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CRS Report for Congress

Legal Issues Related to Prescription Drug Sales on the Internet

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Summary

This report provides a legal analysis of issues related to prescription drug sales on the Internet, including issues involving online pharmacies and physicians who prescribe medications over the Internet. Specifically, this report provides an overview of the various federal and state laws that regulate this field, including laws and regulations covering prescription drugs, controlled substances, doctors, and pharmacies. Legislators have introduced the following bills in the 110th Congress: H.R. 194, H.R. 380, S. 242, S. 251, S. 554, S. 596, and S. 980. Additionally, S. 596 has been introduced in the form of a possible amendment (No. 0993) to S. 1082, the Prescription Drug User Fee Amendments of 2007. If passed, the amendment would enable the Secretary of Health and Human Services to license domestic and foreign online pharmacies.

Introduction

Many individuals have turned to online pharmacies to purchase prescription drugs, and an increasing number of physicians have incorporated the Internet and email into their medical practice. Use of this technology has many advantages for both the doctor and the patient, including cost savings, convenience, accessibility, and improved privacy and communication.[1] Although many online pharmacies are legitimate businesses that offer safe and convenient services similar to those provided by traditional neighborhood pharmacies and large chain drugstores, other online pharmacies — often referred to as "rogue sites" — engage in practices that are illegal, such as selling unapproved or counterfeit drugs or dispensing drugs without a prescription.[2] Some rogue sites operate in a legal gray area in which the online pharmacy, as mandated by federal law, requires a prescription before dispensing prescription drugs, but allows patients to secure a prescription by completing an online questionnaire that is reviewed by a doctor who never

[1] Food and Drug Administration, U.S. Department of Agriculture, *Buying Drugs Online: It's Convenient and Private, But Beware of 'Rogue Sites'* (2001), [http://www.fda.gov/fdac/features/2000/100_online.html].

[2] *Id.*

examines or speaks to the patient. This practice, though potentially unsafe for patients who may be diagnosed incorrectly, is not necessarily illegal.

The regulation of online pharmacies and doctors consists of a patchwork of federal and state laws in an array of areas.[3] At the federal level, the Food and Drug Administration (FDA) regulates prescription drugs under the Federal Food, Drug, and Cosmetic Act (FDCA), which governs, among other things, the safety and efficacy of prescription medications, including the approval, manufacturing, and distribution of such drugs.[4] The FDCA requires prescription drugs be dispensed only with a valid prescription.[5] The Drug Enforcement Agency (DEA) enforces the Controlled Substances Act (CSA), which is a federal statute that establishes criminal and civil sanctions for the unlawful possession, manufacturing, distribution, or importation of controlled substances.[6] State boards of pharmacy regulate pharmacy practice, and state medical boards oversee the practice of medicine.[7] Thus, some laws that govern online pharmacies and doctors vary by state. Laws governing each of these areas are described below.

Federal Oversight

As noted above, the CSA is a federal statute that establishes criminal and civil sanctions for the unlawful possession, manufacturing, distribution, or importation of controlled substances.[8] The primary purpose of the CSA is to facilitate the legal distribution of controlled substances for legitimate medical purposes while preventing their diversion for illegal uses. Although the CSA is generally known for prohibiting illegal drugs that have a high potential for abuse and no accepted medical use, such as heroin or cocaine, the statute also covers a range of other drugs that have a lesser potential for abuse and an accepted medical use, including certain prescription drugs. Although most prescription drugs are not controlled substances and therefore are not regulated under the CSA, some prescription drugs, such as narcotics and opiates that are often used in the treatment of pain, are regulated under the CSA because they have a greater potential for abuse than other prescription drugs and may lead to physical dependence.

It is the latter category of prescription painkillers that appear to be among the drugs most heavily dispensed by certain Internet pharmacies in accordance with prescriptions that are issued based on online questionnaires.[9] This practice has sometimes been abused by rogue sites that dispense large quantities of addictive substances to customers

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[3] For additional information, *see* GAO Report GAO-01-69, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*.

[4] 21 U.S.C. §§ 301 et seq.

[5] *Id*. at § 353(b).

[6] *Id*. at § 801 et seq. For more information on the Controlled Substances Act, see CRS Report 97-141A, *Drug Smuggling, Drug Dealing and Drug Abuse: Background and Overview of the Sanctions Under the Federal Controlled Substances Act and Related Statutes*, by Charles Doyle.

[7] The FDCA excludes the practice of medicine from its jurisdiction. 21 U.S.C. § 396.

[8] *Id.* at §§ 801 et seq.

[9] *See, e.g.*, Gilbert M. Gaul and Mary Pat Flaherty, *Doctors Medicate Strangers on Web*, WASH. POST, October 21, 2003, at A1.

apparently seeking access to prescription painkillers, and it has lead to instances of addiction, overdose, and death. In response to cases in which online doctors have written thousands of prescriptions for controlled substances without examining their patients, the federal government has begun prosecuting certain doctors under the CSA by charging them with the illegal distribution of controlled substances.[10] Penalties under the CSA vary depending on the amount and type of substance involved but generally include monetary fines, forfeiture, and imprisonment.[11]

As noted above, prescription drugs are also regulated by the FDA under the FDCA.[12] Although state law also governs the prescribing of drugs, the FDCA covers certain aspects of the prescribing process, including the requirement that prescription drugs may not be dispensed without a valid prescription.[13] The FDCA, however, does not define the meaning of "prescription." Rather, each state defines what constitutes a valid prescription under its pharmacy laws. Because such definitions differ from state to state, there is no uniform, national definition of the term "prescription."[14] Thus, certain activities, such as prescribing drugs without performing an in-person examination, may be explicitly illegal in one state but of ambiguous legal status in another.

Concerned about reports of rogue online pharmacies, Congress has considered legislation to establish a federal definition of what constitutes a valid prescription.[15] For example, such legislation has included proposals to establish a single federal standard for prescriptions or to require online pharmacies to disclose information about themselves and about the doctors approving prescriptions on their sites.[16] Congress has also explored the possibility of limiting the means by which allegedly rogue sites do business, namely by restricting their ability to advertise on search engines, make credit card sales, and ship prescription drugs,[17] and some companies have responded with their own proposals. For example, Google, an Internet search engine, no longer accepts advertising from unlicenced pharmacies and prohibits the use of certain controlled substances as keywords for search purposes.[18] Because federal and state regulators face many legal barriers when

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[10] *Id.*; *see also* Editorial, *Internet Drug Trafficking*, PHILA. INQUIRER, December 2, 2006, at A8.

[11] 21 U.S.C. §§ 841 et seq.

[12] *Id.* at §§ 301 et seq.

[13] *Id.* at § 353(b).

[14] Inside Washington Publishers, *FDA May Back Changing Law to Define Internet 'Prescription'*, FDA WEEK, March 28, 2003.

[15] *Id.*

[16] *See, e.g., Point, Click, Self-Medicate: A Review of Consumer Safeguards on Internet Pharmacy Sites: Hearing Before the House Comm. On Government Reform*, 108th Cong. (2003).

[17] Gilbert M. Gaul and Mary Pat Flaherty, *Google to Limit Some Drug Ads*, WASH. POST, December 1, 2003, at A1. The Bush Administration has also expressed interest in pursuing such a strategy. Press Release, Office of National Drug Control Policy, U.S. Drug Prevention, Treatment, Enforcement Agencies Take on "Doctor Shoppers," "Pill Mills" (March 1, 2004), [http://www.whitehousedrugpolicy.gov/news/press04/030104.html].

[18] Gaul and Flaherty, *supra* note 17.

attempting to exercise jurisdiction over rogue pharmacies based in foreign countries,[19] placing limits on the degree to which search engines, credit card companies, and shipping entities enable rogue sites to sell prescription drug may be one of the only ways to control illicit sales by foreign online pharmacies.

It is important to note that online prescription drug sales by both U.S.-based and foreign Internet pharmacies may raise additional legal questions involving drug importation. The FDCA prohibits anyone other than the U.S. manufacturer from importing prescription drugs that were originally manufactured in the U.S., and the statute contains various provisions relating to drug approvals and labeling that make it virtually impossible for prescription drugs made for foreign markets to comply with the extensive statutory requirements.[20] Thus, online pharmacies that sell imported U.S.-manufactured drugs or foreign versions of drugs approved for domestic sale appear to violate the FDCA, as do businesses that facilitate such sales. In addition, the CSA prohibits the unapproved importation of controlled substances, as well as causing such importation,[21] so an individual or pharmacy that uses the Internet in a way that causes controlled substances to be mailed or shipped into the U.S. may violate the CSA.[22] The legal issues involved in drug importation are discussed in detail in CRS Report RL32191, *Prescription Drug Importation and Internet Sales: A Legal Overview*, by Vanessa Burrows.

State Oversight

As noted above, state boards of pharmacy are primarily responsible for regulating pharmacy practice,[23] although the FDA does provide some federal oversight of pharmacies. Because virtually all states require a pharmacy that sells drugs in the state to be licensed with the state, a state board of pharmacy traditionally may exercise regulatory authority over pharmacies located within the state, as well as those that dispense drugs across state lines to citizens within the state.[24] Since each state board of pharmacy sets its own policies with regard to both online and traditional pharmacies, state pharmacy laws

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[19] "The enforcement of a state action or the initiation of a mutual action by a foreign licensing body is virtually unheard of, making it difficult, if not impossible, for state actions to have any effect on foreign pharmacies." National Association of Boards of Pharmacy, *Position Paper on the Importation of Foreign Prescription Drugs* 6 (March 2003), [http://www.nabp.net].

[20] 21 U.S.C. §§ 353(b)(2), 355, 381(d)(1).

[21] *Id*. at §§ 957, 960.

[22] *See, e.g.*, Importing Controlled Substances From Canada and Other Foreign Countries, 69 FR 38920 (June 29, 2004).

[23] National Association of Boards of Pharmacy, *Verified Internet Pharmacy Practice Sites (VIPPS): Most Frequently Asked Questions* (2001), [http://www.nabp.net].

[24] *Id.* "These requirements allow state boards of pharmacy to order non-resident pharmacies to stop shipping product into the state. Within the US, such orders can be enforced by the board of pharmacy where the violation took place, or by mutual action by the board of pharmacy in the state where the pharmacy is located." National Association of Boards of Pharmacy, *Position Paper on the Importation of Foreign Prescription Drugs* 6 (March 2003), [http://www.nabp.net]. Foreign shipments of prescription drugs may also violate state laws if the foreign pharmacy is not licensed in the state, although states often face legal barriers when attempting to exercise jurisdiction over foreign pharmacies. *See supra* note 19 and accompanying text.

differ from state to state. While some state laws specify whether or not prescriptions based on online questionnaires are valid, other state laws fail to address the issue, thus rendering it difficult for some states to prosecute doctors who prescribe drugs without performing an in-person evaluation. For this reason, some critics of the current system have proposed establishing a federal definition of what constitutes a valid prescription.[25]

In addition, some organizations have begun to promote uniform national standards for the industry. For example, the National Association of Boards of Pharmacy (NABP) is an organization that helps state boards by developing uniform standards on pharmacy practice. In response to the proliferation of online pharmacies, NABP established the Verified Internet Pharmacy Practice Sites (VIPPS) program, a certification program that "identifies to the public those online pharmacy practice sites that are appropriately licensed, are legitimately operating via the Internet, and that have successfully completed a rigorous criteria review and inspection."[26] According to NABP, the VIPPS program was developed in order to improve the safety of online pharmacy practices and to "provide a means for the public to distinguish between legitimate and illegitimate online pharmacy practice sites."[27] Although NABP notes that legitimate online pharmacies outnumber rogue sites and acknowledges that there are many advantages to ordering drugs online, the Association specifically warns consumers against buying prescription drugs online without obtaining an in-person examination and valid prescription from a doctor. Like U.S. pharmacies, Canadian pharmacies may also be certified under the VIPPS program, but only if they do not export drugs to the U.S.[28] However, NABP has indicated that it may extend its VIPPS certification program to Canadian pharmacies that sell to U.S. consumers if Congress approves drug importation or "if HHS does not stop the state and local governments that already are reimporting drugs."[29]

Like pharmacy practice, the practice of medicine has historically been regulated at the state level by state medical boards. According to the Federation of State Medical Boards (FSMB) "[t]he primary responsibility and obligation of a state medical board is to protect consumers of health care through proper licensing and regulation of physicians."[30] Traditionally, states enact laws that regulate the practice of medicine, and state medical boards implement and oversee state policies.[31] If a doctor violates a state law or regulation, state medical boards generally have the authority to fine or otherwise discipline the doctor through modification, suspension, or revocation of the doctor's

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[25] Inside Washington Publishers, *supra* note 14; *see* notes 15-16 and accompanying text.

[26] National Association of Boards of Pharmacy, *Verified Internet Pharmacy Practice Sites (VIPPS): Most Frequently Asked Questions*, [http://www.nabp.net].

[27] *Id.*

[28] Inside Washington Publishers, *FDA Rebuffs Invitations to Inspect Canadian Pharmacies*, FDA WEEK, May 7, 2004. However, the Canadian International Pharmacy Association maintains a certification program like VIPPS that allows CIPA-certified members to export drugs to the U.S.

[29] Inside Washington Publishers, *Canadian Internet Pharmacies Ask NABP to Certify Their Operations*, FDA WEEK, September 17, 2004.

[30] Federation of State Medical Boards, *What is a State Medical Board?*, [http://www.fsmb.org/pdf/PUB_WhatIs_StateMedicalBoard_Brochure.pdf].

[31] *Id.*

license to practice medicine in that state. In reality, however, laws regarding medical practice vary widely in strength and effectiveness from state to state. While some states have strong laws that explicitly prohibit activities such as prescribing drugs without conducting an in-person examination, other states have weak laws, lax enforcement, or both.

Like NABP, FSMB has developed a specific policy with regard to online pharmacies and doctors that prescribe drugs over the Internet. According to FSMB's model guidelines on the subject, electronic technology "should supplement and enhance, but not replace, crucial interpersonal interactions that create the very basis of the physician-patient relationship."[32] To that end, FSMB guidelines declare that doctors who use the Internet as part of their medical practice should conduct a physical evaluation of the patient before providing treatment. Although FSMB recognizes the benefits of online pharmacies, the organization warns that "[t]reatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care."[33] FSMB further urges that doctors who prescribe drugs on the Internet should be licensed in all states in which their patients reside,[34] a practice that would subject doctors to the oversight of the medical boards in each state in which their patients lived.[35] These professional standards, however, are not legally enforceable in the absence of state laws establishing such requirements.

Conclusion

The current legal framework for regulating online pharmacies and doctors is a patchwork of federal and state laws regarding controlled substances, prescription drugs, pharmacies, and the practice of medicine. Although many doctors and pharmacies who use the Internet prescribe and dispense drugs in a safe and legal fashion, others have exploited gaps in the current system to prescribe and dispense potentially dangerous quantities of highly addictive prescription drugs. To combat such abuses, legislators and interest groups have proposed an array of solutions, including establishing a federal definition of what constitutes a valid prescription, requiring doctors to conduct in-person examinations, mandating that online pharmacies disclose identifying information about themselves and their employees, establishing state prescription drug monitoring programs to track data regarding the prescription and use of controlled substances, giving state prosecutors the authority to seek nationwide injunctions against rogue sites, educating consumers about the potential dangers of buying drugs online, establishing certification programs to identify legitimate online pharmacies, and regulating search engines and shipping companies that enable rogue sites to do business.

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[32] *Id.*

[33] Federation of State Medical Boards, *Model Guidelines for the Appropriate Use of the Internet in Medical Practice* (2002), at 5 [http://www.fsmb.org/pdf/2002_grpol_Use_of_Internet.pdf].

[34] *Id.* at 8.

[35] *Id.* at 9. Other professional medical associations have also established policies regarding the safe practice of online medicine. *See, e.g.*, American Medical Association, *Guidance for Physicians on Internet Prescribing (H-120.949)* (2003), [http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-120.949.HTM].