



National Association of Boards of Pharmacy

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nabp

Internet Drug Outlet Identification Program

Progress Report for State and Federal
Regulators: October 2015

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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: October 2015

I. INTRODUCTION

Representatives of the National Association of Board of Pharmacy[®] (NABP[®]) recently joined international leaders to address what has become widely recognized as a global public health threat. Widespread agreement exists among multiple countries that Internet sales of medicinal products pose a health risk to their citizens. Authorities have reported an increase in illegitimate Internet pharmacies, and many agree that international cooperation is critical as this global phenomenon expands. NABP brings to the conversation expertise and data based on its review of thousands of websites selling prescription drugs from all over the world to United States patients, as well as its recent experience as registry operator for the .pharmacy Top-Level Domain (TLD). The .pharmacy TLD is guided by a global coalition of stakeholders and is available to legitimate Internet pharmacies and other pharmacy-related information and service providers around the world. NABP has established partnerships with regulators in multiple countries to review .pharmacy domain name applications for applicants located in or doing business in those countries. The .pharmacy TLD is an important tool in addressing this public health threat, as are legislative acts and consumer education campaigns put forth around the world. To maximize the benefits and the efficacy of these various efforts, further international, public, and private collaboration is needed to address the problem.

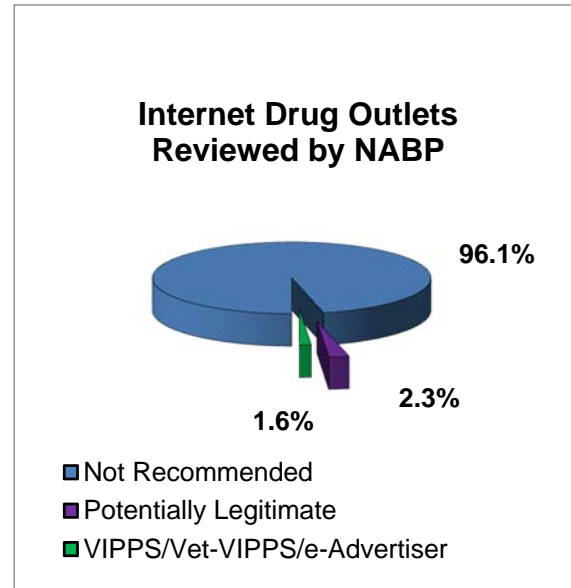
II. RESULTS

A. Findings of Site Reviews to Date: As of September 30, 2015, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 11,065 Internet drug outlets selling prescription medications. Of these, 10,634 (96.1%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards. These sites are listed as Not Recommended in the “Buying Medicine Online” section under Consumers on the NABP website, as well as on NABP’s AWA_RXE[®]

Prescription Drug Safety website, www.AWARERX.ORG. Of the websites identified by NABP as Not Recommended, the majority were found to be dispensing prescription drugs without a valid prescription. These findings include sites dispensing drugs based solely on an online questionnaire, as well as those requiring no prescription at all. For most, dispensing without a valid prescription was one of several other concerning activities observed. Many also offer foreign and

unapproved drugs. Both of these factors pose a public health risk that undermines the regulations put in place in the US and other developed countries to set standards for the practice of pharmacy, standards for medication safety and efficacy, and regulations for safeguarding the medication supply chain from counterfeit drugs. Most sites selling drugs illegally online do not post any address, and nearly half have their domain names registered anonymously. The 10,634 Internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table below.¹

Of the total 11,065 sites reviewed, 257 (2.3%) appear to be potentially legitimate, ie, meet program criteria that could be verified solely by looking at the sites and their domain name registration information. One hundred seventy-four (1.6%) of the 11,065 reviewed sites have been accredited through NABP's Verified Internet Pharmacy Practice Sites[®] (VIPPS[®]) or Veterinary-Verified Internet Pharmacy Practice Sites[®] (Vet-VIPPS[®]) programs, or approved through the NABP e-Advertiser Approval^{CM} Program.



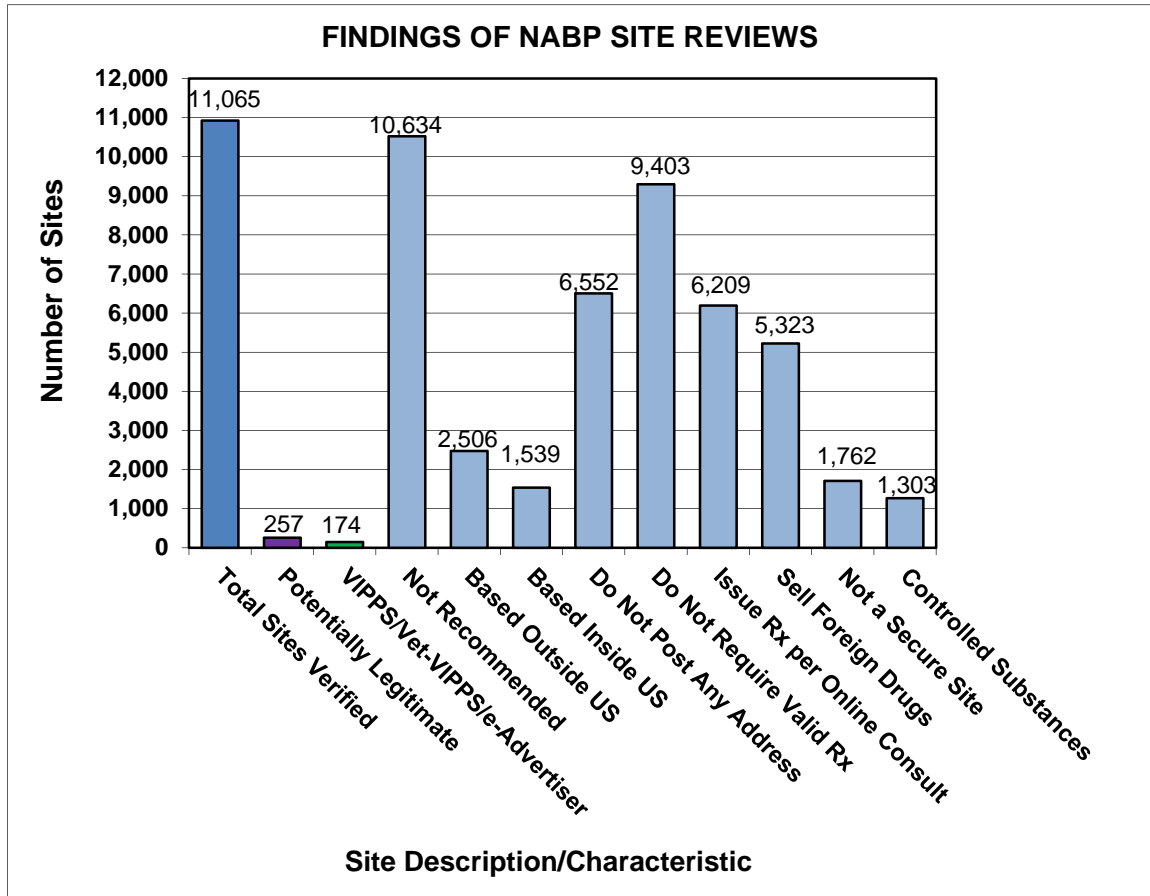
¹ It should be noted that the research findings NABP reports herein and on the Not Recommended list include the total number of websites selling prescription drugs to US patients that NABP staff has reviewed and found to be out of compliance with program standards, including those sites that were found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

Not Recommended Sites

Physical Location:	<ul style="list-style-type: none">• 2,506 (23.6%) outside US• 1,539 (14.5%) inside US• 6,552 (61.6%) no location posted on website
Prescription Requirements:	<ul style="list-style-type: none">• 9,403 (88.4%) do not require valid prescription• 6,209 (58.4%) issue prescriptions per online consultations or questionnaires only
Medications:	<ul style="list-style-type: none">• 5,323 (50.1%) offer foreign or non-FDA-approved medications• 1,303 (12.3%) dispense controlled substances
Encryption:	<ul style="list-style-type: none">• 1,762 (16.6%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	<ul style="list-style-type: none">• 4,464 (42%) outside US• 5,699 (53.6%) inside US• 461 (4.3%) have unknown server locations
Affiliations:	<ul style="list-style-type: none">• 9,604 (90.3%) appear to have affiliations with rogue networks of Internet drug outlets

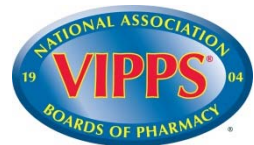
Sites listed as Not Recommended, in total, as of September 30, 2015

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



Findings of NABP website reviews, in total, as of September 30, 2015

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



C. NABP e-Advertiser Approval Program: Sites that have received e-Advertiser Approval status do not fill new prescription drug orders via the Internet, and thus are ineligible for VIPPS, but accept refill requests from their existing customers, provide drug information or pharmacy information, or offer other prescription drug-related services. Sites that have received e-Advertiser Approval status have been found to be safe, reliable, and lawful. These sites are listed on the NABP website as Approved e-Advertisers. Currently, 110 entities are listed on the NABP website as Approved e-Advertisers, and several more applications are in progress.



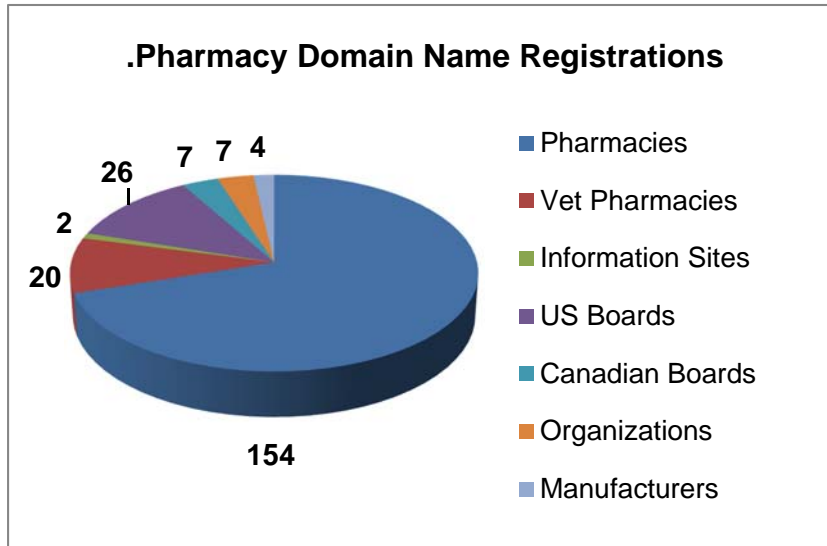
III. **.PHARMACY TLD PROGRAM**

The public health threat posed by rogue Internet drug outlets was the impetus for NABP's development and launch of the .pharmacy TLD. While anyone can register a .com or most any other domain name, use of the .pharmacy TLD is restricted to website operators that meet program standards for safe and legal practice. The .pharmacy initiative aims to provide consumers around the world a means for easily identifying safe and legal online pharmacies and related resources. NABP grants use of the .pharmacy domain only to legitimate website operators that adhere to pharmacy laws in the jurisdictions in which they are based and in which their patients and customers reside, so that consumers can easily find safe online pharmacies and related resources.



The .pharmacy TLD is available to pharmacies and other entities offering prescription drugs or prescription drug-related products, services, or information via the Internet, subject to their completion of the registrant application and approval process to establish compliance with all applicable laws and .Pharmacy TLD Program standards. The application and approval process includes vetting by NABP prior to registration to ensure that applicants meet all applicable regulatory standards, including those addressing pharmacy licensure and valid prescription requirements. Eligible registrants will demonstrate good standing and compliance with the laws of the jurisdiction in which they are based, as well as in all jurisdictions in which they conduct business, including without limitation dispensing or shipping prescription medications in or to a jurisdiction. Entities that are accredited through the VIPPS or Vet-VIPPS program or approved through the e-Advertiser program are pre-approved to register a .pharmacy domain name for their accredited content. The core standards that must be met to be eligible to register a .pharmacy domain name are included in Appendix B of this report.

As of September 30, 2015, NABP has granted approval (in the form of electronic tokens) for 348 domain names, and 220 .pharmacy domain names have been registered, including such high-profile pharmacies as CVS, Express Scripts, PetMed Express, Target,



and Rite Aid. Of the 220 .pharmacy domain names registered, 154 are registered to pharmacies, 20 to veterinary pharmacies, two to information sites, 26 to US boards of pharmacy, seven to Canadian boards of pharmacy, seven to organizations, and four to manufacturers. Additional information about the .Pharmacy TLD Program, as well as a listing of active .pharmacy websites, is available at www.safe.pharmacy.

IV. NABP JOINS GLOBAL EXPERTS IN ADDRESSING ILLEGAL ONLINE DRUG SALES

A. APEC: NABP joined several other countries at a recent meeting of the Asia-Pacific Economic Cooperation (APEC) in Cebu, Philippines, to address what has become widely recognized as a global public health threat. The APEC Life Sciences Innovation Forum Training Program on Global Medical Product Integrity and Supply Chain Security – Internet Sales Track Sessions were held on



August 26-27, 2015. A representative of NABP presented on the dangers of illegal online drug sales, the .pharmacy TLD as a safe web domain for Internet pharmacies, and the importance of cross-industry partnerships to shut down illegal sellers. Other speakers included regulators from Canada, Peru, Italy, Singapore, Malaysia, Nigeria, and Philippines, representatives of the US Food and Drug Administration (FDA) and the Office of the US Intellectual Property Enforcement Coordinator, as well as representatives of the Alliance for Safe Online Pharmacies (ASOP), the Center for Safe Internet Pharmacies, the Pharmaceutical Security Institute, and Microsoft. Workshop highlights included review of a draft APEC Internet Sales Tool Kit and a discussion on voluntary and government actions to shut down illegal drug websites.

All APEC members responding to a recent survey of the APEC Internet Sales Working Group agreed that Internet sales of medicinal products pose a health risk in their countries. Results of the survey, completed by 10 APEC economies including Canada, Indonesia, Papua New Guinea, Philippines, Thailand, Chile, Japan, Peru, Singapore, and the US, indicate a global increase in illegitimate Internet pharmacies, and a critical need for international cooperation.

- B. FIP: NABP also joined practitioners, researchers, and academics worldwide to help shape modern pharmacy practice during the 75th International Pharmaceutical Federation (FIP) World Congress of Pharmacy and Pharmaceutical Sciences 2015. Held from September 29 to October 3, 2015, in Düsseldorf, Germany, the congress focused on how to make evidence-based pharmaceutical science the driving force of modern pharmacy practice globally. Carmen A. Catizone, MS, RPh, DPh, NABP executive director/secretary, shared information about the global risk of rogue Internet drug outlets that distribute dangerous drug products, and information about the .Pharmacy TLD Program.
- C. ASOP-EU: NABP representatives also attended a meeting in Rome, Italy, on October 15, 2015, hosted by ASOP-EU in collaboration with the Italian Medicines Agency, for European Union member states to discuss implementation of the Common Logo in the EU. The Common Logo is an image that must be posted on all websites selling medicine online in EU member states to show that they are appropriately licensed to operate there.
- D. ICANN: In addition, NABP representatives attended the 54th international public meeting of the Internet Corporation for Assigned Names and Numbers October 18-22, 2015, in Dublin, Ireland. There, they participated in a session addressing illegal online drug sellers, as well as multiple other sessions regarding Internet policy. The session, Illicit Internet Pharmacies – A Growing Threat to Online Security and Consumer Safety: An Event for Registries and Registrars, took place on October 19, 2015, and helped to enhance awareness of this important patient safety issue among the registrar and registry community. As part of the panel discussion, NABP presented the .pharmacy TLD as a tool to address the problem. An extension of NABP’s long-standing accreditation programs, .pharmacy is a restricted online community for legitimate entities, where the safety seal is built into the website address.

V. **DISCUSSION**

The .pharmacy TLD is an important tool in safeguarding the public health from rogue Internet drug outlets in today’s Internet reality. With further support and international collaboration, .pharmacy stands to play a larger role in the future of Internet pharmacy. NABP continues to

support the state boards of pharmacy in their mission to protect the public health. The Association applauds the multinational organizations dedicated to this same goal. NABP remains committed to upholding the integrity of the practice of pharmacy – in any practice setting – and ensuring that patients worldwide have access to safe and effective prescription drugs. For further information, please contact Melissa Madigan, policy and communications director, via email at mmadigan@nabp.net.

VI. APPENDICES

Appendix A

Internet Drug Outlet Identification Program Standards

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

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

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

9. **Website transparency.** The pharmacy must not engage in practices or extend offers on its website that may deceive or defraud patients as to any material detail regarding the pharmacy, pharmacy staff, prescription drugs, or financial transactions.
10. **Domain name registration.** The domain name registration information of the pharmacy must be accurate, and the domain name registrant must have a logical nexus to the dispensing pharmacy. Absent extenuating circumstances, pharmacy websites utilizing anonymous domain name registration services will not be eligible for approval.
11. **Affiliated Websites.** The pharmacy, website, pharmacy staff, domain name registrants, and any person or entity that exercises control over, or participates in, the pharmacy business must not be affiliated with or control any other website that violates these standards.

Appendix B

.Pharmacy TLD Program Standards

1. **Licensure.** An applicant, as well as community members to which the applicant site links or with which it is affiliated, must possess all necessary licenses, registrations, or permits to practice in all required jurisdictions. This includes not only the jurisdiction where the entity is located, but also any jurisdiction where its patients or customers reside. All such licenses, registrations, or permits must be in good standing.
2. **Prior discipline.** An applicant, as well as any community members to which the applicant site links or with which it is affiliated, must not have been subject to significant recent and/or repeated disciplinary sanctions.
3. **Location.** An applicant, as well as community members to which the applicant site links or with which it is affiliated, must be domiciled in the US or in a country with a .pharmacy National Standard Setting Committee, or in a country that has established an understanding with NABP that will allow non-US .pharmacy applicant evaluations to be performed by NABP.
4. **Validity of prescription.** A pharmacy shall dispense or offer to dispense prescription drugs only upon receipt of a valid prescription, as defined by the applicable jurisdictions. A valid prescription is one issued pursuant to a legitimate patient-prescriber relationship, as defined by the applicable jurisdictions.
5. **Legal compliance.** An applicant, as well as community members to which the applicant site links or with which it is affiliated, must comply with all provisions of jurisdictional law, including laws addressing regulatory agency approval of prescription medication.
6. **Privacy.** If the applicant website, or any site to which the applicant site links or with which it is affiliated, maintains or transmits patient health information, the information must be maintained or transmitted in accordance with jurisdictional patient information privacy and security laws, including those addressing notice to patients regarding privacy and security of such information.
7. **Patient services.** An applicant pharmacy, medical or veterinary practice, medical or veterinary practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, must provide on the website an accurate street address of the dispensing pharmacy, medical practice, medical practitioner, or corporate headquarters. The applicant pharmacy, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, must provide on the website an accurate, readily accessible and responsive phone number or secure mechanism via the website, allowing patients to contact or consult with a pharmacist or medical practitioner regarding complaints or concerns or in the event of a possible adverse event involving their medication.
8. **Website transparency.** An applicant, as well as community members to which the applicant site links or with which it is affiliated, must not engage in practices or extend offers on its website that may deceive or defraud patients as to any material detail regarding the practice, its staff, prescription drugs, or financial transactions.
9. **Domain name registration.** The domain name registration information of the applicant website, or of any community member it promotes, must be accurate, and the domain name registrant must have a logical nexus to the dispensing pharmacy, medical or veterinary practice, or medical or veterinary practitioner. Applicant websites utilizing anonymous domain name registration services will not be eligible for approval.

10. **Affiliated websites.** The applicant website, any community member it promotes, its staff, domain name registrants, and any person or entity that exercises control over, or participates in the applicant business, must not be affiliated with or control any other website that violates these standards. All .pharmacy registrants must meet these core standards. Registration within the .pharmacy TLD is open to eligible entities in any country, subject to verification of compliance with .pharmacy standards. Additional jurisdiction-specific standards may apply to registrants based in or serving customers in other jurisdictions.