



National Association of Boards of Pharmacy

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Internet Drug Outlet Identification Program

Progress Report for State and Federal
Regulators: January 2015

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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: January 2015

I. INTRODUCTION

Of the websites identified as Not Recommended by National Association of Boards of Pharmacy® (NABP®) in 2014, 99% were found to be dispensing prescription drugs without a valid prescription. In fact, for each of the past seven years that NABP has been reviewing rogue Internet drug outlets, this was by far the most common reason sites were listed as Not Recommended. The second most common reason was offering foreign and unapproved drugs. Both of these factors pose a public health risk that undermines the regulations put in place in the United States and other developed countries to set standards for the practice of pharmacy, standards for medication safety and efficacy, and regulations for safeguarding the medication supply chain from counterfeit drugs. This report shows the year-to-year characteristics, as well as findings to date of the nearly 11,000 websites NABP has reviewed since the inception of its Internet Drug Outlet Identification program. These findings also highlight the necessity of the .pharmacy Top-Level Domain (TLD), which is now active on the Internet, as discussed later in this report.

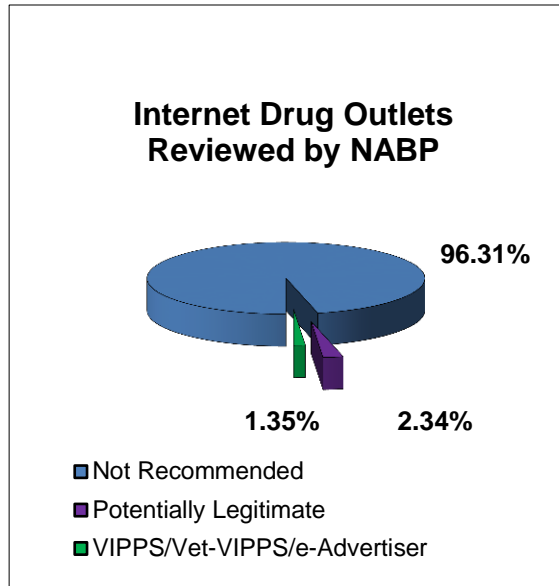
II. RESULTS

A. Year-by-Year Overview: Over the past seven years, NABP has identified nearly 11,000 websites selling medicine illegally online to US patients. The table below provides the number of sites added to the Not Recommended list in each year from 2008 through 2014. Most of those websites were listed as Not Recommended because they were found to be dispensing prescription drugs without a valid prescription. The percentage of Not Recommended sites selling drugs without a prescription over the past seven years, respectively, was 94.8%, 76.9%, 91.6%, 94.3%, 99.1%, 98.1%, 99.0%. These include sites dispensing drugs based solely on an online questionnaire, as well as those requiring no prescription at all. For most, dispensing without a valid prescription was one of several other

concerning activities observed. The number of sites identified as Not Recommended that were found to be dispensing foreign or non-Food and Drug Administration (FDA) approved drugs ranged from 37.2% in 2009 to 88% in 2014. On average, about a third of the Not Recommended sites have posted their location as being in a foreign country. Since 2009, however, most sites selling drugs illegally online do not post any address. These sites tend to be the ones most likely to dispense counterfeit drugs. Openly offering controlled substances online has become less popular since 2008, when 41% of the sites identified as being out of compliance with pharmacy laws and practice standards sold controlled substances. As of the close of 2014, that percentage dipped by more than half to 18.5%, yet remains cause for concern. Nearly half (45.6%) of the websites listed in 2014 as Not Recommended for one of the reasons above had their domain names registered anonymously.

Trait	2008	2009	2010	2011	2012	2013	2014
Total Sites Added to Not Recommended List	1024	3899	2060	1345	1491	362	195
Sites Located in Foreign Country	504 (49.2%)	748 (19.2%)	680 (33%)	216 (16.1%)	126 (8.5%)	53 (14.6%)	61 (31.3%)
Sites Located in US	89 (8.7%)	1084 (27.8%)	41 (2%)	251 (18.7%)	41 (2.7%)	8 (2.2%)	12 (6.2%)
Sites That Do Not Post an Address	431 (42.1%)	2067 (53.0%)	1339 (65%)	878 (65.3%)	1324 (88.8%)	301 (83.2%)	122 (62.6%)
Dispense Controlled Substances	420 (41.0%)	322 (8.3%)	164 (8.0%)	75 (5.6%)	108 (7.2%)	106 (29.2%)	36 (18.5%)
Do Not Require Valid Rx	971 (94.8%)	3001 (76.9%)	1887 (91.6%)	1268 (94.3%)	1478 (99.1%)	355 (98.1%)	193 (99.0%)
Issue Rx Per Online Consult	565 (55.2%)	2285 (58.6%)	180 (8.7%)	1002 (74.5%)	561 (37.6%)	219 (60.5%)	35 (17.9%)
Sites are Not Secured	282 (27.5%)	640 (16.4%)	180 (8.7%)	348 (25.9%)	123 (8.3%)	53 (14.6%)	59 (30.3%)
Offer Foreign or Non-FDA-Approved Drugs	616 (60.2%)	1450 (37.2%)	1033 (50.2%)	637 (47.4%)	1005 (67.4%)	188 (51.9%)	172 (88.2%)
Domain Name Registrations are Not Current and Public	247 (24.1%)	1736 (44.5%)	408 (19.8%)	695 (51.7%)	624 (41.9%)	259 (71.5%)	89 (45.6%)

B. Findings of Site Reviews to Date: As of December 31, 2014, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 10,924 Internet drug outlets selling prescription medications. Of these, 10,521 (96.31%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards. They are also listed as Not Recommended in the “Buying Medicine



Online” section under Consumers on the NABP website, as well as on NABP’s AWARE_XE[®] Prescription Drug Safety website, www.AWARERX.ORG. The 10,521 Internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table below.¹

Of the total 10,924 sites reviewed, 256 (2.34%) appear to be potentially legitimate ie, meet program criteria that could be verified solely by looking at the sites and their domain name registration information. One hundred forty-seven (1.35%) of the 10,924 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[®] Program.

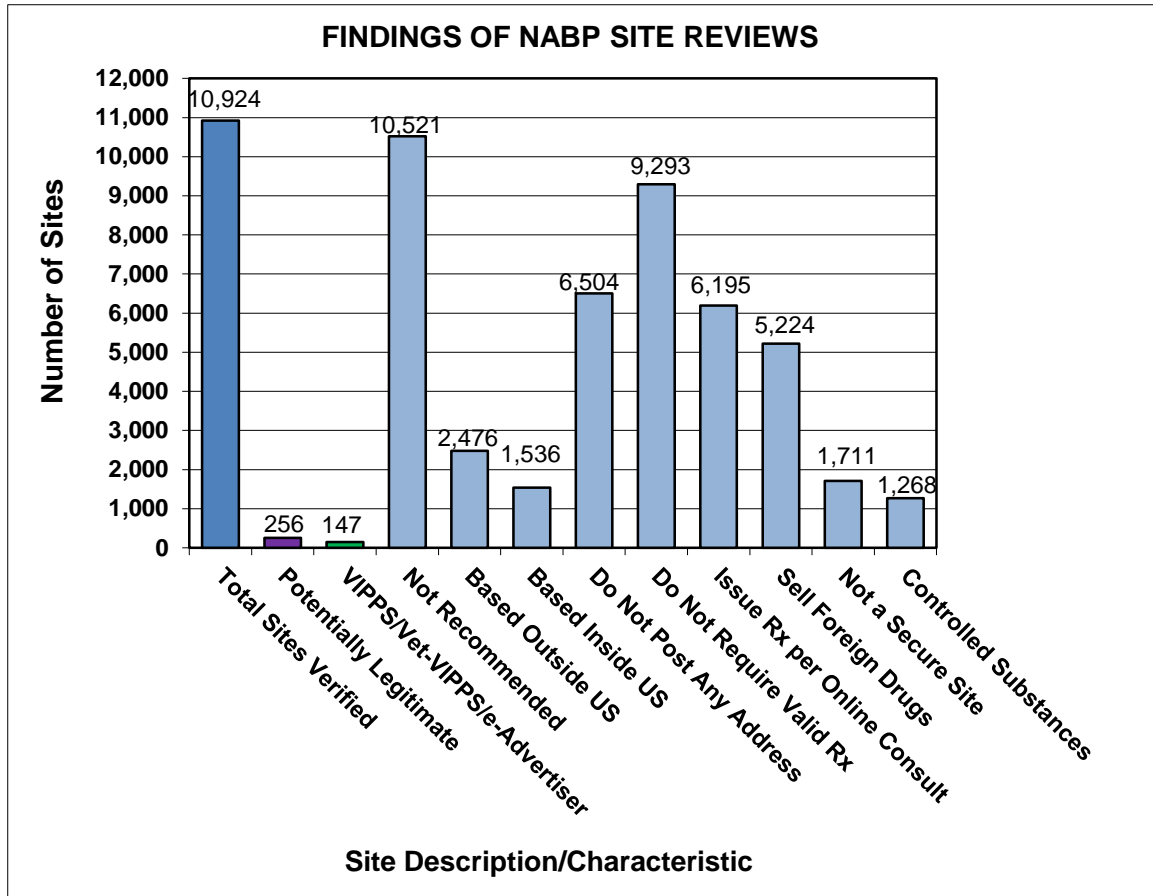
¹ It should be noted that the research findings NABP reports herein and on the Not Recommended list include the total number of websites selling prescription drugs to US patients that NABP staff has reviewed and found to be out of compliance with program standards, including those sites that were found 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:	2,476 (23.5%) outside US
	1,536 (14.6%) inside US
	6,504 (61.8%) no location posted on website
Prescription Requirements:	9,293 (88.3%) do not require valid prescription
	6,195 (58.9%) issue prescriptions per online consultations or questionnaires only
Medications:	5,224 (49.7%) offer foreign or non-FDA-approved medications
	1,268 (12.1%) dispense controlled substances
Encryption:	1,711 (16.3%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	4,385 (41.7%) outside US
	5,672 (53.9%) inside US
	461 (4.4%) have unknown server locations
Affiliations:	9,574 (91.0%) appear to have affiliations with rogue networks of Internet drug outlets

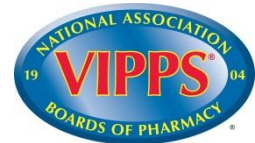
Sites listed as Not Recommended, in total, as of December 31, 2014

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



Findings of NABP website reviews, in total, as of December 31, 2014

- C. Recommended Internet Pharmacies: NABP, along with many patient safety advocates, continues to recommend that US patients use Internet pharmacies accredited through the VIPPS and Vet-VIPPS programs when buying medication online. These sites have undergone and successfully completed the thorough NABP accreditation process, which includes a review of all policies and procedures regarding the practice of pharmacy and dispensing of medicine over the Internet, as well as an on-site inspection of facilities used by the site to receive, review, and dispense medicine. Currently, 62 VIPPS and Vet-VIPPS pharmacy sites are listed as Recommended Internet Pharmacies. Several more applications are in progress.



D. Accreditation and Approval Programs: In addition to identifying rogue sites, the Internet Drug Outlet Identification program staff continues to assist in screening applicant websites for the VIPPS, Vet-VIPPS, and e-Advertiser Approval programs. 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, 85 entities are listed on the NABP website as Approved e-Advertisers, and several more applications are in progress.



III. **.PHARMACY INTERNET DOMAIN**

To help spread public awareness of the dangers posed by rogue Internet drug outlets, and to provide an online domain where consumers can be sure the websites they find there are legitimate, NABP continues to publicize the launch of its .pharmacy TLD. NABP's .pharmacy domain is among the hundreds of new TLDs that became operational, or "went live," in 2014. In November 2014 the first sites were registered using the .pharmacy suffix. Those websites leading the way are many US state boards of pharmacy, several Canadian colleges of pharmacy, and the International Pharmaceutical Federation (FIP). NABP launched the .pharmacy TLD to provide consumers around the world a means for easily identifying safe and legal online pharmacies and related resources. NABP will grant 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.



NABP is currently reviewing applications and requests for .pharmacy domain names received from trademark holders who are registered in the Internet Corporation for Assigned Names and Numbers Trademark Clearinghouse (TMCH). The TMCH Sunrise Application period, which ended January 19, 2015, preceded the TMCH Sunrise Registration Period, which will end March 16, 2015. Only those companies who submitted qualifying applications during the Sunrise Application Period can be approved to register .pharmacy domain names during the Sunrise Registration Period. To be approved, applicants must demonstrate that they adhere to standards and policies that were developed in collaboration with a global coalition of stakeholders, including FIP.

Following the Sunrise Application and Registration periods are two more special registration periods before General Availability begins on June 3:

- VIPPS, Vet-VIPPS, and e-Advertiser Limited Registration Period
 - February 17, 2015 – March 16, 2015: Entities that are accredited through NABP’s VIPPS or Vet-VIPPS programs, or approved through the e-Advertiser Approval program may submit domain name requests to NABP
 - March 17, 2015 – April 1, 2015: VIPPS, Vet-VIPPS, and e-Advertiser entities may register their domain name(s) through an approved registrar
- Dispensing Pharmacy Limited Registration Period
 - April 1, 2015 – April 30, 2015: Pharmacies that dispense medications may submit an application to NABP
 - April 30, 2015 – June 2, 2015: Approved dispensing pharmacies may register their domain name(s) through an approved registrar

General Availability, which will begin on June 3, 2015, is when all entities providing pharmacy-related products, services, or information that meet .pharmacy eligibility standards will be able to apply for and register the domain.

Except for those already VIPPS- or Vet-VIPPS-accredited or e-Advertiser-approved, entities seeking a .pharmacy domain name must first submit an application, supporting documentation, and an application fee to NABP. NABP evaluates these materials to ensure compliance with program standards. NABP is establishing a network of international regulatory groups to facilitate evaluation of international domain name applications. Once approved, applicants are able to register the domain name through an approved registrar.

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

IV. DISCUSSION

NABP’s findings on rogue Internet drug outlets over the last seven years underscore the need for the .pharmacy domain as a public health initiative. NABP continues to support the efforts of regulators, enforcement authorities, and patient advocates worldwide to contain the risks these rogue sites pose. The Association remains committed to upholding the integrity of the practice of pharmacy – in any practice setting – and ensuring that patients worldwide have access to safe and effective prescription drugs. For further information, please contact Melissa Madigan, policy and communications director, via email at mmadigan@nabp.net.

V. APPENDIX

Internet Drug Outlet Identification Program Standards

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

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

6. **Legal compliance.** The pharmacy must comply with all provisions of federal and state law, including but not limited to the Federal Food, Drug, and Cosmetic Act and the Federal Controlled Substances Act (including the provisions of the Ryan Haight Online Pharmacy Consumer Protection Act, upon the effective date). The pharmacy must *not* dispense or offer to dispense medications that have not been approved by the US Food and Drug Administration.
7. **Privacy.** If the pharmacy Web site 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 Web site an accurate US street address of the dispensing pharmacy or corporate headquarters. The pharmacy must provide on the Web site an accurate, readily accessible and responsive phone number or secure mechanism via the Web site, 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. **Web site transparency.** The pharmacy must not engage in practices or extend offers on its Web site 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 Web sites utilizing anonymous domain name registration services will not be eligible for approval.
11. **Affiliated Web sites.** The pharmacy, Web site, 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 Web site that violates these standards.