

Internet Drug Outlet Identification Program *Progress Report for State and Federal Regulators: February 2018*

Prepared By

The National Association of Boards of Pharmacy



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Internet Drug Outlet Identification Program

Progress Report: February 2018

Introduction

The opioid epidemic has taken a deadly turn. Controlled prescription drugs are increasingly being counterfeited using fentanyl and sold illegally, often online. Several popular controlled substances (CS), including opioids, connected with recent overdose deaths – oxycodone, Percocet[®], Xanax[®], and Norco[®] – have been found to be counterfeit and contain fentanyl. Contributing to the spread of the problem, CS, including these often-counterfeited drugs, are readily available for purchase from rogue internet drug outlets and direct-to-consumer shipment through the international postal system. These illegal drug sites are notorious for selling unapproved, substandard, counterfeit, and falsified medicine. A recent U.S. Senate report raises concerns about how easy it is to buy illicit, mail-order opioids online. Investigators for the Senate’s Permanent Subcommittee on Investigations posed as would-be online buyers, entering terms like “fentanyl for sale” into Google and used payment information to track more than 500 US-linked transactions from these illegal sites. While search engines regularly screen online advertisers to prevent them from promoting their drug trafficking operations on their paid advertising platforms, rogue drug sellers continue to rise to the top of organic, unpaid search results, contributing to the drugs’ availability and exacerbating the opioid crisis.

To illustrate the availability of popular CS including opioids online, the National Association of Boards of Pharmacy[®] (NABP[®]) evaluated 100 websites selling medication to patients in the United States during the second half of 2017. All were found to be operating illegally, offering prescription-only medicine without a prescription (98%) and/or selling unapproved drug products (76%). More than half of them (54%) offered CS, and 40% offered one or more of the drugs frequently counterfeited with fentanyl. Further details about these findings are provided later in this report. These 100 sites have been added to the growing list of more than 11,000 drug sites NABP has found to be operating out of compliance with US federal and state pharmacy laws and practice standards. In all, nearly 96% of the total number of sites NABP has evaluated since 2008 have been found to be out of compliance with these laws and standards.

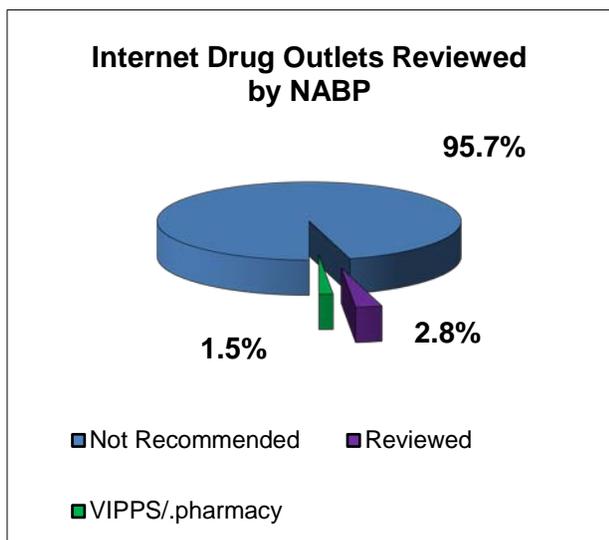
NABP continues to support the efforts of state and federal regulators and stakeholders to tackle the opioid epidemic and to address the role that the internet plays in this increasingly lethal problem.

Results

A. Findings of Site Reviews to Date:

As of December 31, 2017, NABP has reviewed 11,749 internet drug outlets selling prescription medications to US patients. Of these, 11,242 (95.7%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards. These sites are listed as [Not Recommended](#) in the Initiatives

section of the NABP website, www.nabp.pharmacy. Of the websites identified by NABP as Not Recommended, the majority were found to be dispensing prescription drugs without a valid prescription. These findings include sites dispensing drugs based solely on an online questionnaire, as well as those requiring no prescription at all. Many also offer foreign and unapproved drugs that may be substandard or counterfeit. The 11,242 internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table on the next page.¹

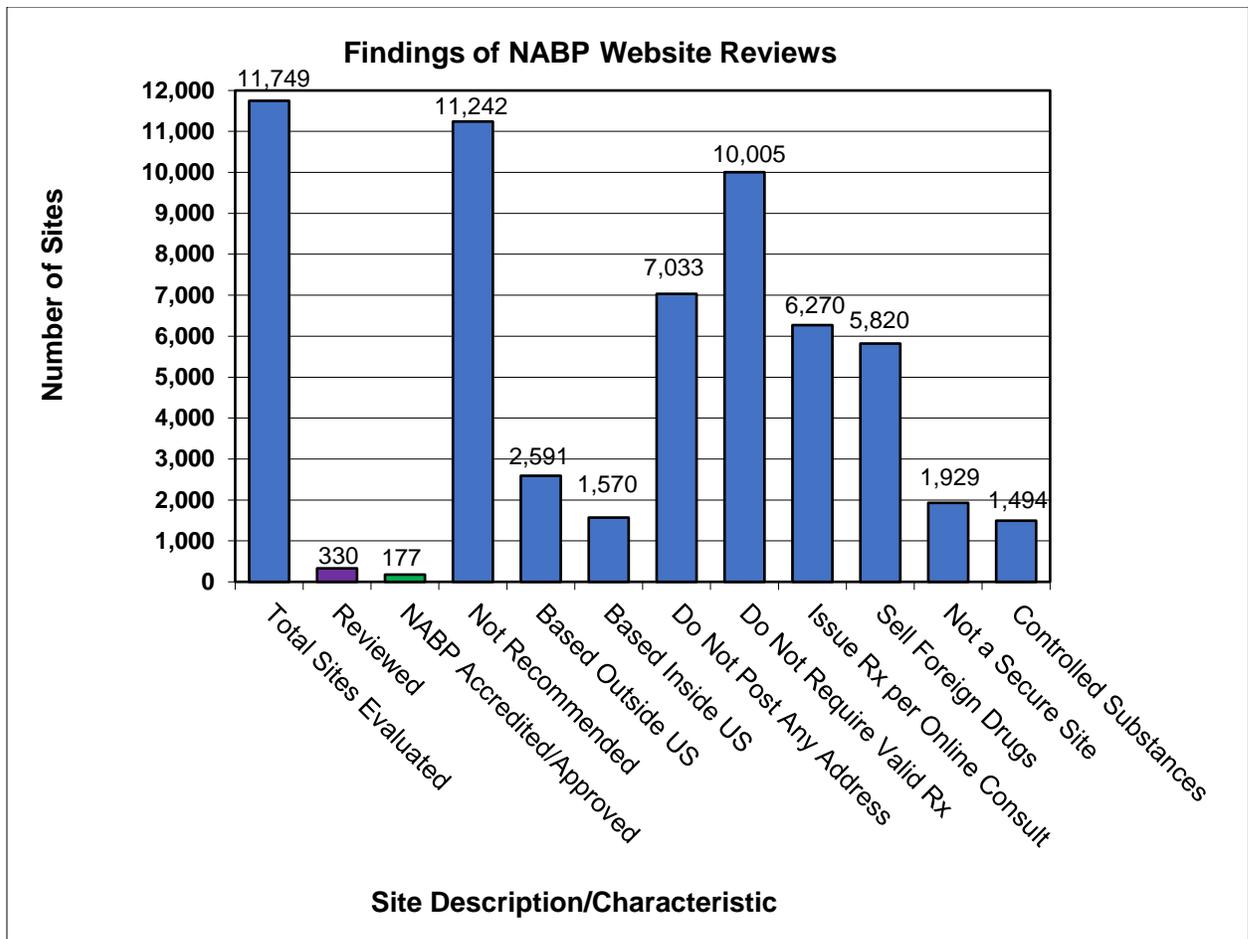


¹ It should be noted that the research findings NABP reports herein and on the Not Recommended list include the total number of websites selling prescription drugs to US patients that NABP staff has reviewed and found to be out of compliance with program standards, including those sites that were found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

Not Recommended Sites

Physical Location:	<ul style="list-style-type: none">• 2,591 (23%) outside US• 1,570 (14%) inside US• 7,033 (63%) no location posted on website
Prescription Requirements:	<ul style="list-style-type: none">• 10,005 (89%) do not require valid prescription• 6,270 (56%) issue prescriptions per online consultations or questionnaires only
Medications:	<ul style="list-style-type: none">• 5,820 (52%) offer foreign or non-Food and Drug Administration (FDA)-approved medications• 1,494 (13%) dispense CS
Encryption:	<ul style="list-style-type: none">• 1,929 (17%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	<ul style="list-style-type: none">• 4,803 (43%) outside US• 5,962 (53%) inside US• 464 (4%) have unknown server locations
Affiliations:	<ul style="list-style-type: none">• 9,686 (86%) appear to have affiliations with rogue networks of internet drug outlets

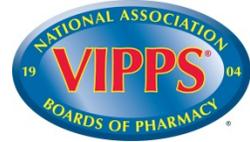
The table above, as well as the bar graph on page 6 of this report, shows the characteristics of drug sites listed as Not Recommended on the NABP website as of December 31, 2017. More than half sell foreign or non-FDA-approved medications to US patients, and 86% are either based outside of the US or, as in most cases, do not post any physical address on the website.



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

Three hundred thirty (2.8%) of the 11,749 sites selling prescription medications to US patients were designated as reviewed. These sites lack any egregious violations that would cause them to be ranked as Not Recommended but have not satisfied the requirements of NABP’s Verified Internet Pharmacy Practice Sites® (VIPPS®) or .Pharmacy Verified Websites Program. One hundred seventy-seven (1.5%) of the 11,749 sites selling prescription medications or offering resources to US patients were accredited through the VIPPS program or verified through the .Pharmacy Program.

B. Recommended Internet Pharmacies: NABP, along with many patient safety advocates and policy partners, continues to recommend that patients use internet pharmacies that have been reviewed and approved by NABP. These sites include entities granted VIPPS accreditation or a .pharmacy domain name. These sites have been evaluated and found to be in compliance with pharmacy laws and meet high standards for pharmacy practice and patient safety. As of December 31, 2017, 55 pharmacies were listed on the [NABP website](#) as VIPPS accredited, and 122 .pharmacy registered pharmacies and resources were listed on the [Buying Safely](#) page of the .Pharmacy Program website, www.safe.pharmacy. While the VIPPS program continues to operate, the Veterinary-Verified Internet Pharmacy Practices Sites® and e-Advertiser Approval programs were streamlined into the .Pharmacy Program as of September 1, 2017. Going forward, all VIPPS-accredited pharmacies will have a .pharmacy domain name.



C. .Pharmacy Program: With thousands of illegal online drug sellers offering body chemistry-altering medications for sale without a prescription, NABP believes strongly in the importance of its .Pharmacy Verified Websites Program to help patients choose safely when buying medicine online. By looking to the right of the dot for the .pharmacy extension in a web address, consumers can be assured they are visiting a safe and law-abiding website. The .pharmacy domain name identifies legitimately operating pharmacies and pharmacy-related entities for consumers, advertisers, and search engine companies by incorporating the “seal of approval” into the domain name. .Pharmacy is a verified Top-Level Domain, meaning that applicants are evaluated for compliance with registry standards prior to being allowed to use a .pharmacy domain name. NABP grants use of the .pharmacy domain only to legitimate website operators that adhere to pharmacy laws in the jurisdictions in which they are based and in which their patients and customers reside.



As of December 31, 2017, a total of 505 .pharmacy domain names have been registered by 122 pharmacies and related resources – up from 353 domains registered as of late July 2017. Of these, 389 were registered to pharmacies, 44 were registered to boards of pharmacy and regulatory agencies, 23 were registered to associations and consumer advocacy sites, 22

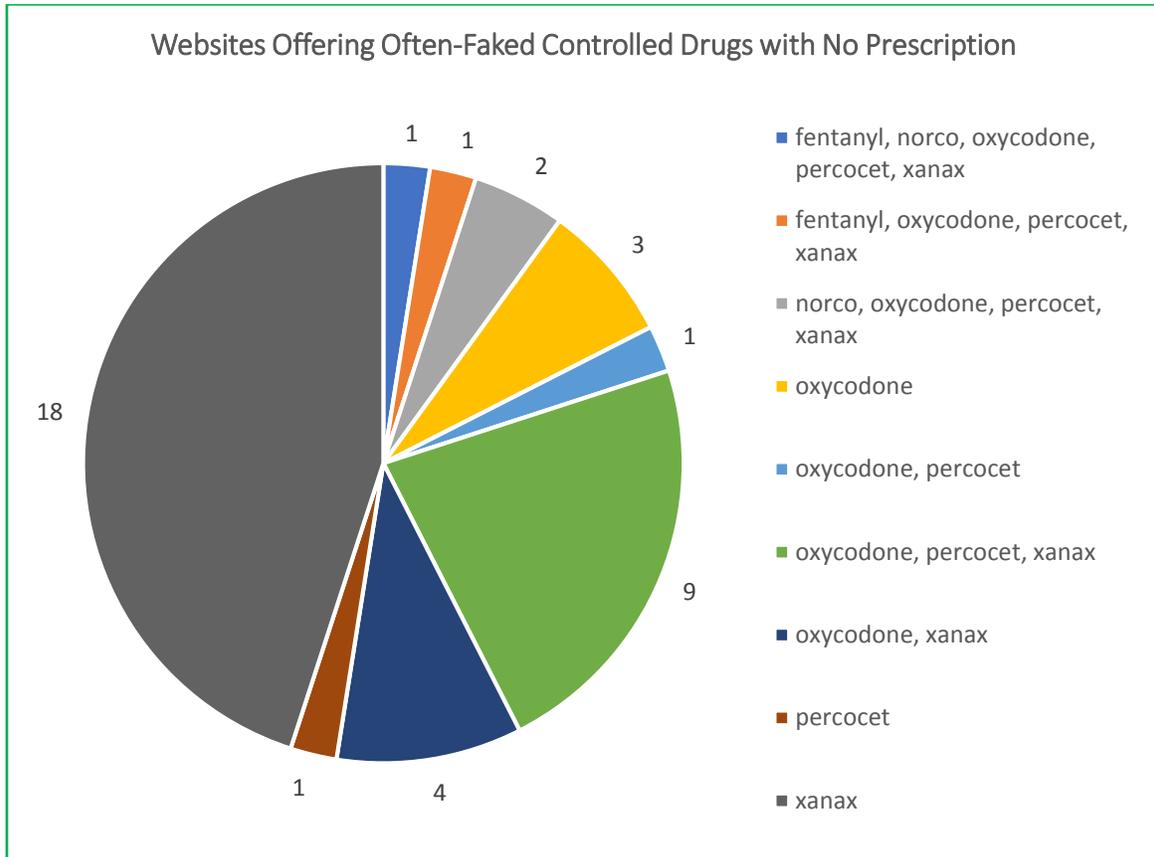
were registered to resource and referral sites, 19 were registered to medical professional sites, 6 were registered to manufacturers, and 2 were registered to schools or colleges of pharmacy. Of the 505 .pharmacy domain names registered, 331 (66%) are in use, while the remaining registered domain names are parked.

NABP Study Substantiates Availability of Controlled Substances Including Opioids Online

To substantiate reports of controlled prescription drugs including opioids readily available illegally online, NABP conducted a small study during the second half of 2017. From July 1 to December 31, 2017, NABP evaluated 100 websites offering to sell medications to customers in the US. All of the sites were found to be out of compliance with US pharmacy laws and practice standards and were listed as Not Recommended on the NABP website. Of these sites, 98% did not require a valid (if any) prescription, and 76% offered foreign or non-FDA-approved drugs. Ninety-one of the sites did not provide an address for the dispensing pharmacy, and 75% did not post any street address at all. The World Health Organization has stated that 50% of counterfeit drugs are obtained from websites that conceal their physical address. Of those that did provide an address, 14 were outside the US: six in Canada, three in Belize, one in India, one in Hungary, one in the United Kingdom, one in the Czech Republic, and one in Australia. Eleven of the sites posted addresses in the US: one in Florida, three in Pennsylvania, two in Texas, one in Colorado, one in Arkansas, two in California, and one in New York.

On each of the 100 websites identified as Not Recommended, NABP searched first for any CS, and second for fentanyl and four other drugs commonly found to be counterfeited with fentanyl: Norco, oxycodone, Percocet, and Xanax. NABP found more than half (54%) of the sites to be selling CS. The 54% of sites found to be selling CS is a substantial jump from the 13% of all sites NABP has reviewed and listed as Not Recommended over the past nine years. This increase supports the reports, discussed in the next section, that CS are coming back into vogue on illegal drug sites. Forty percent of the 100 sites NABP evaluated were selling the drugs frequently linked to fentanyl-related overdoses. The most commonly found drug on the 40 sites was Xanax, followed by oxycodone, Percocet, Norco, and fentanyl.

Most of the sites offered some combination of these drugs. The breakdown of the searched-for CS advertised on the 40 sites is provided in the chart below.



Out of 100 fake online pharmacies NABP evaluated over a six-month period, more than half were offering to sell CS without a prescription. Furthermore, 40% were offering fentanyl, or some combination of Norco, Percocet, oxycodone, and Xanax – all drugs often found to be counterfeited with fentanyl. The chart above shows the breakdown of those 40 sites and the drugs they offered.

Opioid Epidemic Becomes More Lethal with Introduction of Fentanyl in Counterfeit Pills

A. Overdose Deaths and the Emergence of Fentanyl: More than 63,600 Americans died from drug overdoses in 2016, according to the Centers for Disease Control and Prevention. Of those deaths, 66% were caused by opioids, including fentanyl and its many analogues. Multiple drug overdose deaths are attributed to counterfeit prescription opioids containing fentanyl. Fifty times stronger than heroin and 100 times more potent than morphine,

fentanyl can be lethal even at extremely low doses. Every year since 2001, opioid analgesics have been linked to the largest number of overdose deaths of any illicit drug class, surpassing overdose deaths associated with cocaine and heroin combined, the US Drug Enforcement Administration (DEA) reports in its *2017 National Drug Threat Assessment*. Because controlled prescription medicines are commonly abused, other opioids are now being disguised and sold as legitimate medicine, as traffickers look to broaden their market.

Fentanyl traditionally was mixed into or sold as heroin, frequently without the buyer's knowledge. Since 2014, however, US law enforcement agencies have been seizing a "new" form of fentanyl – counterfeit prescription opioid pills containing fentanyls, DEA reports in its 2016 Intelligence Brief, *Counterfeit Prescription Pills Containing Fentanyls: A Global Threat*. The counterfeit pills often closely resemble the authentic medicines they mimic. The presence of fentanyls is usually only detected in laboratory tests, so the actual number of fentanyl-related overdoses is almost certainly underreported. The high profitability of counterfeit prescription pills made with fentanyl incentivizes traffickers to continue producing them. Per DEA, these pills often sell for \$10 - \$20 apiece, and traffickers stand to profit millions. The Partnership for Safe Medicines (PSM) concurs that drug cartels have moved from lacing heroin with fentanyl to using Percocet, Xanax, Norco, and oxycodone molds to press fentanyl powder into counterfeit prescription pills. Traffickers sell these pills on the street and online. PSM traced a wide swath of counterfeit drugs throughout the US in its 2017 report, *Forty States and Counting*. In the report, PSM documents the spread of counterfeit pills made with illegal fentanyl throughout 40 states and finds that counterfeits made with fentanyl have killed Americans in at least 16 of those states.

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– The Partnership for Safe Medicines

B. Easy Availability Online Exacerbates Opioid Crisis: The fact that these deadly drugs are easily available online exacerbates the problem. The US Senate Permanent Subcommittee

on Investigations released a report in January 2018, *Combatting the Opioid Crisis: Exploiting Vulnerabilities in International Mail*, focusing on the ease with which consumers can order opioids online and receive them through the mail, and the devastation that accompanies this trend. The Subcommittee's investigation confirmed, "The Internet has significantly increased the availability of deadly synthetic opioids in the United States. Because illicit drug dealers and distributors can remain anonymous online, these virtual marketplaces significantly reduce the risk of detection associated with purchasing fentanyl and other synthetic opioids." In fact, from May 2017 to June 2017, the Subcommittee found that simple internet searches for "fentanyl for sale" identified websites openly offering opioids for purchase. The Subcommittee corresponded with representatives from six websites who actively encouraged them to buy fentanyl and other synthetic opioids. The report also confirms that counterfeit versions of other opioids, such as OxyContin and Percocet, also contain fentanyl as a key ingredient.

"The ease with which consumers can purchase opioid products online is especially concerning to me, given the immense public health crisis of addiction facing our country," FDA Commissioner Scott Gottlieb, MD, said in a September 25, 2017 news release. "Some of the websites sold unapproved versions of multiple prescription opioids directly to U.S. consumers. This easy and illegal availability of these controlled substances fuels the misuse and abuse of opioids."

So prevalent is the problem on a global scale that Interpol's Operation Pangea X targeted the illicit trade in opioid painkillers, in particular fentanyl, in its 2017 multinational crackdown on illegally operating drug sites. "In the last few years the distribution of illicitly manufactured fentanyl has been linked to thousands of overdoses and deaths worldwide," Interpol said in a September 25, 2017 news release. "Seizures of fentanyl purchased from illicit online pharmacies occurred in several countries." Despite these actions, however, illegal trafficking continues and the death toll rises.

Discussion

Buying prescription medicine from foreign and unapproved sources online is never a good idea. Once US consumers shop outside the tightly regulated US medication supply chain, their chances of obtaining substandard, counterfeit, or falsified medicines increases dramatically. When it comes to opioids, the danger is magnified. Not only does the ease with which consumers can obtain opioids online exacerbate the problems of addiction and misuse, but, in many overdose deaths, the drugs involved have been found to be counterfeit with fentanyl, which raises the chances of overdose exponentially.

After evaluating 100 drug-selling websites in the second half of 2017, NABP's findings support the assertion that CS – including those commonly counterfeited with fentanyl – are readily available from rogue internet drug outlets. Regulators and stakeholders have proposed solutions to address this problem, including beefing up resources to screen international packages entering the US. Another approach, which NABP espouses, is to block illegal online drug sellers from showing up in search results or, in the alternative, promote legal pharmacy operations in search to ensure Page 1 results only include safe and legal pharmacies. These proposed solutions would go a long way toward keeping dangerous – potentially counterfeit – medicines out of the hands of unsuspecting patients.

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

Appendix

Internet Drug Outlet Identification Program Standards

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

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

6. **Legal compliance.** The pharmacy must comply with all provisions of federal and state law, including but not limited to the Federal Food, Drug, and Cosmetic Act and the Federal Controlled Substances Act (including the provisions of the Ryan Haight Online Pharmacy Consumer Protection Act, upon the effective date). The pharmacy must *not*

dispense or offer to dispense medications that have not been approved by the US Food and Drug Administration.

7. **Privacy.** If the pharmacy website transmits information that would be considered Protected Health Information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 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.