinking. Despite knowing his family's history of alcoholism, Kwiatkowski joined in. His first drink was from a bottle of Southern Comfort 100 Proof, and he loved it. By senior year, Kwiatkowski was sneaking whiskey every chance he got.

In 1998, his first year at Madonna University, he was getting tanked at least four days a week and discovered he was a mean drunk who got into fights. Then, at sophomore-year party, he met a man 10 years his senior. Through this wealthy new friend, Kwiatkowski joined a circle of boozers and druggies who frequented strip clubs and partied all night. His buddies paid for

everything and let him share their never-ending supply of cocaine. Soon he was a full-blown coke addict who spent his nights prowling techno clubs in downtown Detroit.

He was also getting loaded off opiates prescribed by his doctor. Kwiatkowski suffered from Crohn's disease, a disorder in which the body's immune system attacks the gastrointestinal tract, often causing serious pain. The alcohol and cocaine provided temporary relief, although it ultimately worsened the severe aches and cramps by inflaming the digestive tract. But Kwiatkowski didn't stop getting high and drunk, and instead he persuaded his unsuspecting doctor to write him prescriptions for Vicodin, a narcotic pain reliever.

Despite all the late nights, booze and drugs, Kwiatkowski kept up with his schoolwork. He grew interested in health care and joined a two-year radiology program through the William Beaumont Hospital School of Radiologic Technology while still attending classes at Madonna. In 2003, he graduated from Beaumont, passed his certification test and registered with the American Registry of Radiologic Technologists. Now he could work at any hospital in the country.

He took a full-time job as a radiology technician at St. Joseph Mercy Hospital in Ann Arbor. That's where his crimes started; he says he learned how to commit drug diversions from a popular nurse there.

At first, Kwiatkowski kept his addictions under control, but the alcohol crept back in. He and two hospital friends started a tradition: After every shift, they would go to a nearby Holiday Inn for beer and eggs. Soon they added whiskey shots to the mix. The three men would stay at the hotel bar for six hours, downing booze as they played Golden Tee Golf, a video arcade game.

As usual, the heavy drinking worsened the pain from Kwiatkowski's Crohn's disease. He started popping Vicodin like candy, but that just made his prescriptions run out faster. Finally, Kwiatkowski told an emergency room nurse about his troubles and asked if he had pills to share. No, the nurse said, but he had a better idea.

"He gave me a shot in the butt," of a strong narcotic called Dilaudid, Kwiatkowski says. "That's when it started with the opiates, because it was so readily available."

Knowing nothing about Kwiatkowski's drinking or Dilaudid use, his doctor prescribed Percocet, another painkiller, to treat the abdominal discomfort. Kwiatkowski was boozing all morning, grabbing a few hours of sleep, popping a Percocet as he headed to work and then getting a shot of Dilaudid from the ER nurse.

One morning after their shift, that nurse drove Kwiatkowski to Detroit so they could gamble. After pulling into the casino parking lot, the nurse took out a rubber tourniquet, a syringe and a bottle of narcotics stolen from the hospital. The nurse injected the drug into his own arm and closed his eyes for a moment as it started to take effect. Then he turned to Kwiatkowski. "Want some?"

Kwiatkowski said yes, but he didn't know how to inject himself, so the nurse did it for him. Then they headed into the casino, where they drank and gambled.

A CDC study has found widespread cases of medical workers using hospital drugs as a narcotic.
GALLEY STOCK

The next day, the ER nurse took Kwiatkowski aside. "Hey, I'm going to leave out a vial in the trauma room after we leave. Grab it." When no one was around, Kwiatkowski snatched the small bottle of what turned out to be morphine.

"That was when I started stealing," he says. It became a routine, with the two men pilfering at least one vial of morphine a day. The nurse had full access to narcotics, but he would be a primary suspect if anyone noticed drugs were missing. Kwiatkowski wasn't cleared to handle opiates, so he wouldn't draw suspicion.

After the first couple of months, the quantity of morphine the men stole skyrocketed. For Kwiatkowski, it became as easy as ordering pizza—before work, he would call the nurse and let him know what narcotic he wanted. The nurse set the vials aside, ready for pickup, even before Kwiatkowski arrived at the hospital. By that point, Kwiatkowski was using lots of Dilaudid, taking as much as 30 times the recommended dosage for critically ill patients.

Everything seemed fine, until one morning a hospital security officer stopped Kwiatkowski. "Grab your bag," he said. "You're going to human resources."

At first, Kwiatkowski thought nothing of it. About two weeks earlier, he had totaled his car and missed work. He figured the HR folks wanted to know about that. But as soon as Kwiatkowski walked in the door, a woman said they wanted him to take a drug test. He assumed he had no choice—if he refused, they would fire him. Besides, he hadn't used any narcotics for a day, so maybe nothing would show up.

They ran the test, then told him to go home and wait for a phone call. Instead, Kwiatkowski drove to the home of his nurse friend, who panicked. "You didn't tell?" he asked. Kwiatkowski assured him he had said nothing, and the two men sat down and started shooting up Dilaudid.

Soon after Kwiatkowski got home, the hospital called. His test showed high levels of opiates. Strangely, no one told him he was fired, but Kwiatkowski figured he had lost his job. He called his father, sobbing as he asked if he could move back with his parents for a while.

Then, an idea. He telephoned the HR department at Beaumont Hospital, where he had received his training. He told them he was just finishing up his studies at Madonna University and didn't have a job. Was Beaumont hiring? They seemed delighted—yes, they had job openings; come fill out the paperwork. Relieved to have found work so quickly, Kwiatkowski typed up a résumé, taking care to leave out St. Joe's.

Two weeks passed. Just before he was scheduled to start at Beaumont, St. Joe's HR department called him in. An HR official and a drug therapist interrogated him, telling him they had heard he was stealing drugs and that he had been seen going in and out of the trauma room. And what was his relationship with the ER nurse? Just friends, Kwiatkowski said, and all the other information they had heard was wrong, he assured them.

Well, they said, he didn't have to lose his job. The hospital had a program offering addiction therapy for a year, but he would be required to take drug tests the entire time. If he finished the program, the drug issues would be wiped off his record.

"I don't need it; there's nothing wrong with me," he said. "I quit." What did he care? He already had another job. His drug thefts weren't reported to law enforcement, the federal government or Michigan's Department of Licensing and Regulatory Affairs.

Kwiatkowski looks back at St. Joe's as the tragic missed opportunity. Had he accepted therapy, the horrific events that followed might never have happened. "They should have called the police," he says. "They should have put a flag on me."

In a statement, St. Joe's says, "We take reporting seriously and comply with all requirements." Moreover, the hospital confirms that it strives "to work with any employee to receive the treatment they may require, as part of our mission to be a compassionate, healing organization."

Hospitals keep drugs under lock and key and, for the most part, they are only accessible to a few. The problem arises when drugs are transported from locked cages to operating rooms or when they're not returned to the cage after use. GAETAN BALLY/KEYSTONE/REDUX

Kwiatkowski lasted at Beaumont only a few weeks. While no one found out about his drug pilfering, the hospital discovered he had lied about his work history. He turned in his badge and drove home at about 9 o'clock in the morning. Immediately, he got on the Internet, found a position open at Detroit Medical Center and applied—this time including St. Joe's on his résumé.

Fairly soon, he heard back. He got the job.

Free Narcotics

His new hospital assigned him the late shift, ending about 2 a.m., which Kwiatkowski thought was great, since it gave him time to party at the Elysium Lounge, a downtown nightclub. For a couple of hours each night, he downed shots of whiskey at Elysium, then headed home for another eight or nine hours of drinking and cocaine. But he always stopped by 1 o'clock in the afternoon. After all, he needed time to sober up for work.

He started hitting on some of the pretty nurses, and soon he had a girlfriend. When they were off-duty, she would join him in drinking and smoking marijuana.

Then the cycle started again. The drinking brought back the pain from his Crohn's, but Kwiatkowski didn't consider stopping his massive daily doses of Crown Royal. Not when he knew there was another treatment available—and a nurse who could get it for him. "Hey, you know, I don't want to go to the hospital, but I've been having these pains," he told his girlfriend. "Is there any way you could hook me up with some morphine or Dilaudid?"

The nurse didn't hesitate. "Sure," she said. "No problem."

His girlfriend brought him plenty of narcotics stolen from the hospital, although they made sure never to make the handoff at work—too dangerous. He started shooting up every day. Soon, though, he found he needed more to get high, but he was embarrassed to ask his girlfriend for it. After all, he didn't want her to find out he was a druggie, a thought he now recognizes makes no sense. Instead, he hit up a different friend, who sold him OxyContin, a narcotic in pill form.

Prescription pills containing oxycodone and acetaminophen are among the most popular substances used by medical workers self-prescribing pain relief. THE CANADIAN PRESS/GRAEME ROY/AP

When he was loaded on drugs, he felt good—worked out at the gym, went out to restaurants, did his job. When the narcotics weren't around, he went into withdrawal and couldn't function. So he would start downing fifths of whiskey, worsening the Crohn's and feeding his craving for more drugs.

Then everything changed. His girlfriend left him, and he received a promotion to the cardiac catheter lab. Kwiatkowski was thrilled. He was now participating in lifesaving procedures and carrying a pager for emergency heart attacks. He decided he wasn't going to blow this opportunity. He quit the narcotics and cut back on the drinking. He found a new girlfriend in the nursing staff of the same department, one who didn't use drugs.

But he started going out to the clubs by himself so he could drink without her seeing him. She complained about his frequent absences, and he worried that all the clubbing might cost him this woman he really liked. Since he couldn't handle all the alcohol, he turned to the first option that came to mind. He started stealing drugs from the hospital.

It was so easy, he could scarcely believe it. The procedures in his unit often required morphine and other narcotics for patients in pain. Nurses would lay out the bottles of opiates on a counter before catheterization began. Full vials were rarely used; usually, a few milligrams remained inside the bottles once the patients were gone. Afterward, nurses logged how much of the narcotics had been used and how much remained in each bottle. Then, with a witness standing by to make sure the drugs were disposed of, the nurses tossed the bottles into the garbage.

Kwiatkowski would fish the vials out of the trash, pocket them, take them home after work and shoot up in the bathroom so his girlfriend wouldn't see. He had found a source of free narcotics, easy and risk-free. For Kwiatkowski, the whole process was a rush: the stealing, the sneaking around, the surreptitious injections.

But it was then that he had the accident that changed his life. He and a colleague were lifting a patient from a stretcher to a bed in the intensive care unit. Neither noticed that a used needle was under the bed sheet. As they settled the patient, the needle poked Kwiatkowski. He never shared

needles with other addicts and always made sure to use new ones on himself. Kwiatkowski believes he contracted hepatitis from that needle-prick in 2006.

Unaware of any new health problems, he and his girlfriend got engaged, and for the first time, Kwiatkowski found a hospital policy he couldn't circumvent: Spouses and fiancées weren't allowed to work in the same department. So he applied in June 2006 for a position at the University of Michigan Health System in Ann Arbor.

Before bringing him on, the university ran a background check and discovered a problem on his official record, one that worried HR. On August 11, Kathleen McCollum, the hospital's employment office manager, sent an email to Donna Eder, director of human resources in radiology.

A background check found something troubling about Kwiatkowski, McCollum wrote; a misdemeanor traffic violation had resulted in a warrant being issued, probably because the fine hadn't been paid. "This may be something that is resolved but still showing up on his record," she wrote. "But it is probably worth asking him about, so there aren't any surprises down the road."

No Polygraph

The traffic violation problem was easily cleared up, leaving Kwiatkowski set to start his new job on August 21, 2006. Quickly, he discovered that procedures for disposing of drugs were different at this hospital, so his garbage technique wouldn't work. Kwiatkowski was a little nervous about stealing full bottles, so he returned to his old supplier of OxyContin and decided to lay off the injectable narcotics.

Still, what he saw at this new hospital amazed him. Extra medications were checked out from the pharmacy for procedures—far more than could possibly be needed. He saw colleagues pocket bottles, but he had no idea how the missing narcotics weren't showing up in the hospital records. One day, a bottle of fentanyl went, which set off gossip among the staff but not much more.

Speaking to a colleague about what he considered to be the hospital's sloppy controls of narcotics, Kwiatkowski said, "This place doesn't even do drug tests."

Then, after just a month on the job, two partially filled vials—one with a narcotic called Versed, the other with fentanyl—disappeared from the procedure room, apparently when the medical staff left the room to get a patient. Linda Campbell, a nurse in radiology, told her boss, and they searched for the missing vials. When they didn't turn up, Campbell called security. The first real drug theft investigation involving Kwiatkowski was about to begin. Security conducted interviews for weeks; while several employees said they could not vouch for Kwiatkowski, investigators found no evidence he had stolen anything.

A few weeks later, more drugs disappeared. A nurse named Wendy Baker signed out three vials of fentanyl and three vials of Versed; two were used on a patient. Baker hid the remaining four vials in a Kleenex box in the patient's room. When Baker returned from lunch, she discovered the vials were gone.

A nursing manager in the radiology department called security and said she suspected Kwiatkowski. Not only was he new, but she had learned of some problems in his past. She gave no further details.

The next day, two security officers interviewed Kwiatkowski. They told him he didn't have to answer questions and was allowed to leave at any time. "Oh, that's fine," he told them. "I want to help you guys out."

One officer asked if he had taken the vials. Kwiatkowski half smiled and said, "No. No, I didn't do it." Then he chuckled.

Under further questioning, Kwiatkowski said he had no idea who had stolen the drugs, but he had some suspicions. He also said he knew everyone thought he was the thief because he was the new guy. People didn't like him, he said, because he had a lot more training and experience than the rest of the staff. "I feel like somebody's setting me up because they think I'm a big know-it-all."

Kwiatkowski told investigators he had worked at Beaumont and Detroit Medical; he didn't mention St. Joe's. When the officer called HR at Beaumont, he was transferred to a recording saying the hospital did not provide previous employment verification. The person who answered the phone at Detroit Medical also told the investigator the hospital would not give out information regarding a previous employee's resignation or whether the hospital would rehire Kwiatkowski.

Then, on December 7, it happened again. A nurse named Staci Royer obtained a vial of fentanyl, placed it on a desk, then left to get a drink of water. When she returned, the bottle was gone. The staff launched a search; four hours later, the fentanyl was discovered under a towel beneath a cart. Once again, Kwiatkowski was the chief suspect, and he was suspended, pending an investigation. Although Kwiatkowski had earlier offered to take a polygraph, he backed out when a date for a test was set, saying that a lawyer had advised him not to do it.

Fentanyl Citrate, a CLASS II Controlled Substance as classified by the Drug Enforcement Agency, is used in the emergency room often to treat trauma patients. JOE AMON/THE DENVER POST/GETTY

The security officers pressed him, but Kwiatkowski stayed adamant. Well then, one of the officers said, he *must* be the one who was stealing the drugs. Then and there, Kwiatkowski decided to quit. The investigation was closed, but since no conclusions had been reached, no formal report about Kwiatkowski was filed with any agency.

There was one other problem, Kwiatkowski says: The hospital never caught the real thief. He hadn't yet grown comfortable with stealing vials from anywhere but the garbage, which meant a drug addict or dealer was still on staff at the radiology department.

"I want to make an emphasis of this," Kwiatkowski says. "I did not take anything from the University of Michigan. I've admitted to everything, but I won't admit to that. That was not me."

'I Can Get It'

In two weeks, Kwiatkowski landed a job on the midnight shift in the radiology department at Oakwood Annapolis Hospital in Wayne. He started partying again, and his life became a blur of drinking, cocaine, sleep and work. But that didn't last. A few months after Kwiatkowski started at Oakwood, a manager told him they were sending him to an offsite facility for a drug test. Kwiatkowski refused. Another job gone. And again, no report filed, since no test was run.

That day, when he drove home, he arrived to an empty house. His fiancée had packed up and left. She didn't want to marry an alcoholic addict. Now, as far as Kwiatkowski was concerned, there was no reason to hold back. He started using more cocaine, drank bourbon by the gallon and hooked up with his old OxyContin connection. Desperately needing money, Kwiatkowski took a job as a day laborer and used the cash for drugs and alcohol.

One afternoon in fall 2007, while downing cheap whiskey, Kwiatkowski saw a website for Advance Med, a staffing company that offered temporary contract jobs with hospitals. He filled out the online form and then took a nap to sleep off the booze. His ringing cellphone woke him up—it was the staffing agency. They asked for more information, then told him there was a job available at St. Francis Hospital in Poughkeepsie, New York, if he could start in a week.

Kwiatkowski agreed. He packed his Pontiac Torrent SUV and drove to Poughkeepsie. He stayed for the length of his short-term contract and then headed back to Michigan. An uneventful trip, but one that placed him on the radar of staffing agencies around the country that were always on the lookout for medical travelers. The first to call was a company called Maxim Staffing Solutions. The University of Pittsburgh Medical Center Presbyterian needed a quick placement. Would Kwiatkowski be willing to go to Pittsburgh?

He drove to Pittsburgh, set up residence in a place arranged by Maxim and started work on March 17, 2008. The first couple of weeks were uneventful; Kwiatkowski was trying, again, to stop the booze and drugs. He befriended a neighbor, a former Marine who also worked at the hospital. One day, the two men were playing on an Xbox when the neighbor asked if Kwiatkowski wanted to do some cocaine. Kwiatkowski asked him if he could also obtain some oxycodone pills. No problem, the guy said. With that, the boozing and drinking began again. He would go to work high, something he had tried to avoid in the past, but now he didn't care anymore.

Then the neighbor came by with a question. Could Kwiatkowski obtain some liquid fentanyl? Kwiatkowski had never used fentanyl, but he had been at this hospital long enough to know how easy it would be to steal the drug. "I can get it," he said.

The hospital kept preloaded fentanyl syringes in the operating room in what was known as a sterile drawer. The syringes were each labeled with a blue sticker to make sure the staff knew they contained that drug. The stickers, though, were available to everyone; Kwiatkowski gathered some and then went to the supply cabinet for an unused syringe—everyone had access to those too. Then he grabbed a bottle of saline, snuck off, loaded the syringe with the harmless water and affixed a blue sticker. He carried that syringe in his pocket until no one was near the sterile drawer. Quickly, he made his move, opening the drawer, dropping in the saline-filled syringe, then snatching one filled with fentanyl that he would later trade with his neighbor for OxyContin.

A couple of weeks passed, and Kwiatkowski got curious. He liked OxyContin, but why was fentanyl such a popular drug among addicts? So he shot up with a dose. He didn't think it was that great; still, it took the edge off of his drug cravings, so he kept on using.

In May 2008, Kwiatkowski took a fentanyl syringe from the sterile drawer, but he immediately felt worried. He thought someone had seen him do it, so he went to the locker room, squirted the fentanyl into the toilet and tossed the syringe into what is known as the "sharps box" that contained hundreds of used needles.

SPENCER PLATT/GETTY

Used syringes are discarded in a bin at a Vermont medical facility on February 6, 2014. In some hospitals Kwiatkowski employed the help of others for his habit, getting them to stash drugs that he could retrieve later.

Kwiatkowski was right. Someone had noticed him entering the operating room, lift his shirt and put a syringe in his pants. Thirty minutes later, his manager instructed him to go the head nurse's office. There, several people were waiting, including a hospital security officer. Someone had seen him steal fentanyl, one official said. Kwiatkowski denied it. The security officer patted him down, found nothing, then he escorted Kwiatkowski to his locker—or at least to the one he was using that day. None of the lockers were assigned, and they couldn't be locked.

Kwiatkowski felt cocky as the officer searched the locker; he knew there was nothing to find. That is, until the officer pulled a glass bottle of morphine off the top shelf. Someone had stolen it and stashed it there.

"What's this?" the officer said.

"I don't know," Kwiatkowski replied. "You said I was taking fentanyl. Nobody said I took morphine."

Damn it. There was another drug thief in the OR who, like Kwiatkowski, apparently preferred morphine. While Kwiatkowski knew he was a criminal, he hadn't committed this crime. He was on the hook once again for someone else's theft.

Kwiatkowski was escorted down to the emergency room, where medical staff took blood and urine for a drug test. He decided not to refuse; maybe, he figured, they would come back like St. Joe's with an offer of a year of a drug therapy. The director of interventional radiology arrived and said, "What's going on, Dave?" Kwiatkowski burst into tears. "I've got a drug problem," he said, explaining that he had become addicted to Vicodin prescribed for his Crohn's disease—oh, and he smoked marijuana. Kwiatkowski had confessed to using a drug he didn't smoke and left out most of the narcotics he was taking.

The next morning, he telephoned a representative from Maxim to tell the staffing agency he had lost his job. They suspected him of stealing drugs and using them, Kwiatkowski said, but it was all bogus. Well, the representative said, Kwiatkowski needed to come down to the Pittsburgh office and take a drug test. Fine, Kwiatkowski said. Kwiatkowski drove to the office and gave a urine specimen. He was sure he would pass the drug test. Apparently, Maxim wasn't aware that it needed a blood test too. After all, as Kwiatkowski knew, fentanyl—the drug in his system—didn't turn up in urine.

The University of Pittsburgh officially reported to Maxim that Kwiatkowski had been terminated for issues related to narcotics. But Maxim declared him drug-free (incorrectly), did not report he had been fired by the university to any official agency, and put him back on its list of radiology

technicians available for hospitals. It never asked officials at the hospital at the University of Pittsburgh what their drug test showed. Kwiatkowski had failed that one; his blood was full of fentanyl.

Ready to Infect

Every chance to stop Kwiatkowski had slipped away. Reports weren't filed, hospitals refused to disclose his drug problems to employers, no one pressed criminal charges, and the wrong drug tests were administered. He had also been moving from hospital to hospital unknowingly carrying the hepatitis C virus, but because of how he had obtained the drugs, he had probably never infected anyone. Had Maxim run a blood test in May 2008—rather than just checking his urine—no one might ever have been infected. But that last chance was lost as Kwiatkowski started using a new technique that left a trail of hepatitis victims.

Fourteen days after his termination from the University of Pittsburgh, Advance Med—another staffing agency—placed him at the Veteran's Administration Hospital in Baltimore. He thought the measures there to stop narcotics thefts seemed almost designed to help addicts on staff get their fix. Kwiatkowski had been hired to work in the interventional radiology lab, and whenever a case was scheduled, nurses would prepare the fentanyl syringes hours in advance. If a patient was to be seen at noon, the drugs might be laid out as early as 9 a.m. and left in the procedure room with no one else there.

Kwiatkowski did nothing for a few weeks, but the setup proved too tempting. Day after day, he would walk into the procedure room, pick up a syringe filled with fentanyl and take it into the bathroom. There, he would screw on a needle, inject himself, take the dirty needle off and put it in his pocket for later disposal. He cleaned the syringe, pulling the plunger back and forth to wash it out, then filled it with saline. Afterward, he returned to the procedure room and placed the water-loaded syringe alongside the narcotics. The cleaning attempts, though, were pointless. Even though he removed the needle, even though he washed the syringe, the hepatitis virus could remain attached to the tubing, still alive and ready to infect.

On September 8, 2008, Linwood Nelson, a Vietnam vet, came to the Baltimore VA Medical Center for a thoracic CT scan and received an injection from one of the syringes Kwiatkowski had used that day for his fentanyl fix. As the nurse unknowingly injected water into Nelson's bloodstream, a microscopic hepatitis virus inside the syringe was pumped into his body. The infection can be devastating. It can cause the liver to fail or grow cancer; it is the most common reason for liver transplants in the United States, according to the CDC. Approximately 15,000 people die every year from liver disease related to hepatitis C. Even if the liver doesn't fail completely, the deterioration of its functioning can lead to feelings of overwhelming exhaustion, nausea and serious health problems. Unfortunately, many people with the disease, like Kwiatkowski, feel few if any symptoms until the liver damage has already occurred. Indeed, four years passed before Nelson learned he had been infected.

In a statement, the Baltimore V.A. said that in the years since Kwiatkowski worked there it has adopted a series of automated drug inventory management and software systems designed to prevent drug diversions.

Immediately after Kwiatkowski's contract ended at the VA, Maxim—the staffing agency that knew he had been fired from the University of Pittsburgh hospital—placed him at Southern Maryland Hospital in Clinton. While he was there, Kwiatkowski stole no drugs and spread no hepatitis. The reason? Southern Maryland employed the simplest and most logical control over its injectable narcotics: Once drugs were out from under lock and key, the nurse kept the syringes or vials in her pocket until it was time to use them. Kwiatkowski says that unless the nurse assigned to carry the drugs stole them, no one on staff could get their hands on narcotics. The pocket system, Kwiatkowski says, was the only safety precaution that ever stopped him.

To keep himself stocked with narcotics, he now needed more money so that, like most addicts, he could buy them outside the hospital. Plus, his drinking was at a peak, which cost a lot too. So Kwiatkowski started falsifying his time sheets. The fourth time, the hospital caught it and fired him. Advance Med, one of the staffing agencies, learned he had been terminated and notified Kwiatkowski that it would not place him anymore.

No matter. Kwiatkowski contacted another agency, Springboard. He faked his credentials—eliminating terminations, resignations, drug tests and all the other problems—and in no time was placed at Maryvale Hospital in Phoenix. Obtaining drugs at Maryvale was simple; three staffers—a patient care provider, an administrator and a security guard—were dealers. From them, Kwiatkowski was able to obtain cocaine, OxyContin and Soma, an addictive oral muscle relaxant that can cause euphoria.

As Kwiatkowski traveled from state to state, he had the luxury of a fresh start but says he always fell in the same self-destructive habits. BLEND IMAGES/ALAMY

By summer 2009, a job opening came up at Johns Hopkins Hospital in Baltimore. But Kwiatkowski had allowed his Maryland radiology license to expire; he reapplied, lying once again about suspensions and terminations—including the one from a Maryland hospital just a few months earlier. Maryland reissued his license 22 days after he applied.

On July 9, he started at Johns Hopkins—a hospital, he says, that is a drug addict's dream. "Johns Hopkins is one of the easiest," he says. "They let the drugs just hang out. You could have had a housekeeper just walk in and get some." It was little surprise, Kwiatkowski says, that he soon crossed paths with another drug diverter. The two stole narcotics almost every shift they worked,

injecting the drugs, changing the needle, replacing the painkillers with saline, then placing the used syringe back with the others ready for use. Kwiatkowski infected at least four patients at Johns Hopkins with hepatitis.

In a statement, Johns Hopkins notes that these events occurred six years ago and says it has continuously updated its procedures ever since. "Patient safety continues to be our top priority," the statement says. "We regularly re-evaluate, seek and implement new ways to improve our processes."

After a quick stop at Maryland General, Kwiatkowski was placed at Arizona Heart Hospital by Springboard. It was there that he accidentally injected himself in the bathroom with a paralytic drug, succinylcholine. After a Springboard representative and the police came, Kwiatkowski told a story about finding a fentanyl syringe in a radiology apron and using it on himself—somehow, he thought they'd be less likely to investigate this story. He was right: Arizona Heart not only declined to press charges but also refused to answer any questions from law enforcement.

For the first time, though, a staffing agency took decisive and responsible action. Springboard told Kwiatkowski it would never work with him again, then asked Arizona Heart for any report signed by Kwiatkowski regarding the incident, the names of employee witnesses and blood tests results. Arizona Heart refused to cooperate but said it had reported the event to the state Pharmacy Board—a bizarre move, since that agency regulates pharmacists and their facilities, not other hospital staff.

The stiff-arming from Arizona Heart left Springboard with little to go on. Still, Melissa Arthur, a manager with the staffing agency, wrote a complaint that included a description of what had happened and instructed her staff to send the document to the American Registry of Radiologic Technologists (ARRT), the licensing board that could pull Kwiatkowski's license and make sure he never worked again. Springboard faxed the complaint to the ARRT five business days after Kwiatkowski was discovered on the bathroom floor. The notification arrived just in time. That day, Kwiatkowski started at Temple University Hospital in Philadelphia, having been placed there by Advantage RN.

Complaint in hand, the ARRT jumped into action and did…nothing. On April 23, 2010—15 days after receiving the complaint—the ARRT Ethics Committee finally sent Kwiatkowski a letter asking for an explanation. He received it in May, while still at Temple. At the time, Kwiatkowski was going cold turkey because Temple kept tight controls on narcotics and he didn't know anyone in Philadelphia who could hook him up.

The letter terrified him. "I could have lost my license right then and there," he says. "So I did a little back research. I tried to find out what [Arizona Heart] reported. [The] hospital never reported it. It was an outside source." That, Kwiatkowski decided, meant Arizona Heart was covering everything up, which told him that whoever had complained wouldn't know the whole story. So, he figured, he could try replying to the licensing board with bald-faced lies and see what happened.

His response to the ARRT arrived on July 2, long after the 30-day deadline had passed, and it was complete fiction. He wasn't feeling well on the day he was found on the bathroom floor, he wrote, and had passed out. He awoke on a stretcher, and people were telling him they found drugs on him—but that wasn't true. He had demanded that the hospital conduct a drug test immediately (while he didn't know what that test showed, he assumed Arizona Heart would refuse to release it). Kwiatkowski also pointed out that Springboard had conducted a urine test, which he passed—not a surprise, since, just like fentanyl, succinylcholine doesn't show up in those.

"I never had any issues before, nor do I want any," he wrote. "Whatever I need to do to continue my love for my job, I will."

The lies were bad enough, but more important was a lethal piece of information he left out of his reply. Two months earlier, despite being notified by Springboard that Kwiatkowski was not rehirable, another medical staffing agency, Medical Solutions, placed him in a radiology job at Hays Medical Center in Hays, Kansas. While he was there, Kwiatkowski was feeling ill and saw a doctor, who checked his blood. And for the first time, Kwiatkowski learned he was infected

with hepatitis C. But that didn't stop him from using syringes loaded with fentanyl; before he left Hays, Kwiatkowski infected at least three patients there.

The ARRT continued its investigation, although using that word to describe what the organization did is more than charitable. It searched for whether Kwiatkowski had a criminal record and found nothing; it checked if he was licensed. On July 16, 2006—98 days after Kwiatkowski had collapsed at Arizona Heart—a paralegal at ARRT requested a copy of the police report. On September 27, the police replied, saying no report existed because Arizona Heart had refused to press charges. Although Springboard provided the name and badge number of the officer who had spoken to Kwiatkowski, no one from the ARRT called him. On January 26, 2011—almost 10 months after Kwiatkowski was discovered on the bathroom floor at Arizona Heart—the ARRT Ethics Committee recommended no action be taken against him.

And throughout that inquiry into the episode at Arizona Heart, officials from staffing agencies and hospitals called the ARRT whenever they considered hiring Kwiatkowski, just to make sure there was nothing bad on his record. Each time, the ARRT gave Kwiatkowski the all-clear, allowing him to move on to the next hospital where he could steal drugs and infect patients.

"We would not have indicated to an outside third party that there's an ongoing investigation," Barbara Kummer, ethics investigation coordinator at the ARRT, later testified in a deposition.

He Waited to Die

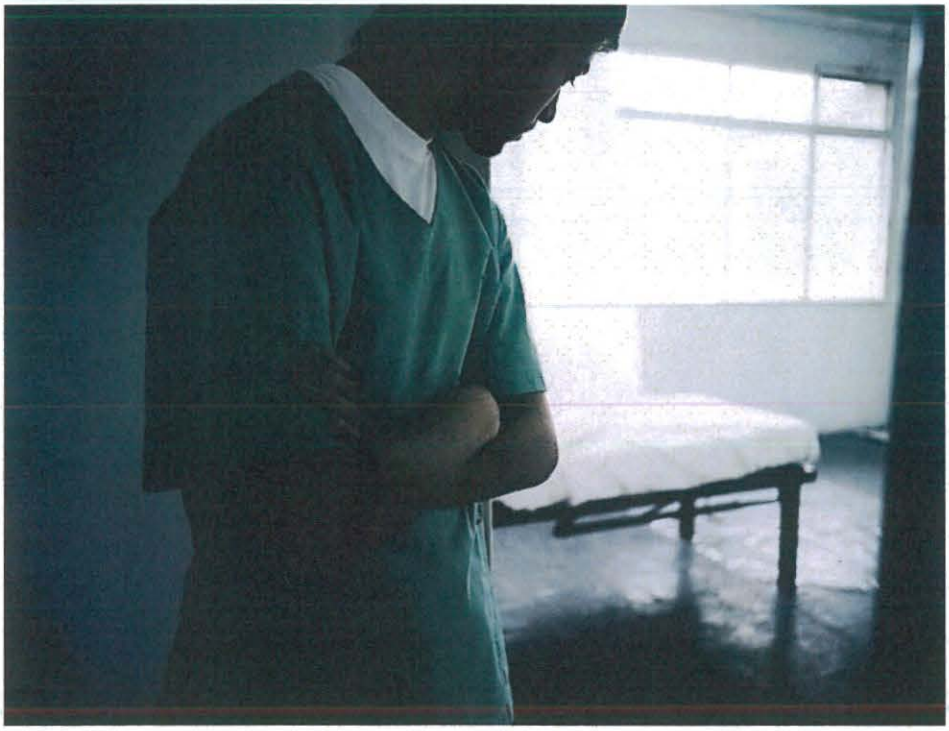
On July 13, 2012, Kwiatkowski sat down on the bed in a dingy hotel room in Marlborough, Massachusetts. That day, he had gotten a haircut, gone to a tanning salon and sent flowers to both his girlfriend and his mother. He wanted to look good and have things in order after his suicide. He popped open three bottles of pills, including anti-psychotics and blood pressure medications, and downed hundreds of them while swigging from a bottle of vodka. Then he lay down and waited to die.

He knew his years of secrets were about to be exposed. For more than a year, he had worked at Exeter Hospital in Exeter, New Hampshire, using his favorite technique for stealing drugs:

injecting himself with preloaded syringes, washing them out, filling them with saline and putting them back. Just like at almost every other hospital where he had worked, he knew other staff members were stealing narcotics too, so he didn't think what he was doing was so terrible. But in May 2012, a patient there was diagnosed with hepatitis. Then a second. And a third. And the hospital also discovered Kwiatkowski was infected with the virus.

On May 15, Exeter reported the outbreak to the state Division of Public Health Services, which in turn called in the CDC. Then the FBI joined in. CDC investigators said they were certain the multiple infections had been caused by a hospital worker's drug diversions. Kwiatkowski denied he had been stealing drugs, denied that he had hurt anyone, but during an interview with law enforcement on July 2, he said he had "lied to a lot of people" and "fabricated my life." He admitted to deceiving colleagues and friends about his fiancée, saying she had died in a car crash, and falsely claiming he had played baseball with the University of Michigan. But in the same interview, he lied about his narcotics use. He also falsely stated he had only discovered he was infected in May, when the Exeter outbreak began. An agent asked Kwiatkowski how he thought patients had contracted the disease.

"You know, I'm more concerned about myself, my own well-being," he replied. "That's all I'm really concerned about, and I've learned here to just worry about myself, and that's all I really care about now."



Drugs are plentiful in hospitals and as David Kwiatkowski, a former health worker, tells Newsweek, it's easy to score a high and much easier still to get away with it as hospitals rarely report the crime. PHOTOALTO/ALAMY

But playing the victim didn't work, and with the numbers of the infected growing, Kwiatkowski knew he would probably go to prison. He decided death was a better choice. After taking the pills, he started sobbing, and a short time later, a housekeeper walked in. Paramedics were called, and they took him to nearby Marlborough Hospital. Once he was well enough, he telephoned his parents from his hospital bed. They promised they would come see him as fast as they could.

On July 19, he heard from his parents. They had just landed at the airport and would be at the hospital in 30 minutes. "OK," Kwiatkowski said. "I can't wait to see you."

He hung up the phone, and the door to his hospital room flew open. Federal agents with guns drawn swarmed in—from the FBI, the Drug Enforcement Administration and the Marshals Service. The room filled up with law enforcement, while the patient in the next bed watched in wonder. Someone handcuffed Kwiatkowski to his hospital bed and read him his Miranda rights.

He confessed to everything. He acknowledged swapping out syringes in the manner that put people at risk of contracting his virus at least 100 times.

Almost immediately after the news of Kwiatkowski's arrest went public, the director of clinical services with Maxim—the staffing agency that had placed Kwiatkowski at several hospitals—dummied up a bogus email that, if true, would prove the company had reported Kwiatkowski on March 9, 2009. (Almost four years later, the fake email was produced in response to a subpoena issued by Maryland investigators; Maxim acknowledged three months afterward that the purported email was a fake.)

As health officials discovered dozens more people infected with the same hepatitis virus carried by Kwiatkowski, he pled guilty to 14 federal charges filed against him in New Hampshire and another two in Kansas. He faced a maximum of 40 years in prison.

By the day of Kwiatkowski's sentencing, December 2, 2013, 45 of his victims had been found, including one who had died after being infected at Hays in Kansas. As Judge Joseph Laplante of the Federal District Court in Concorde listened to the prosecutors and defense lay out Kwiatkowski's crimes, he grew perplexed. Why didn't the hospitals and staffing agencies that figured out what was going on treat it like a criminal issue rather than a personnel problem? No one could provide an answer.

After that, one at a time, Kwiatkowski's victims stepped forward to describe what he had done to them and their loved ones. They told of lives destroyed, how they all knew they faced a death sentence as their livers grew increasingly impaired. Some said they were hospitalized all the time because of damage from the infections; one said he felt so sick and fatigued all the time that he wanted to die.

"The hatred for you, Mr. Kwiatkowski, from our family alone is immeasurable," said Kathleen Murray, a daughter of Lucy Starry, who had been infected at Johns Hopkins and was too sick to travel to the sentencing. 'You may only be facing drug charges, but make no mistake, you are a serial killer. Someone has already died. Many more will."

Donald Page, who had contracted the virus at Exeter, offered no comments to the court. Instead, he simply stared at Kwiatkowski and spoke three sentences. "I just want to look at the man that killed me," he said. "You killed me. Do you have anything to say to me?"

"I'm sorry," Kwiatkowski said. "I'm terribly sorry."

After more than an hour of wrenching comments from Kwiatkowski's victims, Judge Laplante passed down a sentence of 39 years, one less than the maximum. He said he had left off that single year so it would be a constant reminder to Kwiatkowski that human beings could show compassion, something he had failed to do. And with that, Kwiatkowski said goodbye to his parents and was taken away by the federal marshals.

In late 2014, I was in the large visitor area at Hazelton maximum-security prison in West Virginia. I was the first person to come see Kwiatkowski during his incarceration; his family and friends have all cut him off. I had been exchanging emails and letters with Kwiatkowski for months, and he had finally agreed to speak with me face-to-face. Prison officials objected, saying they feared other inmates would harm Kwiatkowski if this article ran because of the number of innocent people hurt by his crimes, but after more months of negotiations, agreed to allow a meeting.

After about 20 minutes, a guard unlocked a metal gate and escorted Kwiatkowski into the room. I was shocked by his appearance. At the time of his sentencing, he looked fat and sickly. In just two years, he had lost 70 pounds and the sallow skin tone, and he appeared quite healthy.

We spoke for six hours, and at the end of our time together I mentioned that he seemed well. "Since I've been locked up, I haven't thought about drugs or alcohol. This place saved my life," he said. "I'm back to the person, right now, that I was before I started drinking in high school."

Once we finished, the guards reappeared. "You make sure you tell them how sorry I am," he said to me as he was escorted away. "I'm trying to make up for what I did. I'm so sorry."

And with that, Kwiatkowski was led away, back to one of the prison cells where he will likely remain for the rest of his life.

Correction: An photo caption in an earlier version of this story incorrectly stated that David Kwiatkowski is 33 years old and a medical technician who worked in six states. He is 35 and was a radiology technologist who worked in seven states.

Update: This article was updated to include a response by the Baltimore V.A

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Safe medicine disposal options

A CDER Conversation with Douglas Throckmorton, M.D., Deputy Director for Regulatory Programs, Center for Drug Evaluation and Research, FDA

Last year Americans filled 4.3 billion prescriptions. It is clear that prescription drugs play an important role in managing a range of medical conditions and are widely used in homes across the United States.. But the drug life-cycle is not complete until the medicine has been consumed in its entirety or eventually discarded properly. However, little attention is given to the potential risks, such as accidental exposure or intentional misuse, related to improper medicine disposal. Where should unused and expired medicines go? Let's look at drug disposal and get a better understanding of why it's important to safeguard medicines in the home and how to properly dispose them when no longer needed.

Let's begin with the basics, how should consumers safeguard and store medicines at home?

Well, it's important to keep medicines in a storage location out of the reach and sight of children and pets too. Be sure to put medicines away after every use. Don't leave them out on the kitchen counter or some place where they can easily be grabbed by kids. Even simple measures like making sure that the safety cap is locked can help prevent accidents.

How should folks dispose of their medicines?

For most prescription medicines, we recommend they be returned through a local, or U.S. Drug Enforcement Agency-sponsored take-back program or DEA-authorized collector. For a small number of drugs, we recommend immediate removal from the home by flushing them down the toilet or sink.

There are several programs consumers can access to help them dispose of unused or unwanted prescription drugs. First, take-back programs. These events are held in many parts of the country and can help you dispose of unused and unneeded drugs quickly and safely. Check with your local government or the DEA's website for information on the next take-back event in your community.

Another good option for safe disposal is to locate a DEA-authorized collection site. Authorized collection sites may be retail pharmacies, hospital or clinic pharmacies or law enforcement locations. Some authorized collection sites may also offer mail-back programs or collection receptacles, sometimes called drop-boxes.

If these options aren't available, the drugs should be removed from their original containers, mixed with coffee grounds, cat litter or some other undesirable substance, and placed in sealable plastic containers or bags. This can be thrown into the trash for pick-up. And when you dispose of prescription medicine bottles, be sure to remove any personal identifying information before throwing them away.

DEA's National Prescription Drug Take-Back program is back. What do you think of this action?

I'm very happy to see that this disposal option is once again available to consumers. We are definitely supportive of any safe and useful way to get medicines that are no longer needed out of the home and disposed of properly. And I'm proud to say FDA has hosted several take-back days at our facility, where we have collected unused medicines for disposal.

You mentioned flushing -- certain drugs should still be flushed?

A few prescription medicines are especially harmful or even fatal if taken accidentally by someone other than the patient. For this reason, if a drug take-back program is not available, these medicines should be flushed down the sink or toilet to eliminate them from the home. This provides an immediate way to prevent any possibility of accidental exposure or overdose.

FDA has a list of medicines on our website that we recommend be disposed of by flushing. If a medicine has special disposal instructions, the directions will be listed in multiple sections of the prescribing information for health care professionals and also in the product's patient information.

Aren't you concerned about the possible environmental impact of flushing?

Here at the agency, we understand that there are concerns about getting rid of drugs by flushing them. While we continue to study the issue, disposal of these select few medicines by flushing has not been shown to cause environmental harm. Actually, the vast majority of drugs that are detected in rivers and streams come from normal bodily excretion by people and animals.

Let me stress that we only recommend flushing a very small number of potentially dangerous drugs – these are drugs that can be especially harmful if taken by the wrong person or not used as intended. It's important to get these drugs out of the home as soon as they are no longer needed to prevent harm to children and pets. For all other drugs, take-back programs or disposal through household trash are recommended.

We often hear about problems with the disposal of drug patches – what issues do they present?

These products pose a risk to others, especially children because a large amount of active medicine remains in the patches even after they've been used. In fact, usually more medicine remains in the patch after treatment than was delivered to the patient during treatment.

We have received reports of women and children accidentally exposed to testosterone from patches. Sadly, we are also aware of four children who have died and another six that required hospitalization from an accidental overdose of the potent pain medicine fentanyl. These children accidentally came into contact with used Duragesic patches. Proper disposal of medicine patches is very important to help keep children and other household members safe from accidental exposure.

Then how should someone dispose of a drug patch when they no longer need it?

To dispose of a drug patch, carefully remove it by the edges and avoid touching the used medicine pad; then fold the patch in half, sticky sides together. Nitroglycerin and testosterone patches can be placed in the trash. Fentanyl patches should be flushed immediately.

Flushing, wrapping, coffee grounds, why not just re-use the drugs when needed or pass them to someone else?

Certain localities and organizations operate medication reuse programs, which take unused and unexpired medicines from patients to give to others. The FDA does not endorse this practice for two reasons - first, the medication may have been tampered with and is no longer safe to take, and second, the medication may have been improperly stored and is no longer effective. The safety and efficacy of a medication cannot be guaranteed after it has been dispensed.

So, they may not work and they may not be safe.

Exactly.

Do you see a time when a flush list will no longer be needed; what must be in place for that to happen?

Well, one major step has already been taken, and that was the passage of the Secure and Responsible Drug Disposal Act in 2010. This legislation is designed to help decrease prescription drug abuse and related crime by allowing patients to turn in controlled substances to an authorized individual or site for collection and destruction. Let me take a step back to explain that controlled substances are drugs, which include some prescription medications that have potential for abuse or dependence. Ok...this act also helps families dispose of drugs that belonged to deceased relatives. Basically, it gives Americans more options to safely get rid of medical products they no longer need.

However, we still need more safe, and widely available disposal options for consumers. For now, we continue to work with our federal partners at the DEA and the Environmental Protection Agency to make sure that our recommendations align and to promote existing safe disposal options.

What else do you think needs to be done to encourage consumers to better dispose of outdated and unused medicine?

Well, from an agency standpoint, one goal is to educate consumers about the risks of leaving certain unused medicines in the home. Then we need to provide information to consumers on how to dispose of certain unused medicines, and explain the agency's recommendations for medicine disposal. We do this by periodically evaluating our disposal recommendations and ensuring that our web pages reflect the most up-to-date information possible.

Overall, I think we are making good progress to educate people about the importance of drug disposal and giving them tools to do it. Of course more can be done – but so far, I'm encouraged by the results I have seen. I'm confident that efforts from FDA, its federal partners and, most importantly, consumers will continue and together we'll be able to reduce medicine-related accidents in the home.

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Related Information

- **Disposal of Unused Medicines: What You Should Know (/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm)**
- **DEA's National Drug Take-Back Day (http://www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html)**
- **Medication Disposal: Questions and Answers (/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186188.htm)**

- Search for a DEA-authorized collection site (https://www.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1)
- Secure and Responsible Drug Disposal Act of 2010 (http://www.deadiversion.usdoj.gov/drug_disposal/non_registrant/s_3397.pdf)

Resources for You

- More CDER Conversations (/Drugs/NewsEvents/ucm420323.htm)

More in News & Events (/Drugs/NewsEvents/default.htm)

CDER Conversations (/Drugs/NewsEvents/ucm416430.htm)

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6 Questions You Should Ask Your Pharmacist

By Dr. Sanjay Gupta

Filling prescriptions is just one of the services the drugstore offers.

The local pharmacist can be a key member of your healthcare team. Terry Vine/Corbis

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One of the key members of your healthcare team is someone you probably have scarcely spoken to — your local pharmacist. Many people think a pharmacist is strictly someone who dispenses drugs as prescribed by a doctor, but pharmacists offer a wide range of patient care services.

“Pharmacists are able to see a whole picture around a patient’s medications that maybe clinicians are unable to know about,” says Scott A. Fields, MD, MHA, professor and vice chair of the department of family medicine at Oregon Health & Science University (OHSU) School of Medicine.

A survey of 5,200 licensed pharmacists in the United States found that less than half their working time was spent filling prescriptions. Six out of 10 pharmacists provide medication therapy management (MTM) which, as defined by the American Pharmacists Association, includes “medication therapy reviews, pharmacotherapy consults, anticoagulation management, immunizations, health and wellness programs, and many other clinical services.”

Easier, More Frequent Access

The 2014 National Pharmacist Workforce Survey shows that patients have greater access to these pharmacist-led services in various healthcare settings. Nearly half of pharmacists at chain drugstores and 57 percent of pharmacists in supermarket-based locations reported offering health screenings and immunizations.

“Patients on average see pharmacists three to 10 times as frequently as they see doctors,” says Brad Tice, PharmD, product leader for medication therapy management at Cardinal Health, a Dublin, Ohio-based healthcare services company. “So this dialogue between a pharmacist and a patient can be especially important for a patient’s overall healthcare.”

Yen Pham, RPh, director of pharmacy services at OHSU, agrees. “Quite often, we are the most accessible healthcare provider for patients,” Pham says.

Helping Patient Adherence

Pharmacists can play a pivotal role in patients’ adherence to treatment and medication guidelines, as shown in a study published April 14 in the Journal of the American Medical Association (JAMA).

Researchers found that patients with atrial fibrillation who were prescribed a new type of blood thinner were more likely to take the medication correctly and not miss doses when a pharmacist was closely involved in their care. The study specifically points to the benefits of “pharmacist-driven patient education” and “pharmacist-led adverse event and adherence monitoring.”

RELATED: OTC Drug Dangers You Should Know About

Pharmacists in the study offered “a high level of scrutiny and review to make sure patients were getting the drugs,” says study co-author Mintu Turakhia, MD, assistant professor of medicine at the Stanford University School of Medicine, in a statement. “There was a lot of consideration of the dose, interaction with chronic kidney disease, and review to make sure that patients should be getting these drugs.”

Come Prepared

Whether you’re seeing the pharmacist about a new prescription or a refill, prepare your questions in advance. Here are some suggestions:

1. **Is there a generic version of the prescribed drug?** A pharmacist can advise you if there is a generic option that is less expensive than a brand-name drug. “The key difference between generic and brand-name drugs is cost,” Pham says. “Generic medications have the same active ingredient as the brand name.” Not all generics are alike, however. As Pham points out, “some of the ‘fillers’ [inactive ingredients] may be different, and patients may prefer one brand over the other based on those.” In some cases, a generic substitute may not be available.
2. **Are there major side effects or special instructions?** Your doctor likely won’t go over every side effect when giving you a prescription, and the printed information about contraindications and side effects that comes with medication can be overwhelming. “They’ll list all these side effects, but there’s nothing that says how relevant they are to a particular patient and the other illnesses they have or medications they’re taking,” Dr. Fields says. Pham suggests asking the pharmacist specifically if there are any special instructions when taking medication, such as “take with or without food [or] stay out of the sun...”
3. **What if I miss a dose?** Accidentally missing a dose of medication is not unusual, and it’s not always cause for concern. But it’s important to know how you should handle the situation, should it happen.
4. **How should I store my medication?** Most medications should be kept in a dry area at room temperature, while others require refrigeration. Talk to the pharmacist about how to store drugs, as well as how to properly dispose of unused medications.

5. **Ask for a medication review.** If you're taking several drugs,Tice suggests asking the pharmacist to help you draw up a schedule to maximize their effectiveness and avoid interactions.
6. **Should I see a doctor?** Even if you're not having a prescription filled, you may want to consult the pharmacist about a condition you're treating with over-the-counter medications. "[The pharmacist] can ask specific questions like where is the condition, what does it feel like, how long has this been happening, and what medications have you tried," Pham says. "Pharmacists are a good resource to ask about common sense medical care."

HPV Facts For Moms
www.HPVInfo.com
Learn To Help Guard Your Teen
Against HPV-Related Diseases.

Working with your primary doctor and other healthcare specialists, the pharmacist can play a central role in "a system of care where [providers] have mutual and distinct responsibilities" in your treatment, Fields says.

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