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

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Ricardo Sanchez, Public Member, Chair
Debbie Veale, Licensee Member, Vice Chair
Ryan Brooks, Public Member
Amjad Khan, Public Member
Victor Law, Licensee Member

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

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

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

3. **Discussion and Consideration of a Proposal by the Chapman University School of Pharmacy Group to Require a Warning Label on Prescription Containers for Chemotherapy Medications**

   Background:
   At the March 2017 committee meeting, a group of students and faculty from Chapman University School of Pharmacy presented research and findings about safe handling and proper disposal of hazardous drugs – particularly oral chemotherapy medications. The group proposed requiring a standardized hazard symbol on prescription labels for NIOSH-designated hazardous drugs.

   The pharmacy students said they were working to educate and promote their proposal among pharmacies, drug manufacturers and other stakeholders. Committee members thanked the group for their presentation and their educational efforts, and the students were invited to submit an article about their research and label proposal for *The Script*.

   Update:
   The Chapman students and faculty submitted an article that is under review for publication in the next issue of *The Script*.

   At this meeting:
   Chapman representatives have requested an opportunity to address the committee about a possible proposal to require a warning label on prescription containers for chemotherapy medications. Afterward, the committee may wish to discuss and consider the proposal and decide on possible next steps.

4. **Discussion and Consideration of a Proposal for a Public Service Billboard Message and Related Communications Materials on Drug Abuse**

Background:
At the September 2016 committee meeting, the committee reviewed proposed concepts for a bulletin board message developed and provided by Mr. Brooks' firm, Outfront Media, to encourage parents to talk to their children about prescription drug abuse. The committee recommended that the board proceed with a proposal featuring drawings of pills around the message "Unattended Drugs are the Leading Killer of Kids." At the October 2016 board meeting, the board agreed with the committee's recommendation and voted to approved the billboard message.

Update:
Since the October board meeting, staff has been informed that Outfront Media will donate printing of five billboards in various locations around California – mostly likely two in Los Angeles, two in Northern California and one in the Central Valley.

Concurrently, board staff has been actively involved with a task force of state agencies working to develop an effective communication campaign to reduce prescription drug abuse in California. Board staff has received additional information regarding key factors in successful state agency-sponsored bill board campaigns as a result of participating in this task force and would like to address this with the committee.

At this meeting:
Board staff will be available to provide aspects of previously proven effective prevention messages for state agency-sponsored messages. The committee will have the opportunity to review and discuss samples of public service messages used in drug-abuse prevention campaigns in other states.

The committee may want to use or modify the current message for the board-approved billboard; select one of the messages used in other states; or recommend a new message. Copies of the billboard message approved by the board and public services messages used in other state campaigns are in **Attachment 1**.

5. **Discussion and Consideration of Safe Medication Transitions for Patients upon Discharge from Health Care Facilities, Consumer and Pharmacist Educational Opportunities, and Any Necessary Statutory or Regulatory Changes**

Background:
At the July 2017 board meeting, Dr. Rita Shane summarized a presentation on *The Safe Medication Transitions: Evidence-Based Solutions*. The presentation highlighted the benefits to patients when pharmacists and trained pharmacy technicians are involved in medication reconciliation as part of the admission and discharge of a patient from a hospital. Dr. Shane shared her recommendations for pharmacy staff to ensure the accuracy of medication lists at admission and discharge for high-risk patients. A copy of Dr. Shane's presentation is in **Attachment 2**.

The board adopted a recommendation from the Enforcement and Compounding Committee to refer the matter to the Communication and Public Education Committee to develop education materials for both consumers and pharmacists highlighting the importance of maintaining and conveying a medication history to health care providers in the hospital and understanding how medication lists may change at discharge.

At this meeting:
The committee will have the opportunity to provide direction to staff on how to proceed. One possible recommendation is to develop a smartphone app that consumers can load with information about their medications in case of emergency. In addition, staff can develop a Script article and website information about the importance of having a patient medication list available when a person goes to a hospital and how medications can change during and after a hospital stay.

6. **Discussion and Consideration of Educational Materials Regarding Drug Take-Back Collection Receptacles and Providing Public Access to Such Information**

Background:
At the July 2017 board meeting, staff reported for the board's information the summary of an audit by the State Auditor Agency on home-generated sharps and pharmaceutical waste services. The board directed the Communication and Public Education Committee to develop information for consumers about how to access drug take-back programs.

A copy of the audit summary is included in **Attachment 3**. Click here to read the full report online at the California State Auditor's website.

Update:
Staff is developing online forms that pharmacies can use to register collection receptacles with the board. Once they have been registered, addresses of receptacle locations will be posted on the website in a format that consumers can search by ZIP code. The website also contains links to the DEA's database of collection locations as well as information about DEA National Drug Take-Back Day events.

In addition, staff is developing a wallet-size information card for consumers explaining how to access drug take-back programs. The card could be posted on the website for printing and made available to be handed out in communities.

7. **Discussion and Consideration of Requests to Use Non-Board Versions of Naloxone Fact Sheet and Notice to Consumers**

Background:
At the March 2017 committee meeting, the committee reviewed a request from a pharmacy to use its own version of a fact sheet for patients receiving naloxone instead of the board's version. CCR section 1746.3(c)(6) requires pharmacists to use "a copy of the current naloxone fact sheet approved by the Board of Pharmacy."

The committee approved a recommendation to the board to change CCR section 1746.3(c)(6) to authorize the executive officer to approve substantially similar naloxone fact sheets for use by individual pharmacies. At its May 2017 meeting, the board adopted the committee's recommendation.

In a second, related matter, the executive officer received a request in June 2017 to allow a pharmacy to use its own version of the Notice to Consumers instead of the board's version. CCR section 1707.6(a) requires pharmacies to use "the standardized poster sized notice provided or made available to the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval."

Copies of the board's versions and non-board versions of the naloxone fact sheet and the Notice to Consumers are in **Attachment 4**.

Update:
Staff has drafted a rulemaking to amend CCR section 1746.3(c)(6) to authorize the executive officer to approve substantially similar naloxone fact sheets. The rulemaking is undergoing pre-review by the Department of Consumer Affairs.

Meanwhile, the executive officer has invited an informal committee of public information officers to compare the board's versions and the non-board versions of the naloxone fact sheet and the Notice to Consumers side by side, and to advise the executive officer on the effectiveness and readability of the non-board versions.

8. **Discussion and Consideration of the National Association of Boards of Pharmacy (NABP) Report on *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: August 2017***

A review by the National Association of Boards of Pharmacy (NABP) of 108 so-called "Canadian" pharmacy websites found that 74 percent of them get their drugs from outside Canada. Half of the websites got their drugs from India or a combination of other countries where counterfeit products are known to originate. In addition, none of the websites required consumers to submit a valid prescription.

Since 2014, NABP has partnered with Canadian regulators to verify online pharmacies located or doing business in Canada as part of NABP's .Pharmacy Verified Websites Program, which helps consumers identify safe and lawful internet pharmacies. The California State Board of Pharmacy has been an active participant in the creation and development of .pharmacy as a top-level domain operated by NABP for use by approved pharmacy websites.

This information is provided for the committee's information. Copies of the NABP report and a press release are in **Attachment 5**.

9. **Update and Discussion of Communication and Public Education Activities by Board Staff**

a. **Communication Plan for Consumers and Licensees**

Background:
At the March 2017 committee meeting, the committee approved a communication plan in accordance with the board's Strategic Plan. A copy of the updated communication plan is in **Attachment 6.**

Update:
Since the March 2017 committee meeting, staff has performed specific activities in furtherance of the Strategic Plan goal to "(educate) consumers, licensees and stakeholders about the practice and regulation of the profession," including:
- Created a calendar on the website homepage and meeting page listing board and committee meetings and training events.
- Redesigned *The Script* with a clean, modern look.
- Established an easy online process for licensees to register their email addresses with the board.
- Sponsored major training events for pharmacists in partnership with the DEA in San Diego, Sacramento and Claremont.
- Established online list of authorized distributors of nonprescription diabetes test devices, as required by AB 602.
- Wrote articles for *The Script*, subscriber alerts and online announcements about important new regulations, including drug take-back programs, self-assessment forms, new fees, travel medications, and prescription labels
- Emailed alerts reminding licensees about the board's naloxone protocol.
- Posted online announcements and subscriber alerts about vaccination regulations and changes to the California Immunization Registry (CAIR).

b. **The Script**

Staff is finalizing review of articles for the next issue of the newsletter, which is planned for publication in late September or early October.

c. **News Media**

The board's executive officer and public information officer participated in interviews or provided background information in response to the following media inquiries:
- **ABC News,** March 13: Gerry Wagschal, individuals selling unused fertility drugs.
- **LA Times,** March 16: Kim Christensen, UCLA Medical Center compounding pharmacy.
- **FiveThirtyEight,** March 23: Amelia Thomson-DeVeaux, self-administered hormonal contraception.
- **News 10,** April 6: Allison Ash, re investigation of fatal turmeric infusion.
- **KVIE,** April 20: Scott Syphax, the opioid epidemic in America.
- **Modesto Bee,** May 4: Erin Tracy, investigation of pharmacy technician Mona Chavarin.

- **KPCC,** May 11: Rebecca Plavin, IV turmeric and hydrogen peroxide medications.
- **Medscape Media News,** May 30: Alicia Ault, disciplinary trends during the opioid epidemic.
- **Bloomberg News,** May 30: Spencer Soper, Amazon getting into the pharmacy business.
- **Sacramento Bee,** June 28: Cathie Anderson, disposal of aid-in-dying medication.
- **Kaiser Health News,** July 17: Melissa Bailey, stats on opioids prescribed in hospices.
- **Valley Public Radio,** July 21: Kerry Klein, SB 493 and role of pharmacists in health care.
- **Valley Mirror,** Aug. 7: Tim Crews, consumer complaint against Walmart pharmacy technician in Willows.
- **KOVR,** Aug. 8: Tamara Christian, consumer complaint against Kaiser for requiring safety caps on mail order prescription bottles.
- **California Health Reports,** Aug. 14: Jessica Portner, impact of prescription label translation requirements in the Chinese community.
- **ABC 7 (San Francisco),** Aug. 29: Michael Finney, Costco pharmacies refusing prescriptions from non-Costco members.

d. Public Outreach

Past events
- April 3: Supervising Inspector Christine Acosta presented compounding regulations at Adventist Health in Roseville.
- April 20: Executive Officer Virginia Herold was interviewed about the opioid epidemic in America for the Studio Sacramento program on KVIE Channel 6.
- April 21: Supervising Inspector Christine Acosta presented on licensing and structural guidance for sterile compounding for a webinar at Western University.
- May 3: Supervising Inspector Christine Acosta presented compounding regulations for a Western University elective series.
- March 16: Executive Officer Virginia Herold spoke about SB 493 and upcoming pharmacy legislation at the annual legislative dinner of the Student Pharmacist Advocacy Coalition at University of the Pacific.
- April 3: Supervising Inspector Christina Acosta presented on sterile compounding regulations to about 30 to 40 management and pharmacists-in-charge at Adventist Health.
- April 21: Inspector Suzy Patell presented on sterile compounding regulations to about 60 in-patient pharmacy directors, oncology managers and others at South Bay-Long Beach Society of Health-System Pharmacists.
- April 21: Supervising Inspector Christine Acosta presented on planning, construction and compliance with sterile compounding regulations for webinar by California Hospital Association.

- May 3: Supervising Inspector Christina Acosta presented on the Board of Pharmacy for first- and second-year pharmacy students at Western University.
- May 31: Executive Officer Virginia Herold presented on the Board of Pharmacy to about 80 pharmacy management students at University of the Pacific.
- June 28: Inspector Anna Kalantar presented on sterile compounding regulations for San Gabriel Valley chapter of CSHP.
- Aug. 8: Supervising inspectors Anne Hunt and De'Bora White presented 2017 New Pharmacy Laws at the Competency Committee meeting.
- Aug. 24: Inspector Anna Kalantar presented on sterile compounding regulations for the San Gabriel Valley chapter of CSHP.
- Aug. 25: Executive Officer Virginia Herold presented on the Board of Pharmacy and its consumer protection activities to the California Health Advocates Senior Medication Patrol.
- Aug. 26: Executive Officer Virginia Herold presented on the new drug take-back regulations at California Northstate University.
- Aug. 26: Chief of Enforcement Tom Lennox presented on preventing pharmacy burglaries and robberies at California Northstate University.
- Aug. 26: Supervising Inspector Antony Ngondara presented on loss prevention in pharmacies and how to prepare for inspection by the Board of Pharmacy at California Northstate University.

Future events
- Sept. 27: Supervising Inspector Antony Ngondara speaking about the opioid crisis in rural California at annual meeting of the Rural County Representatives of California in South Lake Tahoe.
- Oct. 21, 2017: Joint board/DEA training on CURES, prescription drug abuse and drug diversion at Keck Graduate Institute in Claremont
- Nov. 7, 2017: Joint board/DEA training at the California Opioid Policy Summit in San Diego

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

Below are summaries of articles of possible interest to committee members. Click on the headlines to read the stories online.

[Pharmacists Are Now Poised To Ease Physician Shortage—If Only They Could Get Paid For It](#)
KVPR
Sept. 5, 2017
SB 493 has allowed pharmacists to greatly expand their role to become health care providers. The law sets out to make better use of what many say is the most accessible health care practitioner out there. After all, asks Virginia Herold, executive officer of the **California Board of Pharmacy**, what other practitioner can you see in your neighborhood, without an appointment, regardless of insurance? "I think their role in the health care field is tremendously underutilized," she says. "It's not just what I'm saying, it's part of what led to the enactment of SB 493."

['Smart' Pill Bottles Aren't Enough To Help The Medicine Go Down](#)
NPR
Aug. 22, 2017
Companies are now selling wireless "smart" pill bottles, Internet-linked devices aimed at reminding people to take their pills. But recent research suggests that actually changing that behavior may take more than an electronic nudge.

[Pharmacy chains make sweeping changes to prevent drug interactions](#)
Chicago Tribune
Aug. 9, 2017
CVS says it has upgraded its computer alert system at pharmacies nationwide to better protect patients. Walgreens says it has provided additional training for thousands of its pharmacists. Wal-Mart, Costco and Kmart say they have taken similar safety steps since a Tribune investigation exposed how pharmacies often failed to warn patients about deadly drug combinations

[A growing number of people make mistakes when they take their medication](#)
Washington Post
July 16, 2017
More Americans are getting sick from making medication mistakes at home, a new study finds. The most common errors included taking the wrong medication or an incorrect dose, or accidentally taking or giving medications twice in the same day when they were supposed to be taken only once.

[Updating drug labels would greatly help patients — but few companies do it](#)
STAT
July 11, 2017
Do you ever look at the labels of the prescription medications you take? There's a good chance that these labels are out of date and lacking essential new information for appropriate use and safety. Many labels have fallen out of date, posing a serious public health problem.

11. **Future Meeting Dates in 2017 and 2018**

- Dec. 13, 2017
- Jan. 31, 2018
- April 25, 2018
- July 11, 2018
- Oct. 11, 2018

Attachment 1

Take Back Your Meds (WA)

Lock Your Meds Idaho

She gets her hair from her mom.

Her eyes from her dad.

And her drugs from her grandma's medicine cabinet.

BE AWARE. DON'T SHARE.

Billboards

Look. Monitor. Take Back. (ND)

Hope is Here (DE)

Attachment 2

Safe Medication Transitions:
Evidence-Based Solutions

1.3 million people injured by medication errors[1]

Up to 67 % patients have errors on medication lists[2]

14%

Error
No Error

86%

20 % of readmissions are medication-related[3]

Admission → **Inpatient** → **Discharge** → **Post-Discharge**

Admission

Problem

- 1 in 5 hospitalizations result from treatment complications, of which, 1/2 are medication-related[4]
- 7.4 errors per medication list[5]
- 5.3% of patients have accurate medication histories

Evidence

- 20.3% of pharmacist medication histories had at least 1 postoperative medication discrepancy related to home medications compared to 40.2% of the nurse-conducted medication histories[9]
- Pharmacist-conducted medication reconciliations resulted in 16% reduction in all visits to the hospital and a 47% reduction in visits to the emergency department. Drug–related readmissions were reduced by 80%[14]

Inpatient

Problem

- During hospitalization, medication errors occur in up to 50% of adult and 75% of pediatric patients[6]
- Over 1/3 of hospitalized patients had medication order errors - 85% originated with the medication history[7]

Evidence

- Clinical pharmacy services reduced prevalence of discrepancies by 40% compared to usual care. [15]
- For patients on complex medication regimens,i.e., 10 medications per day or 5 new medications started, pharmacists reduced number of medications by 12% and number of doses by 19%. [25]

Discharge

Problem

- ↑ # of medications at discharge results in a statistically higher rate of readmissions; >6 discharge medications predicts 30-day readmissions
- 80% of patients have at least 1 medication discrepancy at discharge.[9]

Evidence

- Pharmacists identified discrepancies in 49% of pts at discharge; preventable ADEs occurred in 1% of patients who received discharge education and follow up compared vs 11% of patients who received usual care[16]
- Discharge medication lists completed by pharmacists resulted in an absolute risk reduction of 46.5% when compared to usual care.[17]

Post-Discharge

Problem

-Post-discharge adverse drug events occur in up to 11% of patients, of which 1/3 are preventable[10]
-52% of patients had > 1 clinically important error
- Up to 90% of hospital-to-SNF discharge summaries contained one or more DRPs[11,12,13]

Evidence

-Post-discharge pharmacist follow up with discharge education reduced readmissions and ED visits vs usual care (39% to 24.8%).[18]
- Post-discharge pharmacist reconciliation and education reduced readmissions and ED visits vs usual care (0% vs 40.5%).[19]

Safe Medication Transitions: Evidence-Based Solutions

Medication discrepancies or errors occur in up to 70% of patients at admission or discharge contributing to adverse drug events, ED visits and readmissions. Evidence supports that pharmacists and trained technicians reduce these errors and adverse outcomes.

℞ Pharmacist

- A study comparing medication reconciliation performed by pharmacists to ED providers found that pharmacists identified 1096 home medications compared with 817 home medications identified by ED providers. 78% of medications documented by ED providers were incomplete and were supplemented with information by the pharmacists.[21]
- Patients who received pharmacist medication reconciliation and counseling had a readmission rate of 16.8% vs the usual care arm of 26% (p=0.006).[24]
- In a randomized trial, pharmacists provided medication counseling, reconciliation at admission and discharge, and a follow up phone call after discharge as part of a care coordination bundle. Patients in the intervention arm had a reduction in 30 day readmissions (10% vs 38.1%, p=0.04) and time to first readmission or ED visit (36.2 days vs 15.7 days, p=0.05).[27]
- Another study found that patients who received discharge medications and follow up phone calls by pharmacists had nearly half the risk of readmission as those who did not receive a pharmacist phone call (5.0% vs 9.5%, p<0.05).[25]
- Post-discharge pharmacist follow up can reduce readmission from skilled nursing facilities by 25%. [20]

Pharmacy Technician

- In the ED, a pre-post study found that pharmacy technicians created an accurate medication history 88% of the time compared to 57% of the time when nurses completed the history (p<0.0001).[22] Nurses were 7.5 times as likely to make an error than pharmacy technicians (p<0.0001).
- Another study found that nurses created an accurate medication list only 14% of the time compared to pharmacy technicians who created an accurate list 94.4% of the time (p<0.0001).[23]
- A randomized controlled study to evaluate the accuracy of admitting medication histories performed by pharmacists, pharmacist-supervised pharmacy technicians (PSPTs) and usual care (nurses, physicians) demonstrated a statistically significant reduction in admitting medication history errors performed by pharmacists and PSPTs vs usual care(p<0.0001). There was also a significant reduction in the severity of errors intercepted (p<0.0001).[5]

Recommendation: For high risk patients, pharmacy staff will ensure the accuracy of the medication list at admission and discharge

References-pending updates

1. Center for Drug Evaluation and Research. (2016, October 10). Medication Errors - Medication Error Reports. Retrieved April 18, 2017, from https://www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm080629.htm

2. Tam VC, Knowles SR, Cornish PL, et al. Frequency, type and clinical importance of medication history errors at admission to hospital: a systematic review. *Canadian Medical Association Journal.* 2005; 173(5):510-5.

3. Angamo MT, Leanne C, Curtain CM, et al. Adverse-Drug-Reaction-Related Hospitalisations in Developed and Developing Countries: A Review of Prevalence and Contributing Factors. *Drug Safety*. 2016;39(9): 847-57.

4. Magdelijns FJH, Pijpers E, Rouhl RPW, et al. Acute Hospital Admissions Because of Health Care-Related Adverse Events: A Retrospective Study of 5 Specialist Departments. *J Am Med Dir Assoc*. 2015;16(12):1055-1061. doi:10.1016/j.jamda.2015.06.019.

5. Pevnick JM, Nguyen CB, Jackevicius CA, Palmer KA, Shane R, Bresee C, Bear ME, Zaitseva O, Seki D, Desai A, Doyle B, Bell DS. Minimizing Medication Histories Errors for Patients Admitted to the Hospital Through the Emergency Department: A Three-Arm Pragmatic Randomized Controlled Trial of Adding Admission Medication History Interviews by Pharmacists or Pharmacist-Supervised Pharmacy Technicians to Usual Care. J Patient-Centered Res Rev.2015;2:93

6. Lewis PJ, Dornan T, Taylor D, Tully MP, Wass V, Ashcroft DM. Prevalence, incidence and nature of prescribing errors in hospital inpatients: a systematic review. Drug Saf. 2009;32(5):379-389. http://www.ncbi.nlm.nih.gov/pubmed/19419233. Accessed January 17, 2017.

7. Gleason KM, McDaniel MR, Feinglass J, et al. Results of the medications at transitions and clinical handoffs (MATCH) study: an analysis of medication reconciliation errors and risk factors at hospital admission. J Gen Intern Med 2010;25:441–7.

8. Salvi F, Marchetti A, D'Angelo F, Boemi M, Lattanzio F, Cherubini A. Adverse Drug Events as a Cause of Hospitalization in Older Adults. Drug Saf. 2012;35(S1):29-45. doi:10.1007/BF03319101.

9. Kwan JL, Lo L, Sampson M, Shojania KG. Medication Reconciliation During Transitions of Care as a Patient Safety Strategy. *Ann Intern Med*. 2013;158(5_Part_2):397. doi:10.7326/0003-4819-158-5-201303051-00006.

10. Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. Adverse drug events occurring following hospital discharge. J Gen Intern Med. 2005;20(4):317-323. doi:10.1111/j.1525-1497.2005.30390.x

11.. Tjia J, Bonner A, Briesacher BA, McGee S, Terrill E, Miller K. Medication discrepancies upon hospital to skilled nursing facility transitions. J Gen Intern Med. 2009;24(5):630e635

12. Kerstenetsky L, Birschbach MJ, Beach KF, Hager DR, Kennelty KA. Improving medication information transfer between hospitals, skilled-nursing facilities, and long-term-care pharmacies for hospital discharge transitions of care: A targeted needs assessment using the Intervention Mapping framework. Res Social Adm Pharm. 2017 Apr 7. pii: S1551-7411(16)30374-6. doi: 10.1016/j.sapharm.2016.12.013.

13. McGaw J, Conner DA, Delate TM, Chester EA, Barnes CA. A multidisciplinary approach to transition care: a patient safety innovation study. Perm J. 2007 Fall;11(4):4-9.

14. Gillespie U, Alassaad A, Henrohn D, et al. A comprehensive pharmacist intervention to reduce morbidity in patients 80 years or older: a randomized controlled trial. *Arch Intern Med.* 2009;169(9):894-900.

15. Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL. Clinical Pharmacists and Inpatient Medical CareA Systematic Review. *Arch Intern Med.* 2006;166(9):955-964. doi:10.1001/archinte.166.9.955

16. Schnipper JL, Kirwin JL, Cotugno MC, Wahlstrom SA, Brown BA, Tarvin E, Kachalia A, Horng M, Roy CL, McKean SC, Bates DW. Role of Pharmacist Counseling in Preventing Adverse Drug Events After Hospitalization. *Arch Intern Med.* 2006;166(5):565-571. doi:10.1001/archinte.166.5.565

17. Tong, E. Y., Roman, C. P., Mitra, B., Yip, G. S., Gibbs, H., Newnham, H. H., … Dooley, M. J. (2017). Reducing medication errors in hospital discharge summaries: a randomised controlled trial. *The Medical Journal of Australia*, *206*(1), 36–39. http://doi.org/10.5694/mja16.00628

18. Phatak A, Prusi R, Ward B, Hansen LO, Williams MV, Vetter E, Chapman N, Postelnick M, Pharmacist Impact on Transitional Care. *J. Hosp. Med* 2016;1;39-44. doi:10.1002/jhm.2493

19. Hawes, E. M., Maxwell, W. D., White, S. F., Mangun, J., & Lin, F. C. (2014). Impact of an outpatient pharmacist intervention on medication discrepancies and health care resource utilization in posthospitalization care transitions. *Journal of primary care & community health*, *5*(1), 14-18. DOI: 10.1177/2150131913502489

20. Rosen B, Nguyen C, Hart K, Shane R. Mitigating the Risks of Adverse Medication Events During Care Transitions from Hospital to Skilled Nursing Facilities [abstract]. Journal of Hospital Medicine. 2014; 9 (suppl 2). http://www.shmabstracts.com/abstract/mitigating-the-risks-of-adverse-medication-events-during-care-transitions-from-hospital-to-skilled-nursing-facilities/. Accessed May 9, 2017.

21. Carter MK, Allin DM, Scott LA, Grauer D. Pharmacist-acquired medication histories in a university hospital emergency department. *Am J Health-Syst Pharm*. 2006; 63:2500-2503.

22. Hart C, Price C, Grazioe G, Grey J. A program using pharmacy technicians to collect medication histories in the emergency department. P T. 2015; 40(1): 56-61.

23. Markovic M, Mathis AS, Ghin HL, Gardiner M, Fahim G. A Comparison of Medication Histories Obtained by a Pharmacy Technician Versus Nurses in the Emergency Department. P T. 2017; 42(1):41-46.

24. Pal A, Babbott S, Wilkinson ST. Can the targeted use of a discharge pharmacist significantly decrease 30-day readmissions? Hosp Pharm 2013;48:380–8

25. Kirkham, H. S., Clark, B. L., Paynter, J., Lewis, G. H., & Duncan, I. (2014). The effect of a collaborative pharmacist–hospital care transition program on the likelihood of 30-day readmission. American Journal of Health-System Pharmacy, 71(9). Retrieved from http://www.ajhp.org/content/71/9/739.long

26. Calabrese, A. T., Cholka, K., Lenhart, S. E., McCarty, B., Zewe, G., Sunseri, D., … Kapoor, W. (2003). Pharmacist involvement in a multidisciplinary inpatient medication education program. *Am J Health-Syst Pharm—Vol*, *60*, 1012–1018. Retrieved from http://www.ajhp.org/content/ajhp/60/10/1012.full.pdf

27. Koehler BE, Richter KM, Youngblood L et al. Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. J Hosp Med 2009;4:211–18.

http://www.leapfroggroup.org/sites/default/files/Files/Medication%20Reconciliation%20Fact%20Sheet_2017.pdf accessed July 4, 2017.

Safe Medication Transitions:

Improving Safety of Medication Lists Using Evidence-Based Solutions

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BACKGROUND

- **Medication discrepancies occur in up to 70% of patients at hospital admission or discharge.** (Leapfrog Hospital Survey Fact Sheet 3/17)

- Medication histories or lists are entered into electronic health records (EHR) by a variety of individuals with varying knowledge about medications across different healthcare settings

- These lists are used to create hospital medication orders and discharge prescriptions resulting in continuation of inaccurate and/or incorrect medications

- Medication reconciliation cannot be accurate if medication lists are inaccurate

  - Medication reconciliation is required by The Joint Commission and the Center for Medicare/Medicaid Services as part of Meaningful Use

75% of hospital executives concerned patient medication data are incomplete, inaccurate (Becker's Hospital Review, 6/22/17)*

Top 3 concerns

➤ Inconsistent practices across departments, disciplines and shifts (59.7%)

➤ Patients being discharged with an incorrect medication list (47.9%)

➤ Difficulty importing external medication history, including home medications (46.2%)

*Survey of 120 administrators

CURRENT SITUATION

➡ Absence of designated "owner" to ensure accuracy of lists results in redundant work and rework by nurses, physicians and pharmacists

➡ Nurses indicate that obtaining a medication list for a complex patient can take an hour

➡ Physicians don't have sufficient time to obtain an accurate list and order based on previous medications listed

➡ Lack of defined process puts patient at risk for significant harm during hospitalization and at discharge

SOURCES OF MEDICATION LISTS

Errors introduced in any of these settings can become "hardwired" into the pt record

Home

· Pt
· Family members
· Caregivers
· Home Health nurses

Outpatient Settings

- Certified medical assistants
- Physicians
- Community pharmacies
- Patients

ED/Hospital

- Nurses
- Physicians
- Pharmacists
- Pharmacy technicians
- Pharmacy residents, students

Skilled Nursing Facility

- Nurses
- Physicians

Medications Reconciliation

Medications prior to Admission	Discharge Medications	Change	Reason/Comment
Aspirin (Ethics Enteric Coated Aspirin) 100mg Enteric coated Tablets mane	–	Stopped	Patient now on warfarin
Dipyridamole (Pytazen SR) 150mg Sustained Release Tablets twice daily	–	Stopped	Pt now on warfarin
Simvastatin (Arrow Simva) 20mg Tablets at night	Simvastatin (Arrow Simva) 40mg Tablets at night 1 month, cc monthly (Script)	Changed	Optimise cholesterol lowering
Felodipine (Felo ER) 10mg Extended Release Tablets mane	Felodipine (Felo ER) 5mg Extended Release Tablets mane 1 month, cc monthly (Script)	Changed	BP drop during admission
Allopurinol (Apo–Allopurinol) 100mg Tablets once daily	Allopurinol (Apo–Allopurinol) 100mg Tablets once daily 1 month, cc monthly (Script)	Continued	
–	Metoprolol succinate (AFT–Metoprolol CR) 23.75mg Controlled Release Tablets PO OD 1 month, cc monthly (Script)	Started	Regular med
–	Warfarin sodium (Marevan) 1mg Tablets As per INR 1 month (Script)	Started	AF

Remove	1 tablet nocte with food ☑ Script ☐ Close Control	▶ Edit	
Remove	Enalapril maleate (Multichem Enalapril) 10mg Tablets Take 1 tablet BD ☑ Script ☐ Close Control	Started ▶ Edit	Changed from Captopril due to rash
⊕ Add Medication Prior to Admission	⊕ Add Discharge Medication		

Medications Prior to Admission populated from "Medication History Form" finalized by Dr Anabel ROSE (Pharmacist) 2 days ago.

CMS 2012-MEANINGFUL USE

- Any licensed healthcare professional and *credentialed medical assistants*, can enter orders into the medical record

- Credentialed medical assistants are:

  - Certified medical assistants-graduates of an accredited medical assisting program

    - Training requirements: 2-6 units of pharmacology training. (based on 4 California programs)

    - 2 yr experience

  - Medical assistants (who are not certified) who have completed a required order entry course

1. https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Stage2_EPCore_1_CPOE_MedicationOrders.pdf,accessed 9/20/16
2. http://aama-ntl.org/docs/default-source/default-document-library/how-medical-assistants-meet-cms-requirement.pdf?sfvrsn=2, accessed 9/29/16

MEDICAL ASSISTANTS
Requirements for Order Entry
into Electronic Health Records

- 2 yr recent experience in a health care facility under the supervision of a licensed health care provider (LHP)

- Application signed by supervising LHP attesting proficiency in areas including pharmacology

- Completion of Assessment-Based Recognition in Order Entry (ABR-OE) Qualifying Courses-5 courses

  - Foundation of Order Entry in Health Care

  - How Medical Assistants Can Meet CMS Requirements

  - Medical Records: The Legal Document

  - Clinical Laboratory: Keeping Up With CLIA

  - Anatomy, Physiology and Disease Screenings

https://learning.aama-ntl.org/Public/Catalog/Home.aspx, accessed 7/8/17

ADMISSION

1.3 million people injured by medication errors annually

Problem

➡ 82% of patients >65 years old have at least 1 discrepancy on their medication list

➡ 7.4 errors per medication list in high risk patients

➡ 5.3% of patients on >5 medications have accurate lists

Minimizing Errors in Medication Histories Obtained at Hospital Admission

Randomized Controlled Trial

- Usual Care: MD or RN

- Pharmacist

- Trained Technician

- **High Risk Patients* admitted via Emergency Dept**

- **300 pt enrolled; 283 in final analysis**

- **Median age: ~76 (range: 50-83)**

- **Median # of meds" 14 (range; 10-19)**

*High risk:≥ 10 chronic meds, Acute MI, CHF, admitted from SNF, on anticoagulants, insulin, narrow therapeutic drugs, history of transplant

Minimizing Errors in Medication Histories **Obtained** at Hospital Admission
Randomized Controlled Trial

- Pt histories independently evaluated within 24 hr by gold standard pharmacist (proven study methodology)

- Gold standard pharmacist took patient history, compared with history taken, determined # errors and severity of errors:

  - ➡ Low capacity for harm: vitamin, laxative

  - ➡ Serious: beta blocker for hypertension

  - ➡ Life Threatening: transplant drug

Results: **Number** of Errors
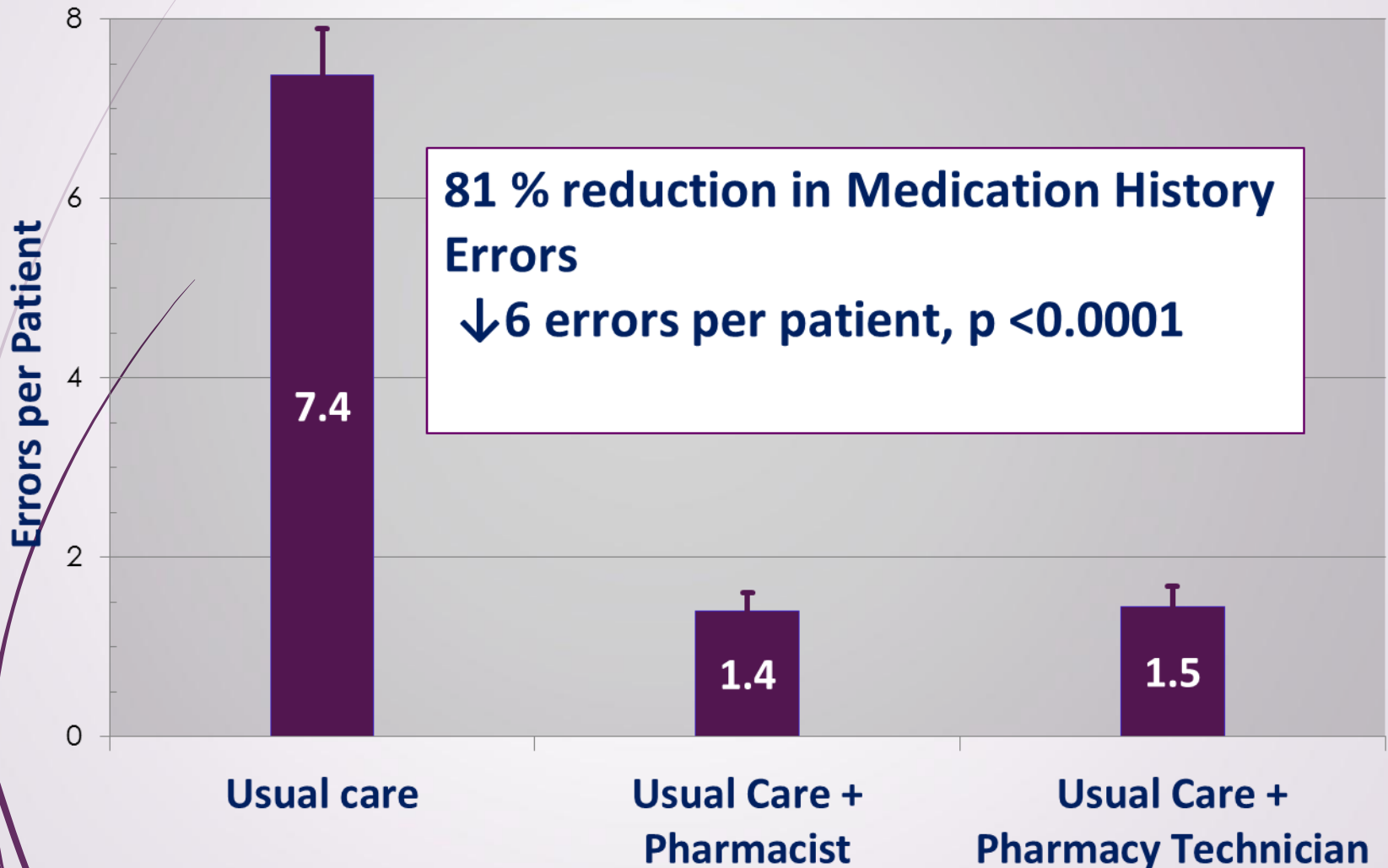
Results: **Severity** of Errors

82% reduction in severity of medication history errors
↓17/per patient, p <0.0001
- 2 Life Threatening Errors or
- 4 Serious Errors or
- 17 Low-Capacity for Harm
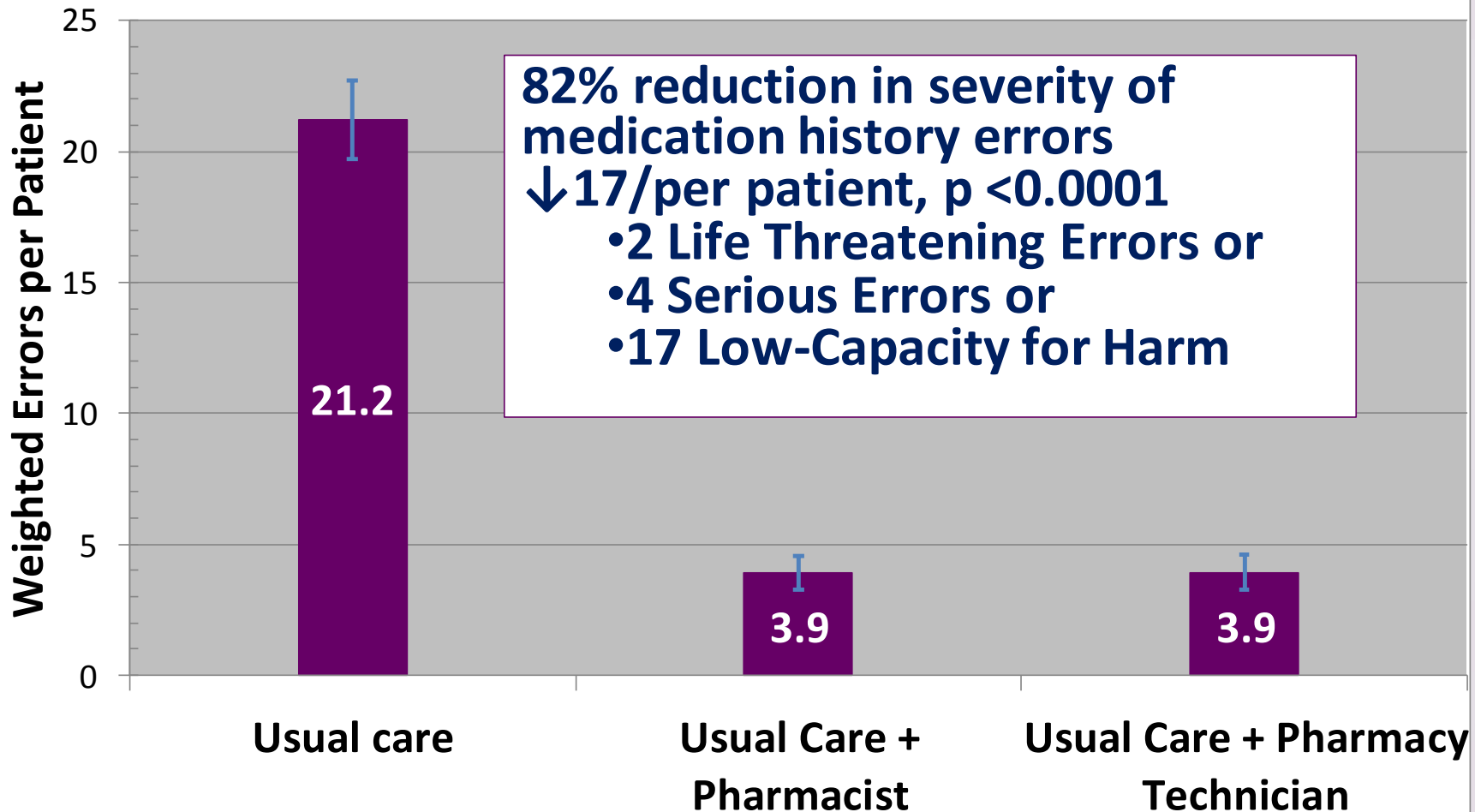
Examples of Admission Drug-Related Problems (DRPs) Resolved

Admission Med List	Drug-Related Problem Identified and Resolved	DRP Type	Capacity for Harm
Metho-trexate	DRP: Ordered as 10 mg daily Finding: Order was weekly	Wrong fre-quency	Life-threatening Pancytopenia
Keppra®	DRP: Ordered as 100mg po BID Finding: Pt reports taking 1000mg mg BID.	Wrong Dose	Significant Seizures
Amlodipine	DRP: amlodipine 10mg daily Finding: MD reordered. Family indicated pt stopped taking due to swelling-allergic reaction	Allergy	Life-threatening-Significant Anaphylaxis

EVIDENCE

- 20.3% of pharmacist medication histories had at least 1 postoperative medication discrepancy related to home medications compared to 40.2% of the nurse-conducted medication histories

- Pharmacist-conducted medication reconciliations resulted in 16% reduction in all visits to the hospital and a 47% reduction in visits to the emergency department. Drug–related readmissions were reduced by 80%

INPATIENT

Up to 67% of patients have errors on medication lists

Problem

- During hospitalization, medication errors occur in up to 50% of adult and 75% of pediatric patients

- Over 1/3 of hospitalized patients had medication order errors - 85% originated with the medication history

- Up to 59% of medication history errors can cause harm

EVIDENCE

- Hospital pharmacists reduce me ("*How To Make Hospitals Less Dead*

- Clinical pharmacists intercept errors originating from inaccur lists

- At discharge, uncorrected err discharge prescriptions

In the Zone on the Web

THE WALL STREET JOURNAL.

How to Make Hospitals Less Deadly

Doctors' errors annually kill hundreds of thousands of Americans. Here are five reforms that would bring down the death toll.

• **Bring in the pharmacists.** A breakthrough in 20th-century care was allowing nurses to make rounds with doctors. Now it's time to include pharmacists. Doctors have only glancing knowledge of how an ever-multiplying number of drugs interact with diet, age, disease, body type and each other. Erroneous medication orders kill thousands of Americans annually, according to the Journal of the American Medical Association. Putting pharmacists in patient areas decreased errors by 45%, and cut errors leading to death or severe harm by 94%, according to a 2001 study.

*Wall Street Journal, May 17, 2016

DISCHARGE

Problem

- Up to 80% of patients have at least one medication list discrepancy upon leaving the hospital

- ↑ # of medications at discharge results in a statistically higher rate of readmissions

- >6 medications at discharge is independently associated with 30-day readmissions   (26% higher likelihood)

EVIDENCE

➡ Pharmacists identified preventable ADEs in 1% of patients who received discharge education and follow up compared with 11% of patients who did not receive these benefits.

➡ Discharge medication lists completed by pharmacists resulted in an absolute risk reduction of 46.5% when compared to usual care.

POST-DISCHARGE

20 % of readmissions are medication-related

Problem

14%

86%
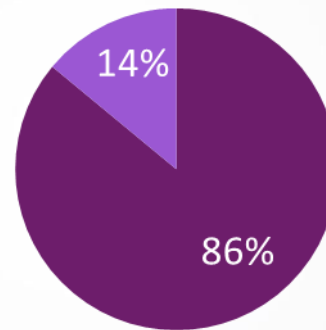
- Errors
- No Errors

➡ Post-discharge adverse drug events occur in up to 19% of patients, of which 1/3 to 2/3 are preventable

➡ Up to 90% of hospital-to-SNF discharge summaries contained one or more DRPs

EVIDENCE

- ➡ Post-discharge pharmacist follow up with discharge education reduced readmissions and ED visits vs usual care (39% to 24.8%).

- ➡ - Post-discharge pharmacist reconciliation and education reduced readmissions and ED visits vs usual care (0% vs 40.5%).

- ➡ Post-discharge pharmacist follow up can reduce readmission from skilled nursing facility by 25%.

Pharmacy Technician

- In the ED, a pre-post study found that pharmacy technicians created an accurate medication history 88% of the time compared to 57% of the time when nurses completed the history (p<0.0001).

  - Nurses were 7.5 times as likely to make an error than pharmacy technicians (p<0.0001).

- Nurses created an accurate medication list only 14% of the time compared to pharmacy technicians who created an accurate list 94.4% of the time (p<0.0001).

R_xPharmacist

- Pharmacists identified 1096 home medications compared with 817 home medications identified by ED providers. 78% of medications documented by ED providers were incomplete.

- Pharmacists involved in transitions of care roles significantly reduce readmissions compared to usual care

  Medication histories, discharge counseling, review of discharge medication lists and post-discharge follow up

  ➡ Results

  ➢ Readmission rate 16.8% vs the usual care arm of 26% (p=0.006).

  ➢ Reduction in 30 day readmissions (10% vs 38.1%, p=0.04) and time to first readmission or ED visit (36.2 days vs 15.7 days, p=0.05).

  ➢ Reduction in 30-day readmissions (5.0% vs 9.5%, p<0.05).

SUMMARY

- Medication discrepancies or errors in medication lists occur in up to 70% of patients at admission or discharge contributing to adverse drug events, ED visits and readmissions.

- High risk patients are the most vulnerable for harm.

- Evidence supports that pharmacists and trained technicians reduce these errors and adverse outcomes.

- Having pharmacy staff perform medication histories supports the health care team by allowing nurses and physicians to focus on acute patient care needs.

Accurate medication list

↓

Increased accuracy of inpatient orders

↓

Increased accuracy of discharge prescriptions

Recommendation: For high risk patients, pharmacy staff will ensure the accuracy of the medication list at admission and discharge

Attachment 3

Home-Generated Sharps and Pharmaceutical Waste
By Designating a Lead Agency, the State Could Increase Proper Disposal

Summary

HIGHLIGHTS

Our review concerning home-generated sharps and pharmaceutical waste highlighted the following:

- The State has not assigned oversight responsibility to a specific state agency for the disposal of home-generated sharps and pharmaceutical waste.
- Consumers receive conflicting guidance regarding the proper disposal of sharps and pharmaceutical waste.
- The State does not maintain an accurate and accessible list of collection sites for sharps and pharmaceutical waste disposal.
- Because it already provides oversight for all state-managed solid waste-handling programs, CalRecycle may be best-positioned to oversee household pharmaceutical and sharps waste.
- California could improve its collection and disposal of home-generated sharps and pharmaceutical waste by adopting programs and practices that other states and countries use.

Results in Brief

When consumers improperly dispose of home-generated sharps and pharmaceutical waste, the waste can pose an unnecessary risk to others and to the environment. Sharps waste—which consists of used needles, lancets, and other medical devices with sharp points or edges—can potentially result in disease transmission. On the other hand, pharmaceutical waste—which consists of prescription and over-the-counter medications—can harm water quality or be misused. Agencies that provide advice offer consumers different, and sometimes conflicting, guidance about how and where to dispose of these types of waste. For example, some agencies recommend that consumers use official collection programs to dispose of pharmaceutical waste, but others recommend placing it in the trash or flushing it down the toilet. Similarly, state agencies generally recommend that consumers dispose of home-generated sharps waste in approved disposal containers, but some federal agencies recommend putting this waste in heavy plastic containers, making it illegal to transport in California if the local enforcement agency has not approved the container. These inconsistencies may confuse

consumers, increasing the likelihood that they will dispose of home-generated sharps and pharmaceutical waste in unsafe or environmentally harmful ways.

Conflicting guidance regarding the disposal of sharps and pharmaceutical waste is in part the result of the fact that the State has not assigned oversight of this issue to a specific state agency. Rather, a number of different agencies have related responsibilities depending on how the waste is collected and processed. Specifically, the California Department of Resources Recycling and Recovery (CalRecycle), the California Department of Public Health (Public Health), the California State Board of Pharmacy, and the Department of Toxic Substances Control all play roles related to the processing of this waste. By placing oversight responsibility with a single agency, the State could ensure the creation of a unified educational campaign promoting consistent and proper disposal methods. We believe CalRecycle may be best-positioned to oversee household pharmaceutical and sharps waste because it already provides oversight for all state-managed solid waste-handling programs.

If the State assigned responsibility to a single agency, that agency could also help to ensure that all Californians have access to and awareness of collection sites and other means of sharps and pharmaceutical waste disposal. Although our analysis suggests that about 89 percent of consumers live within a 20-minute drive of sites for proper disposal, these consumers may not be aware of this access because no state agency maintains an accurate and comprehensive list of such sites. Both Public Health and CalRecycle maintain lists of collection sites; however, these lists are difficult to access and contain numerous errors. Further, our analysis suggests that about four million Californians may not live within 20 minutes of collection sites. An oversight entity could ensure that the State implements options to help these consumers, which might include subsidizing the use of mail-back containers to dispose of sharps and pharmaceutical waste.

California has more than sufficient capacity to process all of the State's home-generated sharps and pharmaceutical waste; however, laws and regulations discourage processing pharmaceutical waste within the State. In California, sharps are generally sterilized at one of the State's 18 medical waste facilities and then deposited in landfills. Home-generated sharps waste represents less than 1 percent of the available capacity of these facilities. If pharmaceutical waste includes controlled substances, the DEA requires collectors to ensure that such waste is rendered irretrievable, which usually means some form of incineration. Although three incinerators operate in the State that could dispose of pharmaceutical waste, government recommendations and legal requirements discourage these in-state incinerators from accepting pharmaceutical waste. Consequently, collection programs dispose of pharmaceutical waste by hauling it to out-of-state incinerators. Both the out-of-state and in-state incinerators have more than sufficient capacity to handle any future increases in the amount of the State's home-generated pharmaceutical waste.

California could improve its collection and disposal of home-generated sharps and pharmaceutical waste by adopting programs and practices that other states and countries use. For example, the state of New York requires all pharmacies to display that state's approved pharmaceutical disposal methods and requires all hospitals to accept household sharps for disposal. Canada uses extended producer responsibility programs (EPR programs) to assign the cost for disposal of pharmaceutical and sharps waste to the producers or manufacturers of the products, although in California these costs could ultimately be transferred to consumers through price increases. Several California counties have also begun implementing EPR

programs but have encountered delays, mainly due to the resistance of the sharps and pharmaceutical industries.

In addition, at the Legislature's request, in 2010 CalRecycle provided options for statewide pharmaceutical waste collection programs. Although we have concerns about three of the four options CalRecycle outlined, one of its proposed models generally aligns with our audit recommendations. Specifically, this option focuses on the Legislature's assigning oversight responsibility to a single state agency, which could then adopt regulations that might increase consumers' proper disposal of pharmaceutical waste.

Summary of Recommendations

To foster consumers' proper disposal of sharps and pharmaceutical waste, the Legislature should provide CalRecycle statutory oversight responsibility for home-generated sharps and pharmaceutical waste disposal and provide CalRecycle additional resources to the extent it can justify the need. This responsibility should include the following activities:

- Developing and implementing a public education campaign about home-generated sharps and pharmaceutical waste. CalRecycle should coordinate this campaign with local, state, and, to the extent possible, federal agencies to ensure consumers receive consistent guidance regarding proper disposal methods.
- Maintaining an up-to-date, well-publicized, and accessible statewide list of free sharps and pharmaceutical waste collection sites.
- Increasing consumer access to proper disposal sites in underserved areas.

To increase in-state options for processing California's home-generated pharmaceutical waste, the Legislature should consider expressly authorizing municipal solid waste incinerators to burn limited quantities of home-generated pharmaceutical waste, but only after considering environmental impacts.

To ensure consistency throughout the State, the Legislature should adopt standard requirements for counties to follow when implementing EPR programs. These requirements should limit any additional costs the programs may impose on consumers.

Agency Comments

Although we only have recommendations directed to the Legislature, we provided a draft redacted copy of our report to CalRecycle for review and comment because we are recommending that it become the lead state agency over the disposal of sharps and pharmaceutical waste. In its response, CalRecycle took issue with certain information in our report and it also expressed significant reluctance in taking on this leadership role.

Attachment 4

What is an opioid overdose?

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

TO AVOID AN ACCIDENTAL OPIOID OVERDOSE:

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

Now that you have naloxone…

Tell someone where it is and how to use it.

Common opioids include:

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

* Heroin is also an opioid.

For patient education, videos and additional materials, please visit

www.prescribetoprevent.org

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

2016

Opioid safety and how to use naloxone

A GUIDE FOR PATIENTS AND CAREGIVERS

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH
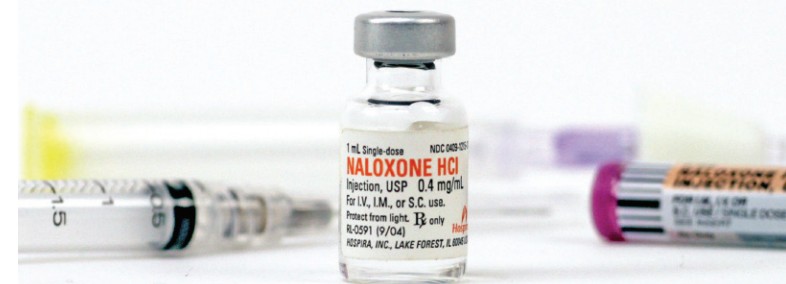
In case of overdose:

1 Check reponsiveness

Look for any of the following:

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

2 Call 911 and give naloxone

If no reaction in 3 minutes, give second naloxone dose

3 Do rescue breathing and/or chest compressions
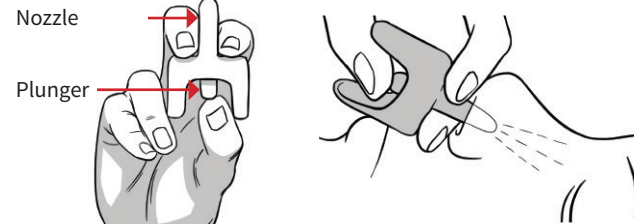
Follow 911 dispatcher instructions

>> STAY WITH PERSON UNTIL HELP ARRIVES.

How to give naloxone:

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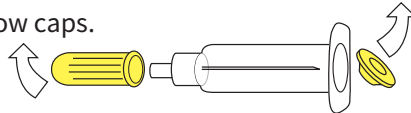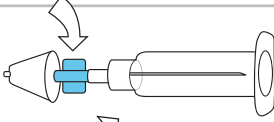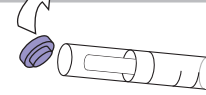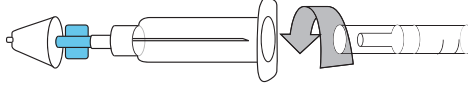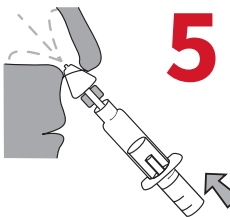
Nasal spray

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

Nozzle

Plunger

Auto-injector

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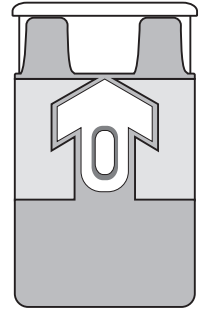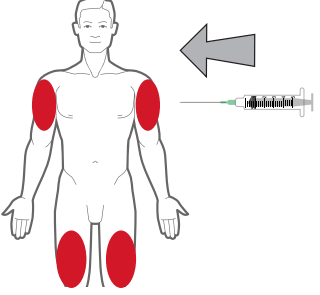
Nasal spray with assembly

This requires assembly. Follow the instructions below.

1 Take off yellow caps.

2 Screw on white cone.

3 Take purple cap off capsule of naloxone.

4 Gently screw capsule of naloxone into barrel of syringe.

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

Push to spray.

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

Injectable naloxone

This requires assembly. Follow the instructions below.

1 Remove cap from naloxone vial and uncover the needle.

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

fill to 1 ml

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

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

Naloxone Guide for Patients and Caregivers

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

What are opioids?

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

What is naloxone?

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

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

It is available for use during opioid emergency situations.

Common opioids include:

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

*Heroin is also an opioid.

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

How to Avoid an Accidental Overdose:

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

STEP 1. Recognizing an Opioid Overdose

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

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

STEP 2. Calling 9-1-1

When calling 9-1-1, it is important to share the following information:
1. Individual's breathing has stopped and they are unresponsive.
2. Exact location of the individual.
3. Whether or not naloxone has been given to the individual and if that helped.

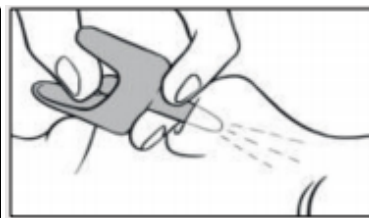### STEPS to respond to an Overdose:

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

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

STEP 3. Rescue Breathing

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

STEP 4. Administer Naloxone

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

Narcan® Nasal spray

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

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

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

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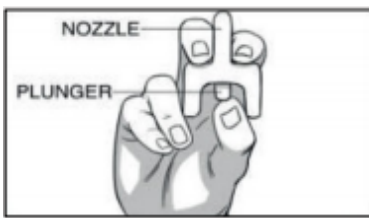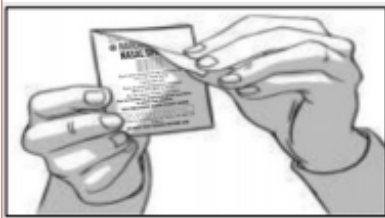
Nasal spray naloxone with atomizer

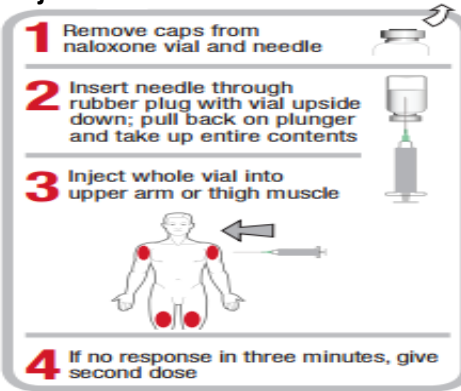**1** Pull off 2 yellow caps from plastic syringe. PLASTIC SYRINGE

2 Pry off Red (or Purple) Cap — Naloxone

3 Grip plastic wings. Screw white spray top on the top of plastic syringe.

4 Gently screw the glass medicine vial into bottom of plastic syringe. Twist about 3 turns until slight resistance

5 Insert into one nostril and give a **short, vigorous push** on the end of the glass vial. Push the vial until the black line "**1**" to give one half dose.

6 Switch to the nostril and push the remaining liquid to give second half of the dose. Push to spray.

HARM REDUCTION COALITION

Injectable naloxone

1 Remove caps from naloxone vial and needle

2 Insert needle through rubber plug with vial upside down; pull back on plunger and take up entire contents

3 Inject whole vial into upper arm or thigh muscle

4 If no response in three minutes, give second dose

Administering a second dose:

- If the naloxone did not work after you waited 2-5 minutes, you may give a second dose of medication.
  ⇒ **Narcan Nasal Spray**: repeat step 2 every **2-3 minutes** until the person responds or emergency medical help is received.
  ⇒ **Intranasal with atomizer**: if there is no change in **3-5 minutes**, remove the second naloxone medication from a new box and a new white spray top and repeat steps 1-4 to assemble. Then give the victim a second dose by giving one half of the dose in each nostril following steps 5-6.
  ⇒ **Injectable naloxone**: if there is no change in **2-3 minutes**, repeat steps 1-4 to administer a second dose.

Recovery Position

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

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

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

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

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

How to recognize Opioid Withdrawal:
- Dilated pupils
- Nausea, vomiting
- Agitation and anxiety
- Sweating

Walgreens
at the corner of **happy** & **healthy**®

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

Ask Your Pharmacist!

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

You have the right to ask the pharmacist for:

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

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

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

Before taking your medicine, be sure you know:

1 The name of the medicine and what it does.

2 How and when to take it, for how long, and what to do if you miss a dose.

3 Possible side effects and what you should do if they occur.

4 Whether the new medicine will work safely with other medicines or supplements.

5 What foods, drinks, or activities should be avoided while taking the medicine.

Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless:

- It is not covered by your insurance;
- You are unable to pay the cost of a copayment;
- The pharmacist determines doing so would be against the law or potentially harmful to health.

If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

BE AWARE AND TAKE CARE:
Talk to your pharmacist!
CALIFORNIA STATE BOARD OF PHARMACY

1625 N. Market Blvd., Suite N-219 • Sacramento, CA 95834
(916) 574-7900 • www.pharmacy.ca.gov

Ask your pharmacist

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- You are unable to pay the cost of a copayment
- The pharmacist determines doing so would be against the law or potentially harmful to your health

If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

You have the right to ask the pharmacist for:

- Easy-to-read pharmacy prescription drug label in 12-point font
- Information on drug pricing and the use of generic drugs
- Interpreter services at no cost—just point to your language

Arabic	Armenian	Cambodian	Cantonese
اختر لغتك. يتم تقديم خدمات الترجمة الفورية لك عند الطلب دون أي تكلفة .	Նշեք ձեր լեզուն: Թարգմանչի ծառայությունները անվճար կտրամադրվեն ձեզ՝ ըստ պահանջի:	ចូរចង្អុលទៅកាន់ភាសារបស់អ្នក ។ មានផ្តល់សេវាកម្មបកប្រែភាសាដល់អ្នក តាមការស្នើសុំ ដោយឥតគិតថ្លៃ ។	指向您的語言。 將根據您的要求免費為您提供翻譯服務。 廣州話
Farsi	**Hmong**	**Korean**	**Mandarin**
زبان خود را مشخص کنید. خدمات ترجمه شفاهی بر حسب درخواست شما به صورت رایگان فراهم خواهد شد.	Taw rau koj yam lus. Kev pab cuam neeg txhais lus yuav muaj pub rau koj raws li kev thov yam tsis yuav nqi.	언어를 지정해 주십시오. 요청 시 통역 서비스를 무료로 제공해 드립니다.	指向您的语言。 将根据您的要求免费为您提供翻译服务。 官話
Russian	**Spanish**	**Tagalog**	**Vietnamese**
Указать на ваш язык. Услуги переводчика будут бесплатно предоставлены Вам по требованию.	Indique su idioma. Se le proporcionarán servicios de intérprete sin costo si lo solicita.	Ituro ang iyong wika. Ang serbisyo ng interpreter ay ibibigay sa iyo kapag hihilingin nang walang bayad.	Xin hãy chỉ vào ngôn ngữ của quý vị. Dịch vụ thông dịch sẽ được cung cấp cho quý vị miễn phí theo yêu cầu.

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Attachment 5

≡Menu

SEARCH THIS SITE:

Enter search terms | Go

So-Called "Canadian" Pharmacies are a Danger to Consumers, NABP Reports

August 21, 2017

Topics: **Internet Pharmacies** _(https://nabp.pharmacy/category/internet-pharmacies/)_, **NABP Program** _(https://nabp.pharmacy/category/nabp-program/)_

The National Association of Boards of Pharmacy® (NABP®) released the **Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: August 2017** _(https://nabp.pharmacy/wp-content/uploads/2016/08/Internet-Drug-Outlet-Report-August-2017.pdf)_. The report discusses how rogue online pharmacies exploit the American perception that Canadian pharmacies provide safe medication at a lower cost.

In a recent study, NABP reviewed more than 100 pharmacy websites that used "Canada" or "Canadian" in their name or URL, or posted a Canadian contact address, and found that 74% source drugs from countries outside of Canada. None of the 108 websites included in the study require a valid prescription, which can pose a serious health risk for patients.

Half of the so-called "Canadian" websites source drugs from India or a combination of countries where counterfeit products are known to originate. Another 20% dispense drugs from unspecified foreign locations.

Sourcing medications from countries without stringent regulation and oversight exposes patients to medications that are not approved by Food and Drug Administration or Health Canada. The risk that these imported drugs are counterfeit, contaminated, or subpotent is high; and quality assurance is a major concern.

States (US) consumers to legally import prescription medications from Canadian pharmacy sites. Without a tightly regulated international supply chain in place, it will be difficult to shield consumers from the risks associated with this type of policy.

Canada would continue to be an intermediate shipment point for unapproved medications. Neither Canada nor the US are in a position to set up the appropriate inspection programs, as stated in the report.

In 2016, NABP partnered with Canada's National Association of Pharmacy Regulatory Authorities to verify online pharmacies located or doing business in Canada. The agreement was formed as part of the .Pharmacy Verified Websites Program, which exists to help consumers identify safe and lawful internet pharmacies.

The "Canadian" websites in this study are among the nearly 11,700 websites selling prescription medicines that NABP has reviewed in the last nine years. Of those websites, 96% were found to be operating illegally. A list of safe online pharmacies can be found on the **Buying Safely** *(https://www.safe.pharmacy/buying-safely/#CanadianPharmacies)* page of **www.safe.pharmacy** *(http://www.safe.pharmacy)*.

Read the full report and learn more about Canadian internet drug outlets and their impact on the US consumer by visiting the Program and Committee Reports page in the Publications and Reports section of **www.nabp.pharmacy** *(http://www.nabp.pharmacy)*.

NABP is the independent, international, and impartial Association that assists its state member boards and jurisdictions for the purpose of protecting the public health.

RECENT NEWS

NABP Earns Better Business Bureau Accreditation *(https://nabp.pharmacy/nabp-earns-better-business-bureau-accreditation/)*
August 14, 2017

NABP's PMP InterConnect Forges New Partnership with St Louis County
(https://nabp.pharmacy/nabps-pmp-interconnect-forges-new-partnership-st-louis-county/)
July 12, 2017

Forty-Two States Now Participating in NABP PMP InterConnect
(https://nabp.pharmacy/forty-two-states-now-participating-nabp-pmp-interconnect/)

Internet Drug Outlet Identification Program

Progress Report for State and Federal Regulators: August 2017

Prepared By

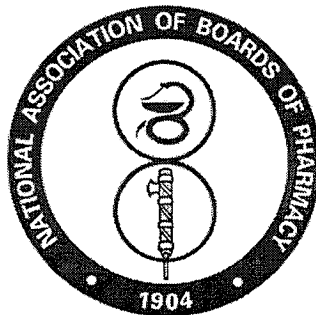The National Association of Boards of Pharmacy

Table of Contents

Internet Drug Outlet Identification Program
Progress Report: August 2017

Introduction

Many online drug sellers display the Canadian maple leaf as a symbol of the safety and reliability of medications approved for sale in Canada. The drugs they sell to customers outside of Canada, however, are often something altogether different. Since the subject of importing prescription medicine from Canada has made a reappearance in the halls of Congress in recent months, many health care regulators and patient safety advocates have voiced their opposition to importation, stating that such policy would open the floodgates for unapproved and counterfeit medications of unknown origins to enter the United States medication supply chain.

The National Association of Boards of Pharmacy® (NABP®) expressed this concern in a letter to Congress earlier this year. "In NABP's nearly 20 years of experience in verifying internet pharmacies, US consumers buying medications from Canadian online pharmacies rarely, if ever, receive the Health Canada-approved products afforded to Canadian customers," NABP wrote. "Instead, these Canadian pharmacy websites sell US patients medicines manufactured in places where buyers would not even drink the water, eg, India, Turkey, or Southeast Asia." According to the US Food and Drug Administration (FDA) article, "Imported Drugs Raise Safety Concerns," "Drugs coming to the United States from Canada may be coming from some other country and simply passing through Canada. The drugs could also be counterfeit, contaminated, or subpotent, among other things."

To substantiate these concerns, NABP recently reviewed more than 100 websites with "Canada" or "Canadian" in their name or URL, or posting a Canadian address on their websites to see how many of them dispensed prescription medicine from outside of Canada. These sites are among the nearly 11,700 websites selling prescription medications that NABP has reviewed since 2008. In all, NABP has found nearly 96% of these sites to be operating illegally, out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice

standards. These findings are described in the Results section below. In many instances, these sites are foreign drug sellers masquerading as Canadian online pharmacies but actually dispensing medications that are approved by neither FDA nor Health Canada. In fact, nearly three-quarters (74%) of the so-called Canadian sites NABP reviewed from July 1, 2016, through June 30, 2017, state on their websites that they source their drugs from countries outside of Canada. These findings are described on pages 9 and 10 of this report. Such products are not approved by Health Canada and would be illegal to sell in that country. Yet, online drug sellers routinely dispense these products to patients in the US, in contravention of US federal law and endangering patient health.

Results

A. Findings of Site Reviews to Date:

As of June 30, 2017, NABP has reviewed 11,688 internet drug outlets selling prescription medications to US patients. Of these, 11,142 (95.8%) 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 Initiatives

Internet Drug Outlets Reviewed by NABP

95.8%

1.9%   2.3%

- Not Recommended
- Reviewed
- VIPPS/Vet-VIPPS/e-Advertiser/.pharmacy

section of the NABP website, *www.nabp.pharmacy*. Of the websites identified by NABP as Not Recommended, the majority were found to be dispensing prescription drugs without a valid prescription. These findings include sites dispensing drugs based solely on an online questionnaire, as well as those requiring no prescription at all. Many also offer foreign and unapproved drugs that may be substandard or counterfeit. The 11,142 internet drug outlets
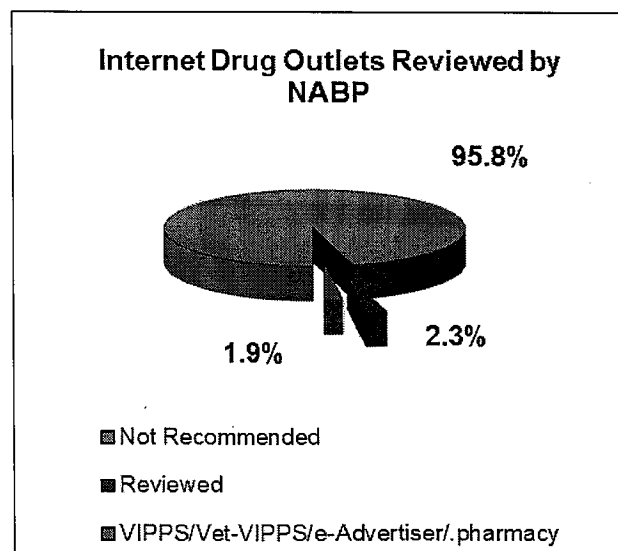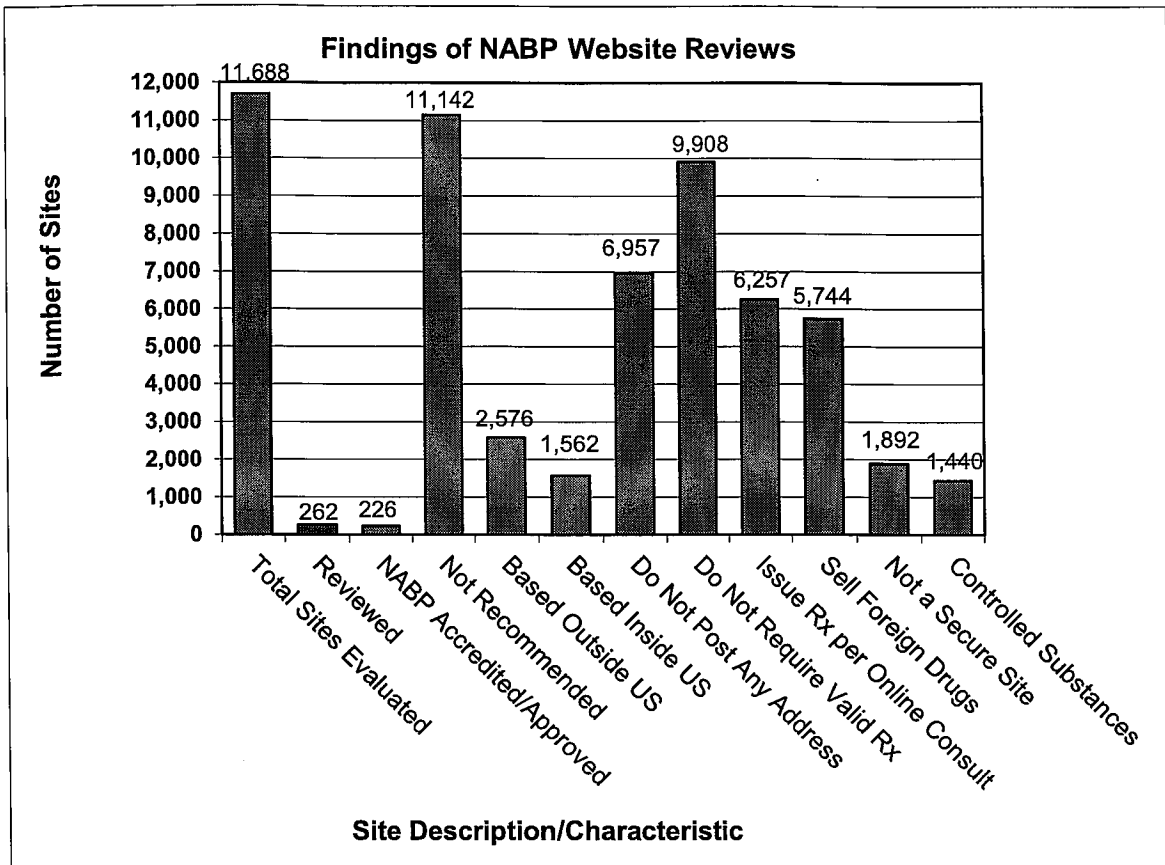
currently listed as Not Recommended on the NABP website are characterized in the table below.[1]

Not Recommended Sites

Physical Location:	• 2,576 (23.1%) outside US
	• 1,562 (14%) inside US
	• 6,957 (62.4%) no location posted on website
Prescription Requirements:	• 9,908 (88.9%) do not require valid prescription
	• 6,257 (56.2%) issue prescriptions per online consultations or questionnaires only
Medications:	• 5,744 (51.6%) offer foreign or non-FDA-approved medications
	• 1,440 (12.9%) dispense controlled substances
Encryption:	• 1,892 (17%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	• 4,762 (42.7%) outside US
	• 5,903 (53%) inside US
	• 464 (4.2%) have unknown server locations
Affiliations:	• 9,681 (86.9%) appear to have affiliations with rogue networks of internet drug outlets

The table above, as well as the bar graph on page 6 of this report, shows the characteristics of drug sites listed as Not Recommended on the NABP website as of June 30, 2017. More than half sell foreign or non-FDA-approved medications to US patients, and 85.5% are either based outside of the US or, as in most cases, do not post any physical address on the website.

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[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 nine years.

Findings of NABP Website Reviews

Chart: Number of Sites vs Site Description/Characteristic

- Total Sites Evaluated: 11,688
- Reviewed: 262
- NABP Accredited/Approved: 226
- Not Recommended: 11,142
- Based Outside US: 2,576
- Based Inside US: 1,562
- Do Not Post Any Address: 6,957
- Do Not Require Valid Rx: 9,908
- Issue Rx per Online Consult: 6,257
- Sell Foreign Drugs: 5,744
- Not a Secure Site: 1,892
- Controlled Substances: 1,440

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

Two hundred sixty-two (2.3%) of the 11,688 sites selling prescription medications to US patients were designated as reviewed. These sites lack any egregious violations that would cause them to be ranked as Not Recommended but have not satisfied the requirements of NABP's Verified Internet Pharmacy Practice Sites® (VIPPS®), Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®), e-Advertiser Approval℠ Program, or .Pharmacy Verified Websites Program. Two hundred twenty-six (1.9%) of the 11,688 sites selling prescription medications or offering resources to US patients were accredited through the VIPPS or Vet-VIPPS programs or were approved through the e-Advertiser Approval or .Pharmacy programs.

B. Recommended Internet Pharmacies: NABP, along with many patient safety advocates, continues to recommend that patients use internet pharmacies that have been reviewed and approved by NABP. These sites include entities granted VIPPS or Vet-VIPPS accreditation, Approved e-Advertiser status, or a .pharmacy domain name. These sites have been evaluated and found to be in compliance with pharmacy laws and meet high standards for pharmacy practice and patient safety. As of June 30, 2017, 80 pharmacies were listed on the NABP website as VIPPS or Vet-VIPPS accredited, and 111 entities were listed as Approved e-Advertisers. While the VIPPS program will continue to operate, NABP is no longer accepting applications for the Vet-VIPPS and e-Advertiser Approval programs, as these programs are being streamlined into the .Pharmacy Program. Several applications for VIPPS accreditation are in progress. Including all types of .pharmacy-registered entities – pharmacy, board of pharmacy and regulatory agency, resource and referral, association and consumer advocacy, professional, pharmaceutical manufacturer, and school and college of pharmacy – 132 .pharmacy registered entities are listed on the Buying Safely page of the .Pharmacy Program website, *www.safe.pharmacy*. Over 100 .pharmacy applications are in progress.
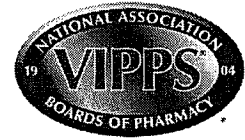
C. .Pharmacy Program: NABP believes strongly that its .Pharmacy Program is the future of safe pharmacy and pharmacy-related services provided online, offering a superior means of displaying approval to consumers and other entities. It is no longer enough to have a seal of approval that can be copied and pasted and displayed fraudulently to dupe patients into thinking they are visiting a safe website. The .pharmacy domain name identifies legitimately operating pharmacies and pharmacy-related entities for consumers, advertisers, and search engine companies by incorporating the "seal of approval" into the domain name. With .pharmacy, patients know they are visiting a safe website.

NABP has, as of July 19, 2017, granted approval for 576 domain names, and 353 .pharmacy domain names have been registered (up from 310 at the close of first quarter 2017). Of these, 261 were registered to pharmacies, 12 were registered to professional sites, 41 were

registered to boards of pharmacy or regulatory agencies, 18 were registered to associations and consumer advocacy sites, 16 were registered to resource and referral sites, 3 were registered to manufacturers, and 2 were registered to schools or colleges of pharmacy.

Of the 353 .pharmacy domain names registered, 192 are in use, while the remaining registered domain names are parked. Of those that are in use, 124 are registered to pharmacies, 31 are registered to boards of pharmacy or regulatory agencies, 16 are registered to associations and consumer advocacy sites, 14 are registered to resource and referral sites, 5 are registered to professional sites, and 2 are registered to schools or colleges of pharmacy. Of the domain names in use, 25 are being used as the registrant's primary web address, 156 are redirecting to another domain name, and 11 are masking another domain name with the .pharmacy name.

.Pharmacy is a verified Top-Level Domain, meaning that applicants are evaluated for compliance with registry standards prior to being allowed to use a .pharmacy domain name. 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. As such, pharmacies licensed in Canada and dispensing medicine only to patients residing in Canada are eligible for a .pharmacy domain name, provided they meet all other program standards.

So-Called Canadian Internet Pharmacies Selling Not-So-Canadian Drugs

The regulations in Canada that ensure medication safety and efficacy – such as those prohibiting the importation of unapproved foreign medications into the country – do not protect US patients buying medicine from so-called Canadian online pharmacies. These drug sellers generally source the medications they sell to the US from all over the world – often from third-world countries where regulations and oversight are not as stringent or effective as they are in the US and Canada. Sourcing medications from outside of a tightly regulated supply chain also

> Nearly three-quarters (80, or 74%) of the 108 so-called Canadian online pharmacies that NABP reviewed state on their websites that they source the medications they sell from outside of Canada.

greatly increases the chances of counterfeit medicines finding their way to consumers.

The pie chart on page 10 of this report shows the results of a year-long study NABP performed and is based on information provided on over 100 websites. All sites reviewed in this study use "Canada" or "Canadian" in their web business name or URL, or post an address in Canada, and offer to sell medications to customers in the US.

A. **NABP Study Findings:** From July 1, 2016, to June 30, 2017, NABP identified 108 websites using "Canada" or "Canadian" in their web business name or URL, or posting an address in Canada, all of which were offering to sell medications to customers in the US. Nearly three-quarters of them (80, or 74%) stated on the website that they sourced their medications from outside of Canada. These medications are not approved by Health Canada, nor are they legal to sell in Canada. The remaining 28 sites did not indicate the locations from which they source the medications they sell.

Half (54) of the 108 so-called Canadian pharmacies that NABP reviewed source the medications they sell from India, or from a combination of various countries including India, Hong Kong, and Singapore. The likelihood of receiving substandard or counterfeit medicine from these countries is considerable. According to the 2017 Special 301 Report issued by the Office of the US Trade Representative (USTR), "studies have suggested that up to 20% of drugs sold in the Indian market are counterfeit and could represent a serious threat to patient health and safety." USTR also reports, "Ninety percent of all counterfeit pharmaceuticals seized at the US border in Fiscal Year 2016 were shipped from or transshipped through four economies: China, Hong Kong, India, and Singapore."

While India was the most common source for medications sold online from so-called Canadian pharmacies, 20% (22) of the 108 source the medications from unspecified foreign locations, and 26% (28) do not say where they get the medications they sell. Only 14% (15) post a physical address for the pharmacy. None of the 108 sites require a valid prescription, and 27% (29) dispense controlled substances.

From Where Do So-Called Canadian Internet Pharmacies Source Their Drugs?
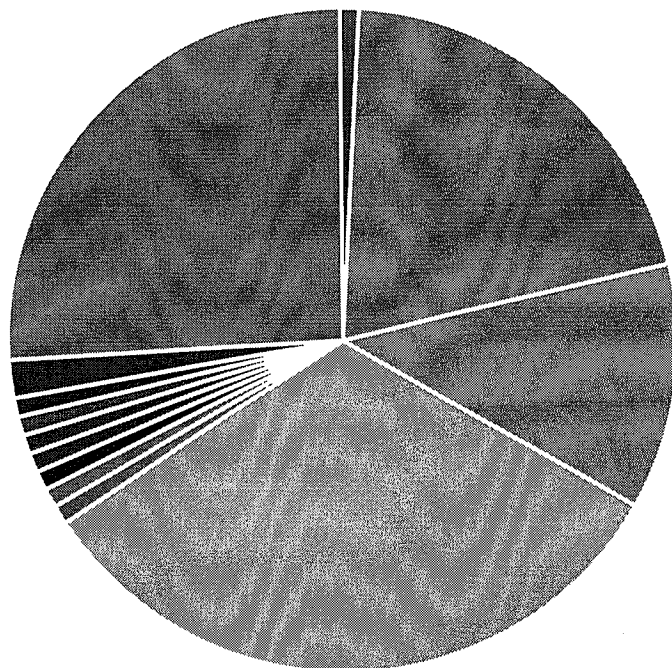
- Mauritius, New Zealand, Singapore, Turkey, UK, and India
- Unspecified international locations
- US and India
- India
- US, UK, Hong Kong, India, etc
- Turkey
- New Zealand
- India, Singapore, Hong Kong, Germany, and Great Britain
- Canada, India, Mauritius, New Zealand, Singapore, Turkey, UK, and US
- Singapore, UK, New Zealand, Turkey, Mauritius, India, Australia, and US
- Hong Kong, India, and Pakistan
- Canada, UK, Australia, and New Zealand
- Does not say

- 74% (80) of the 108 so-called Canadian pharmacy sites NABP reviewed source the medications they sell from outside of Canada.

- Half (54) of them source the drugs they sell from India, or India and some combination of other countries.

- 20% (22) source them from unspecified foreign locations.

- 26% (28) do not say where they get the drugs they sell.

- Only 14% (15) post a physical address for the pharmacy.

- None of them require a valid prescription.

- 27% (29) dispense controlled substances.

B. Proposed Importation Legislation Raises Concerns

These findings underscore the concerns that NABP and others have raised about proposed legislation that would allow US consumers to import prescription medications from Canada. "NABP and many other patient safety advocates have found that the dangers of drugs dispensed outside of FDA's or Health Canada's drug approval process are significant," NABP wrote to Congress. "Outside these closed and tightly regulated drug supply chains, the safeguards put in place to ensure the identity, efficacy, and safety of prescription medications no longer apply." FDA cites quality assurance concerns among the potential health risks with imported drugs: "Medications that have not been approved for sale in the United States may not have been manufactured under quality assurance procedures designed to produce a safe and effective product."

Among those raising such concerns is Leona Aglukkaq, who served as Canada's minister of health from 2008 until 2013. Under proposed plans to allow importation, "Canada would simply serve as an intermediate transshipment point for unapproved drugs heading to the United States," Aglukkaq said in an opinion column appearing in the May 12, 2017 *Washington Post*. "Canadian authorities do not inspect every shipment of products headed for the U.S. marketplace to ensure that packages don't contain adulterated, counterfeit or illegal drugs. Canada does not have the resources to undertake such comprehensive searches, and the Canadian and U.S. governments are not currently set up to facilitate such a program."

The Alliance for Safe Online Pharmacies (ASOP Global) dedicates a section of its website to educating the public about Canadian internet pharmacies selling to US residents. "In short," ASOP Global states in its FAQs, "the drugs U.S. residents get from a site that claims to be a Canadian online pharmacy are *not* Health Canada-approved and are not the same quality drugs that a Canadian resident would receive either from the same Canadian online or brick and mortar pharmacy."

Discussion

Buying prescription medications from a Canadian online pharmacy seems like a great deal, until consumers realize that what they are getting is not what they bargained for. Given that online

drug sellers presenting themselves as Canadian pharmacies rarely, if ever, sell Health Canada-approved medicine to US consumers, and until such time as a safe and tightly regulated international supply chain can be established, importing medication from Canada presents a considerable public health threat. Any US policy that would allow US patients to buy medications from so-called Canadian online pharmacies is considered by many to be irresponsible. Such action would put patients in this country at risk of harm from counterfeit or adulterated medicines.

In keeping with its mission to assist its member boards and jurisdictions in protecting the public health, NABP remains committed to upholding the integrity of the practice of pharmacy – in any practice setting or location – and ensuring that patients worldwide have access to safe and effective prescription medications. For further information, please contact Melissa Madigan, policy and communications director, via email at mmadigan@nabp.pharmacy.

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 6

Communication and Public Education Communication Plan

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

2017-2021

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

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

Communication and Public Education Communication Plan

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2017-2021

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

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

Communication and Public Education Communication Plan

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2017-2021

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

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Research means to collect email addresses	Licensees	Mechanism to collect email addresses	To distribute information to licensees	Board staff C&PE Committee	Completed spring 2017
b. Research means to collect mobile telephone numbers	Licensees	Mechanism to collect mobile telephone numbers	To distribute information to licensees	Board staff C&PE Committee	TBD

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

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

Communication and Public Education Communication Plan

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

2017-2021

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

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

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

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

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

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