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# **Internet Drug Outlet Identification Program**

**Progress Report for State and  
Federal Regulators:  
October 2010**

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### **INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: OCTOBER 2010**

#### **I. INTRODUCTION**

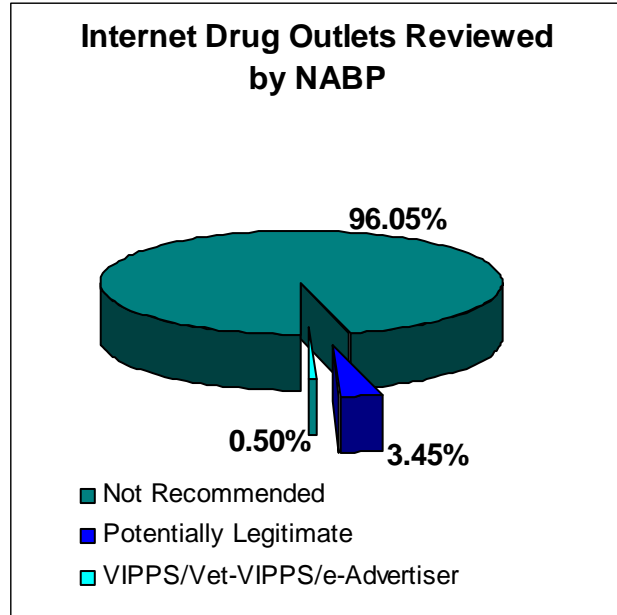
The threat that rogue Internet drug outlets pose to the public health gained worldwide attention in recent weeks, as regulators and stakeholders across the globe joined forces to thwart criminals profiting from counterfeit medications. October 5-12, 2010, the United States Food and Drug Administration (FDA), along with regulators and stakeholders from 45 countries, participated in the International Internet Week of Action (IIWA), a coordinated, cooperative effort to curb online sales and distribution of counterfeit and illicit medical products. These efforts resulted in multiple arrests and the seizure of potentially harmful medicines in operations carried out around the world. In the US, federal lawmakers and regulators are promulgating legislation and strategic plans designed to curb prescription drug counterfeiting. Several domain name registrars and Internet service providers are voluntarily taking action to close off the safe harbors through which counterfeit drugs make their way to unsuspecting patients. Education initiatives in the US and abroad continue to amplify the message that buying medications from unknown and unapproved sources via the Internet exposes patients to considerable risk. These efforts are discussed in further detail in Section IV of this report.

Meanwhile, National Association of Boards of Pharmacy® (NABP®) continues to uncover and review large numbers of rogue Internet drug outlets. Of the 7,127 sites found to be operating in conflict with pharmacy laws and practice standards as of October 15, 2010, approximately 84% do not require a valid prescription, and approximately 45% offer unapproved foreign medications, placing US patients at risk. Approximately 56% (4,000 sites) do not provide any physical address. The World Health Organization estimates that more than half of medicines purchased from Web sites that conceal their physical address are counterfeit. An estimated 94% of the 7,127 sites are part of large networks that host similarly operating rogue Internet drug outlets. NABP continues to stress the importance of educating the public on these risks and to provide patients with the

knowledge and information needed to make informed decisions when purchasing prescription medications over the Internet.

## II. RESULTS

A. Findings of Site Reviews: As of October 15, 2010, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 7,420 Internet drug outlets selling prescription medications. Of these 7,420 sites, 7,127 (96.05%) appear 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.

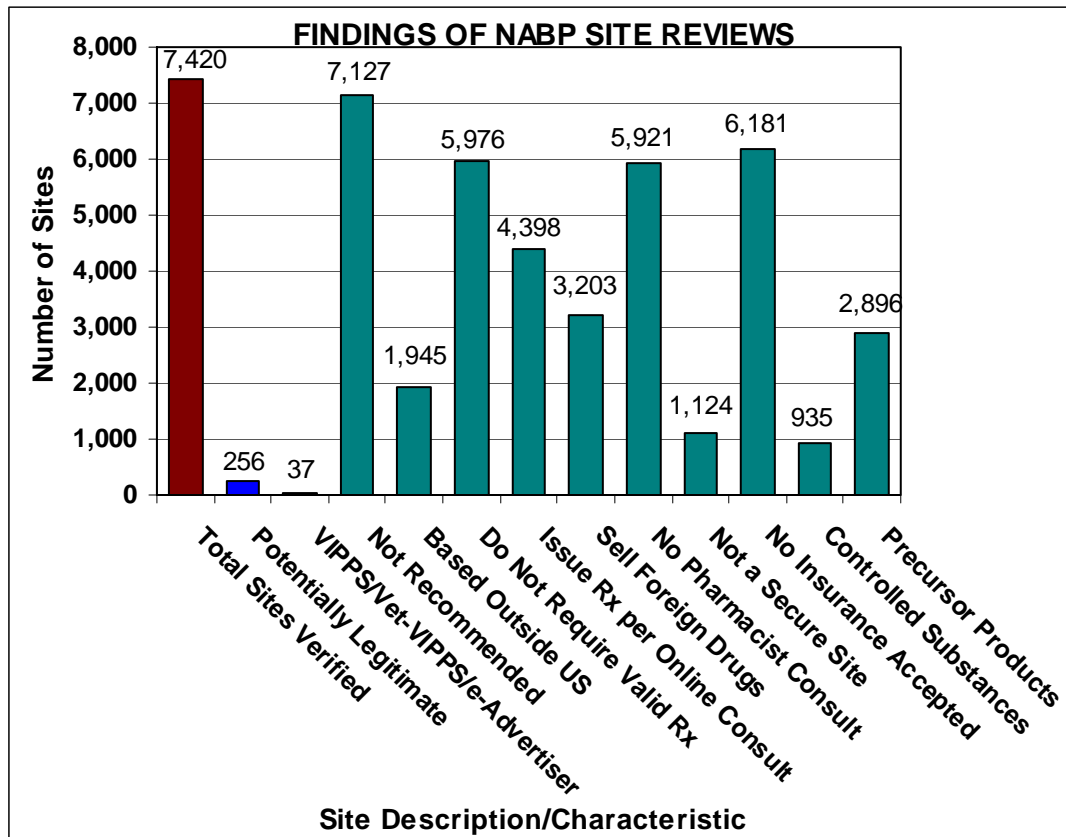


The 7,127 Internet drug outlets currently listed as Not Recommended on the NABP Web site are characterized as follows:

- 1,945 have a physical address located outside of the US
- 4,000 sites do not provide any physical address
- 5,976 do not require a valid prescription
- 4,398 issue prescriptions per online consultation or questionnaire only
- 3,203 offer foreign or non-FDA-approved drugs
- 5,921 do not offer medical consult with a pharmacist
- 1,124 do not have secure sites
- 6,181 do not accept insurance
- 2,431 have server locations in foreign countries
- 6,711 appear to be affiliated with a network
- 935 dispense controlled substances
- 2,896 sell precursor products

Of the total 7,420 sites reviewed, 256 (3.45%) appear to be potentially legitimate, ie, appear to meet program criteria that could be verified solely by looking at the sites. Thirty-seven

(0.50%) of the 7,420 reviewed sites have been accredited through NABP’s Verified Internet Pharmacy Practice Sites<sup>CM</sup> (VIPPS<sup>®</sup>) or Veterinary-Verified Internet Pharmacy Practice Sites<sup>CM</sup> (Vet-VIPPS<sup>CM</sup>) program, or approved through the NABP e-Advertiser Approval<sup>CM</sup> Program.



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

B. Recommended Internet Pharmacies: NABP 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, 30 VIPPS and Vet-VIPPS pharmacy sites, representing more than 12,000 pharmacies, are listed as Recommended Internet Pharmacies, and several more applications are in progress.



### III. NABP e-ADVERTISER APPROVAL PROGRAM

In addition to identifying Web sites selling prescription medications via the Internet and classifying such sites as Not Recommended or potentially legitimate, the Internet Drug Outlet Identification program staff continues to allocate a large portion of their time to screening applicant Web sites for the VIPPS, Vet-VIPPS, and e-Advertiser Approval programs. As of October 15, 2010, staff has screened 50 applicants for all three 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, pharmacy information, or are medical practitioners' Web sites or 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 and included as Appendix A of this report. 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. Currently, seven entities are listed on the NABP Web site as Approved e-Advertisers, and several more applications are in progress.



### IV. DOMESTIC AND INTERNATIONAL ANTI-COUNTERFEITING EFFORTS

While the US is a primary market for rogue Internet drug outlets, the danger they pose to public health is global in scope. Recognition of this problem has led not only to US federal efforts, but also to international initiatives, such as the International Internet Week of Action (IIWA).

A. International Internet Week of Action: Through the combined efforts of 45 countries, IWA culminated earlier this month in the seizure of more than one million illicit and counterfeit pills valued at \$2.6 million, according to an October 15 INTERPOL [news release](#). INTERPOL was one of the several international law enforcement agencies that coordinated the effort, code-named Operation Pangea III, which was carried out in support of the International Medical Products Anti-Counterfeiting Taskforce. Other coordinating entities included the World Customs Organization, the Permanent Forum of International Pharmaceutical crime, the Heads of Medicines Agencies Working Group of Enforcement Officers, the pharmaceutical industry, and the electronic payments industry.

‘We hope that that by raising public awareness about the dangers of illegal Internet pharmacies, consumers will exercise greater care when purchasing medicines online.’

INTERPOL Secretary  
General Ronald K. Noble

“Through a multi-sector operation involving law enforcement and health, INTERPOL’s key objective in Operation Pangea III was to alert and protect members of the public by assisting our 188 member countries shut down illegal pharmaceutical websites, chase money flows and backtrack to the sources behind these illicit pharmaceutical products which represent such a threat to the health of the public,” INTERPOL Secretary General Ronald K. Noble stated in the news release. “While this international operation, the third of its kind, shows that criminals attempting to use the Internet as an anonymous safe haven are not safe any more, we hope that that by raising public awareness about the dangers of illegal Internet pharmacies, consumers will exercise greater care when purchasing medicines online,” he added.

In conjunction with Operation Pangea III, INTERPOL also launched a consumer outreach campaign to build awareness of the dangers of buying medicines online using a series of [Web videos](#) of individuals sharing their personal accounts of the harm caused by counterfeit drugs purchased online. The US Drug Enforcement Administration (DEA), FDA, and other US health and law enforcement agencies and patient advocate groups also provide a variety of educational materials through myriad electronic media channels.

FDA took part in IWA by warning Web site operators believed to be illegally peddling unapproved drugs to US consumers, and by targeting illegal shipments of pharmaceutical products. The FDA’s Office of Criminal Investigations (OCI), in conjunction with the Center for Drug Evaluation and Research and the Office of Enforcement within the Office of Regulatory Affairs, targeted 294 Web sites that appeared to be engaged in the illegal sale of

unapproved or misbranded drugs to US consumers, according to an October 14 FDA [news release](#). FDA sent warning letters to the operators of these Web sites, all of which appear to be associated with the same individuals and corporate entities located outside the US.

FDA also notified the associated Internet service providers (ISP) and domain name registrars (DNR) that these sites using their services are operating in violation of US law. In many cases, conducting illegal activities also violates ISP and DNR policies and agreements, giving the hosting companies the opportunity to terminate the Web sites and suspend the use of the domain names. Of the 294 Web sites addressed in the warning letters, FDA reports, 274 have been suspended or no longer offer prescription drugs for sale. FDA says it is working with its foreign counterparts to address the remaining 20 Web sites that continue to offer unapproved prescription drugs to patients in the US. Also as part of IIWA, FDA's OCI and FDA's import specialists joined US Immigration and Customs Enforcement, US Customs and Border Protection, US DEA, and US Postal Inspection Service to intercept illegal shipments of pharmaceutical products at international mail facilities and express courier hubs.

- B. Joint Strategic Plan on Intellectual Property Enforcement: In the US, efforts to counteract the proliferation of counterfeit prescription medications received a boost with the federal government's 2010 [Joint Strategic Plan on Intellectual Property Enforcement](#), released in June by the Office of the Intellectual Property Enforcement Coordinator (IPEC). The plan includes strategies focused on fighting counterfeit pharmaceuticals and securing the US drug supply chain, as part of a multi-faceted approach to address threats to US intellectual property in general.

As one of its 33 "enforcement strategy action items," the plan announced that IPEC will establish a counterfeit pharmaceutical interagency committee to "examine the myriad of problems associated with unlicensed Internet pharmacies, health and safety risks in the U.S. associated with the distribution of counterfeits and the proliferation of the distribution of counterfeit pharmaceuticals in Africa." The committee, composed of experts from numerous federal agencies, will release a report recommending specific government actions.

On September 29, 2010, IPEC hosted a meeting at the White House with DNRs and senior US government officials to discuss voluntary efforts to confront the illegal sale of non-controlled prescription drugs – many of them counterfeit – online.

- C. Voluntary Efforts of Registrars and Search Engines:

Several DNRs have taken voluntary actions to terminate domain names that have been identified as operating unlawfully.

1. eNom-LegitScript Partnership: Potentially thousands of rogue Internet drug outlets will have to board up their virtual storefronts, thanks to a new partnership agreement enforcing a major DNR's ban on illegal use of the Web sites it hosts. On September 21, 2010, the domain name registrar eNom Inc, and the Internet pharmacy verification and monitoring service LegitScript LLC announced that LegitScript will assist eNom in identifying customers (ie, Web site operators whose domain names, or URLs, are registered with eNom) who are violating eNom's terms of service by operating online pharmacies in violation of US federal or state law, particularly focusing on those selling prescription drugs without requiring a valid prescription.

Under the agreement, and in consultation with law enforcement authorities, LegitScript notifies eNom of domain names that knowingly facilitate the unlawful sale of prescription medications, the partners state in a September 21 news release. This information enables eNom to better enforce its policy of taking action against Web site holders engaged in illegal activity.

The announcement follows NABP's recent petitioning of the Internet Corporation for Assigned Names and Numbers and 20 US-based domain name registrars, including eNom, to enforce policies prohibiting the use of Web sites for unlawful purposes – namely, the illicit sale of prescription medications. NABP sent letters on August 31, urging these entities to take additional steps to protect users from rogue Internet drug outlets that endanger the public health.

2. Network Solutions: DNR Network Solutions has expressed its interest in working with US regulators to terminate domains being used for the unlawful sale of prescription drugs. Toward this end, Network Solutions has conferred with LegitScript and NABP about certain Internet drug outlets that have been identified as operating unlawfully. Based on this information, Network Solutions has deactivated several domains.
3. Search Engines: The three major search engines, Google, Yahoo!, and MSN's Bing, continue to require VIPPS or Vet-VIPPS accreditation for Internet pharmacies and NABP e-Advertiser Approval for other prescription-drug related entities to display advertisements (sponsored links) in their search results. Still, many illicit sellers attempt to circumvent the search engines' filters. Google has taken decisive action against such perpetrators. In a September 21, 2010 blog post, Google announced that it is suing certain rogue Internet drug outlet advertisers that have knowingly violated Google's policies. Google states, "Rogue pharmacies are bad for our users, for legitimate online pharmacies

and for the entire e-commerce industry—so we are going to keep investing time and money to stop these kinds of harmful practices.” LegitScript assisted the search engine by identifying rogue Internet drug outlets that have violated Google’s advertising policies.

## V. COMMUNICATION AND OUTREACH EFFORTS

- A. Media Exposure: Consumer outreach remains an important goal of the NABP Internet Drug Outlet Identification Program. In furtherance of these efforts, NABP Executive Director/Secretary Carmen Catizone will participate as a guest on Aging Info Radio on December 30, 2010, to discuss the dangers of purchasing prescription medications online. Mr. Catizone will be interviewed by show host Sue Zawacki. Aging Info Radio reaches the Chicago area and streams live online. Outreach efforts such as this allow NABP to connect with its local community and spread the word about dangerous rogue Internet drug outlets and inform consumers on the avenues they can take to be sure they are purchasing safe prescription medications online.

On September 29, NABP issued a news release, “NABP Purchases AWA<sub>R</sub><sub>x</sub>E Consumer Protection Program,” announcing NABP’s acquisition of the AWA<sub>R</sub><sub>x</sub>E program. NABP purchased the program from the Minnesota Pharmacists Foundation, which created it in 2007. NABP will continue to educate consumers through AWA<sub>R</sub><sub>x</sub>E, which was designed as a means to inform the public on the dangers of buying prescription medications online, counterfeit drugs, prescription drug abuse, and other important prescription drug related issues. Additionally, on October 12, NABP issued a news release, “AWA<sub>R</sub><sub>x</sub>E Recognizes American Pharmacists Month,” which discusses how rogue Internet drug outlets undermine the vital role of pharmacists in patient care.

- B. Public Events: To further its consumer outreach efforts, NABP participated in the 15<sup>th</sup> Annual Senior Lifestyle Expo, August 24-25 in Oakbrook Terrace, IL. The goal of our attendance was to inform the public of the dangers of purchasing prescription medications online and empower them to make educated decisions when buying medications via the Internet. Staff handed out 1,288 AWA<sub>R</sub><sub>x</sub>E pill boxes and personally spoke with nearly 600 attendees about the AWA<sub>R</sub><sub>x</sub>E program and prescription drug safety.

Through networking at the Senior Lifestyle Expo, NABP arranged for staff to speak to the Senior Citizens Services Coordinating Council, a group of 50 plus business and health care professionals in the Chicago area who meet monthly to discuss the council’s activities and to provide educational programming relevant to the care of senior citizens. On September 16, NABP staff introduced the council to the AWA<sub>R</sub><sub>x</sub>E program and spoke about

purchasing prescription medications online and what consumers can do to make this a safer experience. Staff also highlighted the alarming data NABP has found during its research of Internet drug outlets, exposing the dangers that rogue sites pose to consumers. Participants were provided with handouts, illustrating the key points of the presentation, for their own reference as well as additional copies for distribution to their co-workers and patients.

NABP plans to speak to more groups of this nature in the future to continue educating consumers on the potential dangers of buying medication online.

C. Informative Materials on NABP Web site: NABP staff routinely updates the “Buying Medicine Online” page of the NABP Web site with new articles and other patient educational materials. The following articles were added from August 14 to October 15:

- [“Canadian Man Sentenced for Internet Cancer Drug Fraud”](#)
- [“Growing Problem of Counterfeit Drugs is Hurting Patients, Companies”](#)
- [“Counterfeit Drug Infiltration of the Legitimate Supply Chain”](#)
- [“Warnings About Discounted Pet Drugs”](#)
- [“Detention Without Physical Examination of Unapproved New Drugs Promoted in the U.S.”](#)
- [“Online ED Drug Purchases Pose Health Risks, Korean Study Shows”](#)

## VI. DISCUSSION

In the last year, NABP, and the world, has seen significant progress in the effort to protect consumers from rogue Internet drug outlets selling illicit and counterfeit medications. As national health care and law enforcement agencies and stakeholders worldwide continue to make the Internet a safer place for patients to buy prescription medications, NABP remains committed to assist the state boards of pharmacy, federal regulators, and patient advocates in their efforts to ensure that pharmacies online are as safe and reliable as those on the corner. Additionally, through the AWA<sub>R</sub><sub>x</sub>E program, NABP will continue to educate the public on the dangerous and illicit practices of rogue Internet drug outlets and empower them to make informed decisions about their online medication purchases.

NABP prepares and releases these status reports every other month 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 seeking to curtail the online trade of illicit and counterfeit

medications. NABP encourages regulators, health care professionals, and others to educate patients within their practices and jurisdictions and offers resources to facilitate such efforts.

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.

For further information, please contact Melissa Madigan, policy and communications director, via e-mail at [mmadigan@nabp.net](mailto:mmadigan@nabp.net).

## **VII. APPENDICES**

## APPENDIX A

### NABP e-Advertiser Approval Program Standards

Pharmacies conducting limited pharmacy services over the Internet and other businesses or persons conducting drug-related services over the Internet must meet the following standards to earn NABP e-Advertiser Approval status. 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.

1. **Licensure.** The pharmacy, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, must be licensed or registered in good standing to practice in all required jurisdictions.
2. **DEA registration.** The pharmacy, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, if dispensing controlled substances, must be registered with the United States Drug Enforcement Administration (DEA).
3. **Prior discipline.** The pharmacy, pharmacist-in-charge, medical practice, medical practitioner, or any such practice or practitioner 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.
4. **Location.** The pharmacy, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, must be domiciled in the US.
5. **Validity of prescription.** A pharmacy shall dispense or offer to dispense prescription drugs only upon receipt of a valid prescription, as defined below, issued by a medical practitioner authorized to prescribe under state law and, as applicable, federal law. A medical practitioner authorized to prescribe must not prescribe, distribute, or offer to prescribe or distribute prescriptions or prescription drugs solely on the basis of an online questionnaire or consultation without a pre-existing 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, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, 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). The pharmacy, medical practice, or medical practitioner must not prescribe, dispense, or offer to prescribe or dispense medications that have not been approved by the US Food and Drug Administration (FDA).
7. **Privacy.** If the applicant Web site, or any site to which the applicant site links or with which it is affiliated, transmits information that would be considered Protected Health Information (PHI) under the 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

## APPENDIX A (CONT.)

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, 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 Web site an accurate US street address of the dispensing pharmacy, medical practice, medical practitioner, or corporate headquarters. The 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 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 or medical practitioner regarding complaints or concerns or in the event of a possible adverse event involving their medication.
9. **Web site transparency.** The pharmacy, medical practice, medical practitioner, or any such practice or practitioner to which the applicant site links or with which it is affiliated, 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 practice, its staff, prescription drugs, or financial transactions.
10. **Domain name registration.** The domain name registration information of the applicant Web site, or of any pharmacy, medical practice, or medical practitioner it promotes, must be accurate, and the domain name registrant must have a logical nexus to the dispensing pharmacy, medical practice, or medical practitioner. Absent extenuating circumstances, applicant Web sites utilizing anonymous domain name registration services will not be eligible for approval.
11. **Affiliated Web sites.** The applicant Web site, any pharmacy, medical practice, or medical practitioner 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 Web site that violates these standards.