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Internet Drug Outlet Identification Program

Progress Report for State and
Federal Regulators:
October 2011

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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: October 2011

I. INTRODUCTION

Rhinoceros horn has been purported to have medicinal properties capable of enhancing virility. So, too, have snake blood, sparrow brains, oysters (both the aquatic and “Rocky Mountain” varieties), and such products as “Hot Rod,” “Fornatab,” “Viagra Professional,” and “Cialis Super Active.” These potions have another commonality: not one of them is an approved drug. Prescription medications indicated for the treatment of erectile dysfunction (ED) are among the most commonly counterfeited drugs, and they are frequently bought and sold over the Internet. Embarrassed to discuss ED symptoms with their doctors, patients instead place their health in the hands of unknown drug sellers, many of whom turn a hefty profit by selling dangerous, substandard, and counterfeit drugs without regard for patient safety. Counterfeiters and rogue sellers take advantage of patient confidence in trusted brands to sell pills that may contain too much or too little, if any, of the approved drug’s active ingredient, an entirely different active ingredient, or contaminants ranging from talcum powder to printer ink.¹

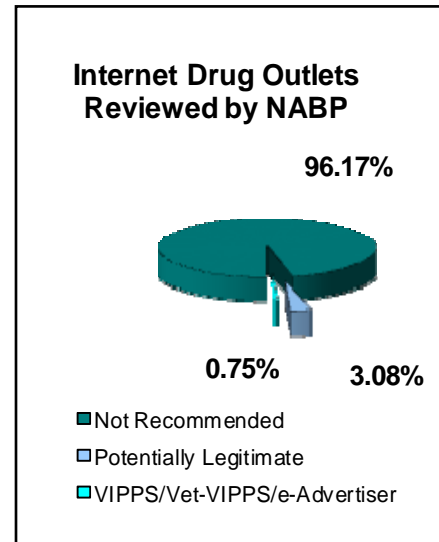
While a precise number of Web sites selling counterfeit drugs is difficult to determine, their prevalence and ill effects have garnered the attention of medical professionals, health regulators, and enforcement agencies worldwide. Through its own research, the National Association of Boards of Pharmacy® (NABP®) has identified 3,703 Web sites selling drugs that have not been tested or approved by the United States Food and Drug Administration (FDA) and are illegal to sell in the US, and most of these sites offer unapproved ED remedies. The prevalence of counterfeit ED drugs on the Internet, the ongoing efforts to educate patients, and the enforcement actions taken to shut down rogue sites are discussed further in sections III and IV of this report. In addition to Web sites selling foreign and unapproved drugs, approximately 80% of the sites NABP lists as Not Recommended sell prescription medication without requiring a valid prescription, exposing patients to additional health risks. Without medical oversight, medical

conditions that could be contributing to the symptoms, or that could be exacerbated by the drugs, are often overlooked.

In all, NABP has found more than 8,100 Web sites – 96% of the total number of sites reviewed – to be out of compliance with pharmacy laws and practice standards established in the US to protect the public health. NABP is taking steps to expose these dangers, and to assist regulatory and enforcement agents in eliminating these unlawful practices.

II. RESULTS

A. Findings of Site Reviews: As of September 30, 2011, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 8,445 Internet drug outlets selling prescription medications. Of these, 8,122 (96.17%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards, and are listed as Not Recommended in the “Buying Medicine Online” section, under Consumers, on the NABP Web site. Sites listed as Not Recommended include those that were found to be noncompliant at the time of review but may since have been deactivated.

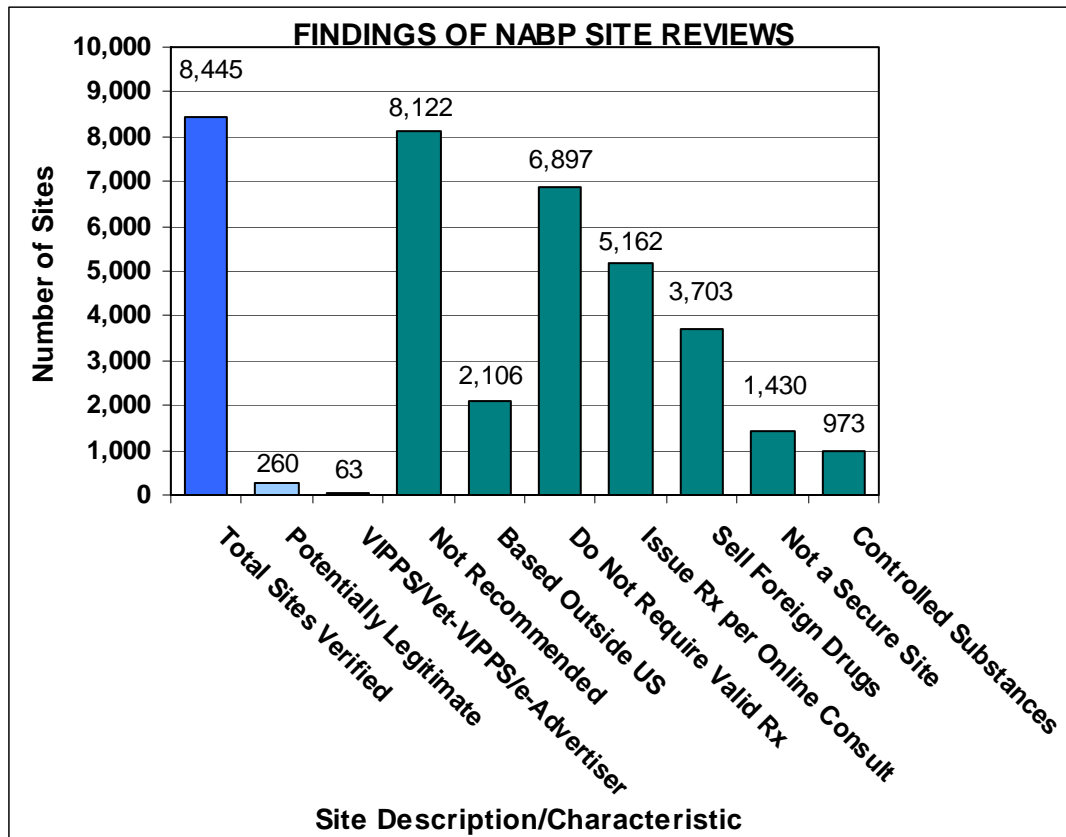


The 8,122 Internet drug outlets currently listed as Not Recommended on the NABP Web site are characterized as follows:

- 2,106 have a physical address located outside of the US
- 6,897 do not require a valid prescription
- 5,162 issue prescriptions per online consultation or questionnaire only
- 3,703 offer foreign or non-FDA-approved drugs
- 1,430 do not have secure sites
- 2,892 have server locations in foreign countries
- 7,862 appear to be affiliated with a network
- 973 dispense controlled substances

¹ J Men’s Health 2010 October; 7(3): 321

Of the total 8,445 sites reviewed, 260 (3.08%) appear to be potentially legitimate, ie, meet program criteria that could be verified solely by looking at the sites. Sixty-three (0.75%) of the 8,445 reviewed sites have been accredited through NABP's Verified Internet Pharmacy Practice Sites^{CM} (VIPPS[®]) or Veterinary-Verified Internet Pharmacy Practice Sites^{CM} (Vet-VIPPS[®]) programs, or approved through the NABP e-Advertiser Approval^{CM} Program. The criteria against which NABP evaluates Internet drug outlets are provided in the appendix of this report.



Findings of NABP Site Reviews as of September 30, 2011

- B. Recommended Internet Pharmacies: NABP, along with FDA and other patient safety advocates, continues to recommend that 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, 43 VIPPS and Vet-VIPPS pharmacy sites, representing more than 12,000 pharmacies, are listed as Recommended Internet Pharmacies. Several more applications are in progress.

- C. Accreditation and Approval Applicant Screenings: In addition to identifying rogue sites, the Internet Drug Outlet Identification program staff continues to assist in screening applicant Web sites for the VIPPS, Vet-VIPPS, and e-Advertiser Approval programs. Sites that have received e-Advertiser Approval 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 have been found to be safe, reliable, and lawful. These sites are listed on the NABP Web site as Approved e-Advertisers. The standards that NABP screens e-Advertiser Approval Program applicants against are posted in the e-Advertiser Approval Program section, under Accreditation, on the NABP Web site. These standards are essentially the same as those used to assess Internet drug outlets, only modified to accommodate a broader range of drug-related practices. As of September 30, 20 entities were listed on the NABP Web site as Approved e-Advertisers, and several more applications are in progress.



III. INTERNET FUELS GLOBAL COUNTERFEIT ED DRUG MARKET

Fake versions of Pfizer’s Viagra® (sildenafil citrate) tablets and Lilly’s Cialis® (tadalafil) tablets are prevalent online, bearing deceptive names such as “Viagra Professional,” “Viagra Soft Tabs,” “Lady Viagra,” “generic Viagra,” “Cialis Super Active,” “Cialis Professional,” and “generic Cialis.” These knock-off products are not made by the manufacturers’ whose trademarks they bear, nor have they been tested or approved by the US FDA, nor are they legal to sell in the US – contrary to the claims of many rogue online drug sellers. Of the 8,000-plus Web sites NABP has identified as Not Recommended, nearly half offer foreign or non-FDA-approved drugs, and most of those offer one or more of the fakes noted above. The popularity of virility-enhancing and other lifestyle drugs has provided a marketplace ripe for counterfeiters, many of whom reach consumers online. The March 2010 *International Journal of Clinical Practice* reports, “[g]rowth of the counterfeit medication market is attributable in part to phosphodiesterase type 5 inhibitor (PDE5i) medications for [ED]. Millions of counterfeit PDE5is are seized yearly and account for the bulk of all counterfeit pharmaceutical product seizures.” The *Journal* also reports that, “[o]f

men who purchase prescription-only medication for ED without a prescription, 67% do so using the Internet.”²

In the August 2011 *Journal of Sexual Medicine*, Wayne J.G. Hellstrom, MD, professor of urology and chief of andrology at Tulane University School of Medicine in New Orleans, LA, notes that most counterfeit ED drugs enter the US drug market via fraudulent Web sites that are easily accessible online. Counterfeiters tend to focus their efforts on two types of drugs – those that are most expensive, including life-saving medications to treat cancer and HIV/AIDS, and those that cause patients the most embarrassment, such as products to treat hair loss and ED. Hellstrom calls the popular ED drugs Viagra, Cialis, and Levitra “the most common ‘embarrassment’ counterfeit prescription drugs in the world.”³ The profit motive for counterfeiters is clear. When sold at market price, counterfeit ED drugs reportedly can generate 2,000% profit margins – approximately 10 times the profitability of heroin.⁴ Additionally, penalties for the illegal sale of prescription drugs are generally less severe than for illicit drugs. This profile provides some explanation for the prevalence of counterfeit ED drugs that has been observed worldwide, many of them originating in China and India. Several examples follow.

- In August 2011, US Customs and Border Protection (CBP) officers working in a Cincinnati, OH, facility seized a package from India manifested as containing “Harmless Generic Medicine,” the agency reported in an August 10 news release. After inspection, CBP officers found the parcel contained more than 8,000 counterfeit tadalafil tablets.
- BBC News reported on September 29 that the United Kingdom’s Medicines and Healthcare products Regulation Agency (MHRA) seized more than a million doses of fake and unlicensed medicines worth more than \$4 million US dollars during a recent crackdown. Lifestyle drugs such as anti-anxiety and ED remedies are the most commonly sold online, but the agency warns that counterfeiters are starting to offer drugs for cancer, heart conditions, epilepsy, asthma, and depression. The report quotes

‘No one involved in those websites is medically qualified. None of the products are licensed or tested. They are selling them to you as a drug dealer would. They are not interested in your health; they are interested in taking your money. And the money is big.’

MHRA

² Int J Clin Pract. 2010 March; 64(4): 497-504

³ J Sex Med 2011;8:1-3

⁴ Louv Med 2007;126:S138-42

MHRA investigator Danny Lee-Frost: “No one involved in those websites is medically qualified. None of the products are licensed or tested. They are selling them to you as a drug dealer would. They are not interested in your health; they are interested in taking your money. And the money is big.”

- In South Korea, a study of confiscated counterfeit ED drugs compared 19 counterfeit ED drugs against prescription Viagra and Cialis, provided by the manufacturers. As reported in a June 1, 2010 supplement to the *Journal of Urology*, researchers found that 58% of the fake drugs contained excess (up to 2.4 times more) active ingredients, 3% had no active ingredient, and only 1% showed proper dose levels. Only one of the counterfeit drugs contained “proper active ingredients,” the researchers stated. Some contained potential toxins, including mercury and lead.⁵
- In a recent study conducted by Pfizer and announced in a September 29 news release, the manufacturer purchased and tested so-called Viagra from 26 Internet drug sites that appeared in the top results for “buy Viagra” on two major search engines. Pfizer found that all analyzed pharmacies claiming to sell Viagra were operating illegally, and 81% were selling counterfeit Viagra, the company reported. In a 2009 study supported by Pfizer, 483 seizures of pharmaceuticals suspected of being counterfeit that were ordered using the Internet were tested for authenticity using spectral analysis. The study found that only 24% were authentic; the remaining 76% were counterfeit.⁶

Based on these findings, it is not surprising that counterfeit ED drugs have been the culprit in adverse health events around the world. In Singapore, in the first five months of 2008, 150 non-diabetic patients – 149 of them men – were hospitalized for severe hypoglycemia, as reported in the *New England Journal of Medicine*.⁷ Seven of them were comatose, and four subsequently died. Glyburide was detected in blood or urine samples obtained from 127 of these patients (85%), many of whom had reportedly taken counterfeit copies of drugs purporting to treat ED but which contained a dangerous amount of glyburide, a drug used for treating diabetes. Between January and June 2008, similar cases of hypoglycemia were reported in the press in Hong Kong; these reports implicated other brands of illegal sexual-enhancement drugs. The author notes, “It would appear that more effective collaboration between national and international drug-regulatory bodies and enforcement agencies will be required to address clandestine

⁵ J Urol 2010; 1371 A:e530

⁶ J Men’s Health 2010 October; 7(3): 321

⁷ N Engl J Med 2009; 360:734-736

manufacturing processes, the cross-border movement of drugs, and the subsequent spread of these adulterated medications through online sources.”

Responding to the need for global action, FDA, along with regulatory agencies from 81 countries, participated in this year’s International Internet Week of Action (IIWA) September 20-27. The project, dubbed Operation Pangea IV, was a cooperative effort to curb online sales and distribution of counterfeit and illegal medical products. During the project, FDA targeted 997 Web sites that were

illegally selling unapproved and/or misbranded drug products, including ED remedies, to US consumers. An FDA news release explains that, “[a]lthough some drugs containing these active ingredients are approved by FDA for use under the supervision of a licensed medical practitioner, the drugs offered for sale on these websites were not FDA approved, and were offered for sale without requiring a valid prescription.” FDA sent warning letters to the operators of 717 identified Web sites, “all of which appear to be associated with the same individuals and corporate entities located outside of the United States.” FDA reports that 578 of these sites “have been suspended or no longer offer pharmaceuticals for sale,” and the agency is working with its international partners to address the remaining Web sites. INTERPOL reports that, as a result of the efforts of all of the project’s international partners, nearly 13,500 Web sites engaged in illegal activity were shut down. In addition, the agency reports, regulators and customs authorities inspected approximately 45,500 packages, seized almost 8,000 of them, and confiscated 2.4 million illicit and counterfeit pills – including antibiotics, steroids, anti-cancer, anti-depression and anti-epileptic pills, as well as slimming or food supplement pills and ED drugs – originating from 48 countries. Enforcement officers reportedly are investigating some 55 individuals for a range of offences, including illegally manufacturing, selling, and supplying unlicensed or prescription-only medicines.

‘The drugs offered for sale on these websites were not FDA approved, and were offered for sale without requiring a valid prescription.’
FDA

IV. NABP EDUCATIONAL INITIATIVES FOCUS ON MEDICATION SAFETY

A. NABP and Pfizer Collaborate to Raise Patient Awareness of Counterfeits: In one of several patient education initiatives, NABP is partnering with Pfizer to draw attention to the risks associated with counterfeit drugs and to help patients learn to identify safe Internet pharmacies. “We believe this joint effort with Pfizer will inform consumers about the dangers of counterfeit medicines and help them find legitimate websites and pharmacies licensed by

the state boards of pharmacy that provide medicines approved by the FDA,” NABP Executive Director/Secretary Carmen Catizone, MS, RPh, DPh, said in a news release issued by Pfizer on September 29. “Together, we hope to lessen the dangers related to purchasing medicines online.” Pfizer and NABP’s educational initiative involves the use of multiple communication channels, including a YouTube video series that features experts from Pfizer, NABP, Microsoft, and the cyber-security company McAfee. Additionally, the NABP consumer Web site, www.AWARERX.ORG, provides patient-focused information about the dangers of counterfeit medicines and tips on how to select an online pharmacy from which to safely buy medicine. The Viagra Web site, www.Viagra.com, includes additional patient-education resources, including the “Anatomy of a Fake Website” and the “Spot the Fake” quiz, which illustrate the gimmicks counterfeiters use to trick them into buying fake medicines. Pfizer Global Security also announced its planned takeovers of Web sites once used by counterfeiters to sell fake Pfizer medicines. To reach potential buyers, Pfizer will repopulate these sites with facts about the dangers of counterfeit medicines and ways to determine if online pharmacies are legitimate.



- B. AWAR_xE Consumer Protection Program Provides Educational Resources: NABP encourages regulators, health care professionals, and others to educate patients within their practices and jurisdictions and offers resources to facilitate such efforts. NABP provides the AWAR_xE™ consumer protection program, for instance, as a resource not only for consumers, but also to help the boards of pharmacy, their licensees, and other stakeholders educate patients on medication safety. The Web site, www.AWARERX.ORG, provides information about rogue Internet drug outlets, prescription drug counterfeiting, proper medication use, storage and disposal, and other medication safety issues.



This past August, NABP launched its first advertising campaign, “Does a Drug Dealer Lurk in Your Medicine Cabinet?” under the AWAR_xE program. The ad, as shown here, appeared in an August edition of the *Journal & Topics Newspaper*, distributed throughout Chicago’s northwest suburbs. This campaign draws attention to teen prescription drug abuse and the

importance of proper medication storage and disposal. The information also has appeared, or will appear soon, in several other editions of the *Journal & Topics Newspaper*, as well as in the *Senior News*, and national editions of the *AARP Bulletin*. Through AWA_R_XE ads such as this, NABP hopes to educate consumers on the various medication safety issues arising today.

NABP staff continues to reach out to consumers under the banner of the AWA_R_XE program and has spoken one-on-one with hundreds of consumers during trade shows and other consumer expositions in the Chicago metropolitan area. In addition to educating consumers on the dangers of rogue Internet drug outlets, NABP staff informs expo attendees about proper medication disposal, local and national discount prescription sources, the dangers of counterfeit drugs, and other medication safety issues. Staff will be presenting at another Chicago area expo in November and will continue to educate consumers at future venues.

Boards of pharmacy addressing the problem of prescription drug abuse in their state may recommend to their licensees and registrants that they use the AWA_R_XE Web site as a resource for educating their patients about this problem. AWA_R_XE bookmarks are available for boards and other groups to distribute at public meetings, through mailings, or in association with other outreach activities. As AWA_R_XE.ORG resources are further developed, NABP will provide the boards and other pharmacy organizations with updates on using AWA_R_XE tools.

- C. 'White List' of Legitimate Online Pharmacies: To provide guidance for regulators, Internet commerce providers, and consumers, NABP supports the creation of a "White List" of legitimate Internet pharmacies. As proposed in the March 2011 Counterfeit Pharmaceutical Inter-Agency Working Group Report to the Vice President of the United States and to Congress, the White List would allow Internet commerce providers and others to know which pharmacies are operating in compliance with federal law and can therefore lawfully use their services.

V. **DISCUSSION**

As we have seen, where there are profits to be made, counterfeiters will go. Likewise, where there is significant risk to the public health, it is inherent in the mission of health regulators to mitigate it. NABP encourages and continues to work with the state boards of pharmacy, federal regulators, and other public and private stakeholders to educate the public about counterfeit drugs and other potential dangers of buying medication from unknown and unapproved sources over the Internet. The Association remains committed to upholding the integrity of the practice of pharmacy – in

any practice setting – and ensuring that patients have access to safe and effective prescription drugs.

NABP prepares and releases these status reports quarterly to provide the boards of pharmacy, other state and federal regulatory agencies, and interested stakeholders with updates of Web site review findings and outreach efforts, as well as other events and trends related to Internet pharmacy practice. Through communication and cooperation, we hope to advance the efforts of regulators and other entities to curtail the online trade of illicit and counterfeit medications, in the interest of protecting the public health. As always, NABP welcomes feedback on these reports, and on its Internet program, to determine how we can better serve your needs and better protect patients from these threats. In addition, we ask that you share with NABP any knowledge or concerns you might have pertaining to illegally or unprofessionally operating Internet drug outlets, so that we may support your efforts, assist in your research, or pass the information along as appropriate. As we have seen, the combined efforts of multiple parties are a powerful force in bringing about positive change and protecting the public health, and we anticipate further improvement in the future.

For further information, please contact Melissa Madigan, policy and communications director, via e-mail at mmadigan@nabp.net.

VI. APPENDIX

Internet Drug Outlet Identification Program Criteria

Patient Safety and Pharmacy Practice 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.