

Internet Prescribing Jurisdictions

| ISSUES RELATED TO REGULATING INTERNET PRESCRIBING | REGULATORY REQUIREMENTS | ENFORCEMENT AUTHORITY | ENFORCEMENT |
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| <p>Licensure of Internet Pharmacy Site</p> | <p>Pharmacies are required to be licensed or registered in good standing with the state pharmacy board in the state where they are located. They are also required to assure:</p> <ul style="list-style-type: none"> • proper storage and handling of prescription drugs • appropriate record keeping • patient privacy • confidentiality of medical records <p>Currently, 40 state pharmacy boards license or register out-of-state pharmacies that provide services to resident in their respective states.</p> | <p>State Board of Pharmacy – Pharmacy Practice Act</p> <p>State Attorney General – Consumer Protection Act</p> | <p>The State Board of Pharmacy has jurisdiction over pharmacies located in their state whether they are Internet pharmacies or brick and mortar pharmacies. Pharmacy boards are responsible for licensing pharmacies. They also inspect pharmacies ensuring that pharmacists and pharmacies comply with applicable state and federal laws and investigate and discipline those that fail to comply. While most pharmacy boards require out-of-state pharmacies that provide services to residents in their respective states to be licensed in their state, they have limited ability and authority to investigate and act against out-of-state pharmacies. The State Attorney General’s Office may exercise jurisdiction over out-of-state pharmacies not licensed in their respective state under the state’s consumer protection laws.</p> |
| <p>Licensure of Pharmacists filling prescriptions on Internet Pharmacy sites</p> | <p>Pharmacists are required to be licensed by the state pharmacy board.</p> | <p>State Board of Pharmacy – Pharmacy Practice Act</p> | <p>Pharmacists must be appropriately licensed or registered with the state pharmacy board. Questions or complaints about a pharmacist should be directed to the State Board of Pharmacy in the state in which they are licensed. The pharmacy board can discipline licensees for violations of both federal and state laws governing the legal distribution of prescription drugs.</p> |
| <p>Licensure of Physicians Approving Prescriptions Online</p> | <p>Most states define “prescribing medications” as the practice of medicine in their Medical Practice Acts. Accordingly, most states require physicians to have a full and unrestricted or a telemedicine license in order to practice medicine in their state. Generally physicians are required to be licensed in the state(s) where patients they are treating reside.</p> | <p>State Medical Board – Medical Practice Act</p> <p>State Attorney General – Consumer Protection Division</p> | <p>Licensure and regulation of physicians is state-based. Questions regarding licensure or complaints about physicians prescribing online should be referred to the State Medical Board in the state where the patient resides. If the physician is not licensed in the state where the patient resides, contact any state where the physician is licensed. Unlicensed or improperly licensed physicians approving prescriptions over the Internet may be referred to the State Attorney General in the state where he/she is practicing or where the patient resides. Some state medical boards have the authority to take action for the unlicensed practice of medicine.</p> |

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| <p>Licensure of Non-Physician Practitioners Approving Prescriptions Online</p> | <p>Some states have given independent prescriptive authority to non-physician practitioners. In such states, questions about licensure and/or standard of care should be referred to the appropriate state licensing authority.</p> | <p>Appropriate State Licensing Authority – Applicable Practice Act</p> | <p>In states where non-physician practitioners have independent prescriptive authority, questions about licensing and/or standard of care should be referred to the appropriate state licensing authority.</p> |
| <p>Prescriptions Approved Based on Responses to an Online Questionnaire</p> | <p>Prescription drugs may be prescribed, dispensed or distributed only with a valid prescription issued under the supervision of a licensed physician.</p> <p>Prescriptions issued on the basis of an online questionnaire do not meet accepted standards of care and are outside the bounds of professional medical conduct. In order to meet acceptable standards of practice, the prescribing physician must demonstrate:</p> <ul style="list-style-type: none"> • a <i>bona fide</i> physician/patient relationship • the prescription is being written pursuant to a course of individualized treatment for a legitimate medical purpose • an appropriate medical record • a follow-up and treatment outcome evaluation | <p>State Medical Board - Medical Practice Act or Board Rules</p> <p>FDA – Food Drug and Cosmetic Act – 21 U.S.C. § 301 et seq. Contact: Don Vasbinder Consumer Safety Office (301) 827-0414 dvasbind@ora.fda.gov</p> <p>Department of Justice (DOJ) – Food Drug and Cosmetic Act Contact: Linda Marks Office of Consumer Litigation (202) 307-0060 Linda.Marks@usdoj.gov</p> | <p>Most State Medical Boards have interpreted their Medical Practice Acts to require an existing physician/patient relationship for a prescription to be valid. Some states have adopted rules or issued statements clarifying standards for online prescribing including defining the elements of a proper physician/patient relationship. In most states it is unprofessional conduct for a physician to issue a prescription without first having an established physician/patient relationship.</p> <p>FDA authority over sale of prescription drugs comes from the Food, Drug and Cosmetic Act (FDCA). The FDCA generally prohibits the manufacture and distribution of misbranded and adulterated drugs, requiring them to be labeled accurately and manufactured and properly handled in ways that prevent contamination and misuse. The FDCA relies on two health professionals—the patient’s physician and pharmacist- to protect patients from potentially harmful drugs. Accordingly, drugs that are considered prescription drugs under the FDCA must be distributed only with a valid prescription issued by a licensed practitioner. If a prescription drug is not dispensed with a valid prescription, it is considered “misbranded” by the FDA (21 U.S.C. § 353(b)) State Medical Boards generally require an established physician/patient relationship for a prescription to be valid. If judicial intervention is required, the DOJ will become involved to enforce the FDCA. DOJ enforces consumer protection acts administered by the FDA and FTC.</p> |
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| Prescriptions Approved without a Valid Prescription | In order for a prescription to be valid, it must be written by a licensed practitioner for FDA approved drugs. Most state medical boards require the existence of a legitimate physician/patient relationship in order for a physician to prescribe for a patient. Consequently, a prescription written based on an online questionnaire would not be a valid prescription. | <p>State Medical Board – Medical Practice Act</p> <p>FDA – Food Drug and Cosmetic Act (FDCA) in conjunction with the DOJ. (see contacts p.2)</p> | <p>State Medical Practice Acts or State Medical Board rules generally state that it is unprofessional conduct for a physician to issue a prescription without the existence of a legitimate physician/patient relationship.</p> <p>The FDA considers drugs dispensed within the U.S. without valid prescription to be “misbranded” under the FDCA. The FDA may bring enforcement actions criminally or civilly and such actions would be initiated by the DOJ.</p> |
| Prescribing Controlled Substances Online | To prescribe controlled substances, physicians must be registered with the Drug Enforcement Agency (DEA). Controlled substances cannot be dispensed without a valid prescription. In most states, a prescription cannot be valid unless it is issued by a physician having a bona fide physician/patient relationship. | <p>DEA – Controlled Substances Act (CSA) Contact: Local DEA Office or check www.deadivision.usdoj.gov or call Internet Technology Unit (703) 495-6550</p> <p>DOJ – Controlled Substances Act – 21 U.S.C. §§ 822, 829 and 841. (see contact p.2)</p> | <p>The manufacture, dispensing or distribution of controlled substances is regulated by the DEA. Prescriptions for controlled substances must be written by a physician properly registered with the DEA. The Controlled Substances Act (CSA) prohibits the dispensing of controlled substances without a valid prescription issued by a properly licensed practitioner. Violations of the CSA are enforced by the DOJ.</p> <p>Under the CSA, all substances that are regulated under federal law are placed in one of five schedules on the basis of the substances’ medicinal value, harmfulness, and potential for abuse or addiction. The act also regulates the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances.</p> |
| Questions About Standards of Medical Practice | <p>Appropriate standards for medical practice are established by the medical profession.</p> <p>The state Medical Practice Act defines the practice of medicine and what constitutes the unlawful practice of medicine in that state.</p> | State Medical Board – Medical Practice Act | Medical Practice Acts empower the State Medical Board to discipline physicians for violations of established standards of practice. Many of the complaints received by the state medical board pertain to standards of care. Complaints that appear to involve violations of the Medical Practice Act are investigated by the board and may result in a variety of disciplinary actions against the physician. |
| False or Questionable | Internet pharmacy sites may not make | FTC , Bureau of Consumer Protection | The FTC works to enhance the smooth operation of the |

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| <p>Advertising Claims or Labeling of Products or Services Sold or Distributed by an Internet Pharmacy Site</p> | <p>fraudulent claims about their products or services. The FTC Act protects consumers from unfair or deceptive acts or practices. Also state pharmacy boards generally have jurisdiction over false advertising/ claims made by their licensees.</p> | <p>- Federal Trade Commission Act - 15 U.S.C. § 45 et seq. Contact: Richard Cleland Bureau of Consumer Protection (202) 326-3088 rcleland@ftc.gov</p> <p>State Board of Pharmacy – Pharmacy Practice Act</p> | <p>marketplace by eliminating acts or practices that are unfair or deceptive, including false advertisement of drugs. It has the authority under the Federal Trade Commission Act (FTCA) to bring an enforcement action when an online pharmacy makes false or misleading claims about products or services it provides, including:</p> <ul style="list-style-type: none"> • safety or efficacy of a drug • misrepresentation of privacy practices • marketing practices that cause or are likely to cause substantial consumer injury • online questionnaire is the equivalent of a visit to the doctor’s office • a physician reviews each purchase of prescribed drugs <p>Advertising must tell the truth and not mislead consumers. A claim can be misleading if relevant information is left out or if the claim implies something that’s not true. (The FDA and FTC have overlapping authority in areas regarding fraudulent claims, advertising, and labeling of products and services offered or sold over the Internet.)</p> <p>State Boards of Pharmacy generally have jurisdiction over false advertising/claims made by their licensees. Such activity may be pursued by the licensing board in the state where the pharmacy is licensed.</p> |
| <p>Fraudulent Health Claims False Labeling and Product Claims</p> | <p>Internet pharmacy sites and entities that advertise on those sites may not make false claims about the safety or efficacy of drugs or other products they distribute, i.e., claims that a product or treatment could cure or treat a specific disease.</p> | <p>FDA – Food Drug and Cosmetic Act (see contact p.2)</p> | <p>FDA has primary jurisdiction to regulate labeling and advertising claims made by the manufacturer, distributor, or packer of prescription drugs under the FDCA. The FDCA requires drugs to be labeled accurately and handled in ways that prevent them from being contaminated or misused. Violations of the FDCA are enforced by the DOJ. (The FDA and FTC have overlapping authority in areas regarding fraudulent claims, advertising, and labeling of products and services offered or sold over the Internet.)</p> |
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| <p>Adulterated, Misbranded, Expired, Counterfeit, Unapproved or Otherwise Illegal Drugs</p> | <p>Internet pharmacy sites may not sell or distribute adulterated, misbranded, expired, counterfeit, unapproved or otherwise illegal drugs. Internet pharmacies are bound by the same regulations in this regard as brick and mortar pharmacies.</p> | <p>FDA – Food, Drug and Cosmetic Act (see contact p.2)</p> | <p>The FDA has jurisdiction over the sale or distribution of adulterated, misbranded, counterfeit, unapproved and otherwise illegal drugs. The FDA pursues enforcement of the FDCA through the DOJ.</p> |
| <p>Drugs Shipped from Pharmacy Located Outside the U.S.</p> | <p>Drugs shipped from outside the U.S. are subject to the same requirements as drugs shipped within the U.S:</p> <ul style="list-style-type: none"> • Valid prescription • physician/patient relationship • approved drugs • no fraudulent claims <p>Generally, it is illegal to import prescription drugs that are not approved by the FDA and manufactured in an FDA-approved facility.</p> | <p>FDA – Office of Criminal Investigations - Food Drug and Cosmetic Act (see contact p.2)</p> <p>U.S. Postal Service – Contact: Chris Giusti (202) 268-5430 cgusti@uspis.gov</p> <p>U.S. Department of Homeland Security U.S. Immigration and Customs Enforcement – Title 18, U.S.C. 542 and Title 18, U.S.C. 545 Contact: SS/A Linda Phillips (703) 293-9558 linda.phillips@dhs.gov</p> | <p>FDA has jurisdiction over sales from foreign individuals or businesses, however, enforcement is difficult. Generally, it is illegal to import prescription drugs that are not approved by the FDA and manufactured in an FDA-approved facility. FDA activity has been focused on working with foreign governments in taking action against foreign-based sellers. The FDA has also sent warning alerts to foreign business operators informing them that they may be illegally selling drugs not approved for sale in the U.S.</p> <p>The U.S. Postal Service is required to present all international mail to the U.S. Customs Service. Customs staffs 14 International Mail Branches at various Postal facilities across the U.S. Customs inspects suspicious shipments, but is not able to inspect all shipments because of the volume.</p> <p>Customs works jointly with the FDA and the DEA to prohibit the illegal importation of pharmaceuticals and other dangerous drugs into the U.S. via the Internet.</p> |
| <p>Verified Internet Pharmacy</p> | <p>The VIPPS “Seal of Approval” verifies</p> | <p>National Association of Boards of</p> | <p>A voluntary program which verifies the legitimacy of Internet</p> |

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| <p>Practice Sites – VIPPS Certification</p> | <p>that Internet Pharmacies meet state licensure requirements and NABP standards. In addition, pharmacies displaying the VIPPS seal must demonstrate compliance with VIPPS criteria for patient rights to privacy, authentication and security of prescription orders, and provision of meaningful consultations between patients and pharmacies.</p> | <p>Pharmacy – Verified Internet Pharmacy Practice Sites – VIPPS Contact: Mary Dickson (847) 698-6227 mdickson@nabp.net</p> | <p>sites dispensing prescription drugs. The VIPPS seal is intended to assure consumers that the related pharmacy distributes only FDA approved pharmaceuticals and is in compliance with all appropriate state and federal laws.</p> |
| <p>Misuse of Personal Medical Information</p> | <p>Online pharmacies must adhere to federal and state laws regarding collection, use and privacy of individual health information.</p> | <p>FTC – (see contact p.4)</p> | <p>The FTC has federal authority for protection of consumer privacy online, including the privacy of individual health information. Online pharmacies making false or misleading claims about how they collect and use personal health information are subject to FTC challenge.</p> <p>Some States have legislated requirements for medical records privacy and created civil remedies for damages incurred by an individual. State statutes would apply to individual health information collected by Internet pharmacies.</p> |