RxLegal

Regulation of Internet Pharmacies: A Continuing Challenge

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The ability of consumers to obtain prescription medications via the Internet has grown exponentially over the past decade, with the Federal Bureau of Investigation (FBI) estimating that there are more than 80,000 “portal” Web sites that allow individuals to place medication orders through illegal pharmacies.¹ Consumers choose to utilize online pharmacies over traditional “brick-and-mortar” pharmacies for a variety of reasons, including accessibility, time constraints, and potential cost savings.² Indeed, there are reputable online pharmacies (eg, walgreens.com, cvs.com, healthwarehouse.com) that are widely available, provide access to a pharmacy professional if needed, and adhere to both the laws and regulations of the country in which the Web site operates and the destination country.^{2,3} However, the number of reputable online pharmacies is dwarfed by those that operate illegally.

In June 2013, the US Food and Drug Administration (FDA) shut down 1,677 Web sites for selling counterfeit or substandard medications or for selling medications to consumers without appropriate safeguards.⁴ In addition to dispensing counterfeit, unapproved, misbranded, or adulterated medications, many illegal online pharmacies dispense prescription-only medications without a valid prescription or fill prescriptions generated by “cyberdoctors” who obtain patient information solely from a questionnaire.² Obviously, these practices can have a potentially negative impact on the health of the consumer.

Although national and international regulations and laws exist regarding online pharmacies, effective regulatory oversight and enforcement is often difficult, if not impossible, to achieve.³ Until an international legal framework is constructed and agreed upon, illegal pharmacies will continue to expand and inappropriately dispense medications to consumers. Therefore, pharmacists need to be aware of indicators that an online pharmacy Web site is unsafe in order to counsel patients. Unsafe sites⁵:

- Do not provide contact information including a phone number.
- Offer prices for medications that are dramatically lower than competitors.
- Offer to dispense prescription-only medications without a valid order from a licensed prescriber.
- Deliver medications that are of unknown quality or origin or dispense an incorrect medication for the patient’s illness.
- Do not protect the personal health information of the patient.

Conversely, a trustworthy online pharmacy site requires a valid prescription from a licensed health care professional prior to dispensing, contains appropriate contact information for the site, provides access to a licensed pharmacist, and is licensed by the state board of pharmacy where the Web site is located.⁵ In addition, a trustworthy site can be identified by the appearance of the National Association of Boards of Pharmacy’s (NABP) Verified Internet Pharmacy Practice Sites or VIPPS seal. To receive the VIPPS seal, a pharmacy must satisfy the requirements of the VIPPS program standards and criteria, which are available through the NABP site. The criteria may be broken up into various categories and are summarized in **Table 1**. A list of current online pharmacies that have received the VIPPS seal of approval is available at: <http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy>.⁶

Online pharmacies continue to grow in number, and many sites operate illegally or inappropriately through distributing counterfeit or substandard medications, dispensing medications without a valid prescription, or filling prescriptions from “cyberdoctors” who do not have a legitimate relationship with the patient. Although several laws exist to regulate online pharmacies, oversight and enforcement are poor. Pharmacists should be aware of the far-reaching nature of this problem and direct patients to legitimate

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Table 1. Criteria for Verified Internet Pharmacy Practice Sites accreditation⁷

Category	Criteria
Licensure and policy maintenance	Provide NABP with the necessary documents to ensure that the pharmacy is licensed to operate in all applicable jurisdictions. Provide NABP with documentation that all individuals affiliated with the site are appropriately licensed. Develop and enforce a comprehensive policy and procedure document. Comply with all applicable statutes and regulations.
Prescriptions	Develop and enforce policies and procedures that ensure the integrity, legitimacy, and authority of the prescription drug order. Prevent drug orders from being submitted and filled by multiple pharmacies. Prevent medications from being prescribed or dispensed based upon telephonic or online medical consultations that do not result from a pre-existing prescriber-patient relationship.
Patient information	Develop and enforce policies and procedures that ensure reasonable verification of the identity of the patient, prescriber, and caregiver if applicable. Obtain and maintain patient medication profiles. Conduct a prospective drug use review prior to medication dispensing. Ensure patient confidentiality and protect patient-specific information when such information is transmitted over the Internet.
Communication	Develop and enforce policies and procedures that require pharmacists to offer consultative services to patients. Develop a system regarding reporting of adverse drug reactions and errors. Develop a mechanism for contacting patients regarding delays in delivering a prescription medication as well as drug recalls. Develop a mechanism for educating patients regarding disposal of expired, damaged, or unusable medications.
Storage and shipment	Develop a system for shipping controlled substances safely and securely. Ensure that medications are shipped to patients appropriately.
Over-the-counter products	Comply with all federal and state laws regarding the sale of over-the-counter products that may be used in the manufacture of illegal drugs.
Quality improvement programs	Maintain a quality improvement program.
Reporting to NABP	Notify NABP of any change in information provided as part of the accreditation process within 30 days; notify NABP within 10 days after ceasing operation of the site.

Note: NABP = National Association of Boards of Pharmacy.

online pharmacies that have the NABP VIPPS seal of approval in order to promote ordering of safe medications through the Internet.

REFERENCES

1. The Federal Bureau of Investigation. Don't put your health in the hands of crooks. March 2009. https://www.fbi.gov/news/stories/2009/march/pharmacy_030309. Accessed June 11, 2015.
2. Fung CH, Woo HE, Asch SM. Controversies and legal issues of prescribing and dispensing medications using the Internet. *Mayo Clin Proc.* 2009;79(2):188-194.
3. Fittler A, Bosze G, Botz L. Evaluating aspects of online medication safety in long-term follow-up of 136 Internet pharmacies: Illegal rogue online pharmacies flourish and are long-lived. *J Med Internet Res.* 2013;15(9):e199.
4. Hellerman C. FDA shuts down 1677 online pharmacies. <http://www.cnn.com/2013/06/27/health/online-pharmacies-closed/>. Accessed June 11, 2015.
5. FDA Consumer Health Information. The possible dangers of buying medicines over the Internet. <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM204943.pdf>. Accessed June 11, 2015.
6. National Association of Boards of Pharmacy. Find a VIPPS online pharmacy. <http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy>. Accessed June 11, 2015.
7. National Association of Boards of Pharmacy. VIPPS criteria. <http://www.nabp.net/programs/accreditation/vipps/vipps-criteria>. Accessed June 11, 2015. ■