

The Challenge of Regulating Internet Prescribing

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Advances in telecommunications and the growth of Internet commerce have extended what we have defined as telemedicine and allow individual consumers increasing access to health information and services online. This situation raises new issues regarding Internet prescribing.

Telemedicine, telehealth and related online health information and services has become one of the major developments in healthcare delivery in our lifetime, transforming patients into consumers. It is a clear indication of how the use of telecommunications for healthcare can be very positive while also being a disruptive technology.

Such advances present a challenge to traditional providers of medicine as well as lawmakers and regulators. A natural reaction to such disruptions is to try to thwart its impact and to protect the status quo. However, the danger in such actions is losing all of the good for the sake of some resolvable problems.

Overview

The use of the Internet has become a major component in the provision of healthcare. Millions of people regularly search the Internet to obtain answers to questions they have about healthcare in general and in reference to specific questions they may have about their own health. Some of the information is excellent while some of it has proven to be misleading.

This has provided a challenge to regulators and healthcare providers who are interested in making sure consumers get accurate information. It also provides an interesting challenge to healthcare professionals who face patients who have become aware of the latest advances and research findings about a specific subject area. Traditionally considered ultimate authorities on medical care, physicians are sometimes challenged by their patients who are armed with good information and sometimes with bad. This transformation has caused many physicians to change from acting as a “god” to a “guide” as they take on a role of helping steer patients toward reliable sources of online health information.

The use of remote telecommunications has also become a way of obtaining prescribed medications. For example, several telemedicine programs have established remote telepharmacy applications to make prescription medicines available to people in remote areas. In other cases telemedicine is used for normal follow-up visits that result in an extended or revised prescription order.

Of course, online pharmacy web sites have become another source of obtaining prescription drugs. Filling a prescription online has become a major vehicle used by consumers. Online pharmacies provide efficient services and often discounted prices. In the United States, the National Association of Boards of Pharmacy (<http://www.nabp.net/>) accredits online pharmacies through its VIPPS program. Online filling of prescriptions have become an important vehicle in the delivery of healthcare. In fact every major pharmaceutical chain in America now offers online filling of prescriptions.

Obtaining a Prescription Online

The core issue arises in how a consumer obtains a prescription. In some cases, internet sites have provided illegal drugs, issued prescriptions for controlled substances without the approval of an authorized practitioner, and have used counterfeit or low quality materials. In rare cases this has even led to the death of innocent consumers.

State regulations for internet prescribing vary considerably from state to state. The Federation of State Medical Boards established a National Clearinghouse on Internet Prescribing (http://www.fsmb.org/ncip_overview.html). The site includes a state-by-state breakdown of jurisdiction, regulations and actions related to the regulation of internet prescribing.

In 2008, Congress and the President enacted the Ryan Haight Online Pharmacy Consumer Protection Act¹ designed to clamp down on the illegal sale, abuse and trafficking of prescription drugs over the Internet. ATA was able to get the bill sponsors to exempt remote-site pharmacies that operate under approved telemedicine procedures and prescribing practitioners legitimately using telemedicine.

A key factor in this issue is the validity of the prescription and the basis upon which a prescription is provided. There are several issues that affect the use of online pharmacies and online prescribing. States and the federal government have reacted in different ways to each one.

Federal and State Issues

Who can prescribe? Each state licenses healthcare professionals and designates the specific authority that an individual has in providing a prescription. According to the Department of Justice, as many as 12 different types of mid-level healthcare professionals are authorized by various states to issue some form of prescriptions. These professionals include physician assistants, nurse practitioners, medical psychologists and registered pharmacists. Often these individuals are only allowed to prescribe certain low risk drugs. In some cases, but not all, the prescribing professional

¹ Public Law No: 110-425

is required to be under the direct supervision of a licensed physician. In most areas a nurse or allied health professional is used to administer flu shots, a normally prescribed drug, without the need for a prescription.

Where can a prescription be issued? Each state licenses healthcare professionals and requires that only healthcare professionals licensed in that state are eligible to write a prescription for someone located in that state. However, if the patient is temporarily located in another state, the patient's prescription will usually be filled in that state even if it originates from their regular physician located back at home. This is normal practice but the legality has not been tested in court.

What can not be prescribed? Schedule 1 controlled-substance drugs as identified by the Drug Enforcement Agency are not available for a prescription anywhere. The restrictions on other levels of medications vary based on the risk as measured by the level of potential abuse and effects. Low risk drugs receive the least amount of restrictions in their control. Other medications fall under regulations established by the Food and Drug Administration.

On what basis can a prescription be made? Generally, there is agreement by government regulating bodies that a prescription should be normally provided based on an understanding of the patient's complaint, current health status and medical history. Although the U.S. Department of Justice and about 10 states have addressed the issue of minimal standards for issuing a prescription, which includes a determination of current health status based on a face-to-face physical examination, there are no legal specifications as to what constitutes "face-to-face" or what makes up such an examination. Does this include taking blood pressure? Temperature? Blood oximetry? Weight? Glucose levels? In some cases additional lab tests may be required. These judgments are left up to the health professional who issues the prescription. However, it is clear that certain types of conditions and resulting medications require different types of an examination. Low risk drugs would require the least amount of an assessment from the health provider. Also, as stated above, in some states certain prescribed drugs can be issued by pharmacists without a physical examination.

In practice, many physicians issue prescriptions for many low risk drugs based on a survey filled out by the patient, a set of vital signs (usually taken by a nurse or an assistant) and a brief conversation with the patient. Increasingly, health providers are using e-mail to provide follow-up communications with a patient including the issuance of additional prescriptions for certain medications. Such email communications are starting to be reimbursed by major private insurers and employer health plans.

Considerations for ATA Policy Setting

Although ATA has not taken an official position on the basis for a prescription, it is clear that certain types of medications should only be made available based on a direct

consultation with the patient. However, in established telemedicine programs such consultations can and often do involve an electronic visit with the patient where the prescribing professional is not physically in the same room but can still access vital signs and communicate directly with the patient. Such electronic visits have become common place throughout the United States and in many other parts of the world. In rural and out of the way locations this often affords access to healthcare that could otherwise not be achieved. It also allows more efficient use of healthcare services by all involved.

In some cases, there is still a critical need to physically see a patient or make a referral to a specialist who may need to physically see the patient. When a patient and physician are physically face to face, it should be the judgment of the licensed health professional about what vital signs are taken, what additional tests are made and when a patient should be seen in-person by another health professional.

Any proposed state or federal regulation or rule of law regarding the issuance of a prescription based on electronic communications should be very carefully crafted and hold foremost the needs and rights of the individual. In the past, some have questioned whether certain state medical practice regulations were merely enacted as a trade barrier, protecting the economic well-being of resident health professionals above the rights of consumers in the state to seek alternative and lower cost care.

Whatever action is taken by the federal or state policymakers should be crafted in such a way that does not interfere with regular, ongoing practices of established telemedicine programs. It is an important government role to protect patients and consumers. However, just as in medicine, it is critical that such actions first do no harm.