Special Section: Cyberethics:
The Internet and Allied Technologies

The Internet, Confidentiality, and the Pharmacy.coms

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The advent of the Internet has had a significant impact on the formation of an information-driven, rapid-paced society. The number of Internet users reached 50 million in only five years compared to 13 years for television and 38 years for radio.[1] Consumer expectation for access, convenience, and speed has made the cyberspace superhighway a medium for knowledge exchange and for e-commerce. The Internet offers a wide variety of health services and products to healthcare professionals as well as to the public. Online pharmaceutical sales are predicted to reach $20–25 billion over the next four years. This is a dramatic increase when compared to the $1.9 billion in 1999. At the click of the mouse, medications can be ordered and delivered conveniently to your door. Yet, consumer discomfort with the security of information provided via the Internet is growing,[2] and recent incidents involving disclosure of healthcare information serve to heighten this concern.[3,4]

Do pharmacy records constitute "healthcare information" and is there a legal mandate that they be kept private? Do the confidentiality obligations of Internet pharmacies, such as drugstore.com, CVS.com, Merck-Medco, Walgreens.com, and so on, differ from traditional pharmacies?

Disclosure without Patient Authorization

Curiously, an oft-quoted Supreme Court decision on privacy of healthcare information, *Whalen v. Roe*, involved the confidentiality of pharmacy records and a New York requirement that pharmacies supply information (patient, prescriber, and pharmacy identities; drug name strength and quantity) to a central authority for schedule II (high abuse potential) drugs.[5] The Court found that New York's law was constitutional because the state had established sufficient safeguards against improper disclosure.

The circumstances surrounding *Whalen v. Roe* involved a limited list of drugs with information from "triplicate" prescriptions populating a database that was intended to identify illegal diversion of drugs. In contemporary community practice, patient profiles are constructed, including patient and prescriber identity and a listing of prescriptions supplied by that pharmacy. The profile also typically includes information such as chronic diseases and allergies. For some pharmacy chains, the profile may include prescription information for transactions from any member store. For a majority of prescriptions, the pharmacy is

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reimbursed by a third-party payer following receipt of an electronic claim. The claim includes numeric fields identifying the patient, prescriber, and pharmacy, the drug, strength, and quantity and days supply (calculated by the pharmacy from prescription instructions and quantity dispensed). Many insurers also require that date of birth and gender be included in the claim for data integrity checking.

Third-party payers also assemble patient profiles for activities such as those identified in the Proposed Rule on Standards for Privacy of Individually Identifiable Health Information:

- determinations of coverage, improving payment methodologies or coverage policies, or adjudication or subrogation of claims
- risk-adjusting payments based on enrollee health status and demographic characteristics
- billing, claims management, medical review, medical data processing
- review of healthcare services with respect to medical necessity, coverage under a health plan policy or contract, appropriateness of care, or justification of charges
- utilization review activities, including precertification and preauthorization of services[6]

Prescription transactions are routed to third-party payers via claims clearinghouses ("data switches"). In addition to passing the claim along to the appropriate payer, the data switches vend "de-identified" records to payer business partners assisting in activities identified above, as well as various secondary users, such as pharmaceutical manufacturers, researchers, the U.S. Food and Drug Administration, and the Centers for Disease Control.[7]

Besides the constitutional protection of privacy articulated in *Whalen*, other federal protections against disclosure without patient authorization generally are confined to data collected for federal programs. For instance, the Privacy Act and Freedom of Information Act protect information where "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."[8]

State protection of prescription information varies considerably in approach and type of information held. A few states (Washington, Montana, and California) have passed medical information privacy acts modeled after the Uniform Health Care Information Act[9] and provide broad protections for information collected or disclosed in these states. In many states, disease-specific privacy laws restrict access to information about patients with sexually transmitted diseases, AIDS, or mental illness.[10] However, coverage is piecemeal, and many states fail to address issues such as secondary use of data, data-holders' disclosure obligations, or appropriate penalties for unauthorized disclosure.[11]

Internet Pharmacies and Disclosure

Legitimate Internet pharmacies offer such services as consultation with pharmacists via telephone or e-mail, and general drug/health information assistance. Patients can order prescription drug refills, over-the-counter medications, and health, beauty, and cosmetic products, for either mail-order delivery or

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pickup at a local store. The process is simple: the patient can start up the computer, go to one of the Internet pharmacy sites, type in name, health insurer, home address, and credit card number. To avoid potential drug interactions, new patients must complete a form indicating what other medications they are currently taking, allergies, and medical history and conditions. The patient is offered the opportunity to participate ("opt-in") in various programs offered by the pharmacy, such as e-mail prescription refill reminders. Each patient is provided a unique personal identification number. To avoid inadvertent disclosure of prescription information via e-mail, reminders refer the patient to a web site, and patient-specific information is only transmitted following entry of the personal identification number.

The rapid proliferation of "rogue" Internet operations providing prescription drugs outside legal pathways[12] has chastened the legitimate ones. The National Association of Boards of Pharmacy has developed a Verified Internet Pharmacy Practice Site (VIPPS) certification program that requires licensure in each state to which the Internet pharmacy dispenses pharmaceuticals, as well as conformance to privacy, authentication, security, and pharmacy practice standards.[13] Another organization, TRUSTe, has established privacy disclosure criteria regarding the type, use, and distribution of information gathered through the Internet site.[14] Both firms permit posting of a "seal of approval" with hotlinks to a site verifying the status of the Internet enterprise.

Although legitimate Internet pharmacy activities are bound by the laws of the state where the "brick and mortar" pharmacy exists and in the state in which the prescription is delivered, consumers have no reasonable expectation that rogue Internet pharmacies will be so constrained. The U.S. Food and Drug Administration has begun enforcement activities against domestic operations offering to prescribe a prescription drug for the first time without a physical exam, prescription drugs without a prescription, or unapproved drugs.[15,16]

Do Internet pharmacies pose a new threat to confidentiality? It appears that legitimate operations are using all available technology to assure the security of their data, and are otherwise no different from traditional pharmacies. For rogue sites, caveat emptor.

Notes

1. Angaran DM. Telemedicine and telepharmacy: current status and future implications. *American Journal of Health System Pharmacy* 1999;56(14):1405–26.
2. The Pew Internet and American Life Project. Trust and privacy online: why Americans want to rewrite the rules. http://63.210.24.35/reports/pdfs/PIP_Trust_Privacy_Report.pdf.
3. Lo B, Alpers A. Uses and abuses of prescription drug information in pharmacy benefits management programs. *JAMA* 2000;283(6):801–6.
4. Martinez B. Kaiser e-mail glitch highlights pitfalls of placing personal-health data online. *Wall Street Journal* 2000;August 11;B10.
5. *Whalen v. Roe*, 429 U.S. 589. 2/22/1977.
6. Standards for privacy of individually identifiable health information: proposed rule. *Federal Register* 1999;64(212):59918.
7. House Committee on Ways and Means. *The Confidentiality of Patient Records*. 2/17/2000.
8. Privacy Act 5 USC §552(b)(6). Public information: agency rules, opinions, orders, records, and proceedings.
9. Uniform Health Care Information Act §2–101.(9). Northport, N.Y: E. Thompson Co., 1985. Uniform laws annotated.

https://doi.org/10.1017/S0963180101002067 Published online by Cambridge University Press

10. Hodge JG Jr. National health information privacy and new federalism. *Notre Dame Journal of Law, Ethics & Public Policy* 2000;14:791.
11. Hodge JG Jr, Gostin LO, Jacobson PD. Legal issues concerning electronic health information: privacy, quality, and liability. *JAMA* 1999;282(15):1466–71.
12. Bloom BS, Iannacone RC. Internet availability of prescription pharmaceuticals to the public. *Annals of Internal Medicine* 1999;131(11):830–3.
13. National Association of Boards of Pharmacy. Verified Internet Pharmacy Practice Site (VIPPS) Program. http://www.nabp.net.
14. TRUSTe. http://www.truste.org, accessed 8/30/2000.
15. Henney JE, Shuren JE, Nightingale SL, McGinnis TJ. Internet purchase of prescription drugs: buyer beware. *Annals of Internal Medicine* 1999;131(11):861–2.
16. Department of Justice. Indictment in Internet Sale of Prescription Drugs. http://www.usdoj.gov/opa/pr/2000/August/460civ.htm, accessed 8/31/2000.

https://doi.org/10.1017/S0963180101002067 Published online by Cambridge University Press