Prescribing in the Age of the Internet

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August 2010
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This publication was made possible by grant number G22RH20216 from the Office for the Advancement of Telehealth, Health Resources and Services Administration, DHHS.

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Acknowledgements

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Welcome To CTeL

The Center for Telehealth & e-Health Law (CTeL) was founded in 1995 to overcome the legal and regulatory barriers to the utilization of telehealth and related e-health services. CTeL, formerly known as the Center for Telemedicine Law, was created under the vision and leadership of a number of individuals and organizations, including Dr. Yadin David, Bob Waters, the Mayo Foundation, the Cleveland Clinic, the Midwest Rural Telemedicine Consortium, and the Texas Children’s Hospital.

CTeL has established itself as a leader in the telehealth community and is known for its ability to compile and analyze complex legal, regulatory and public policy information. CTeL provides vital support to the community by providing critical analysis and information on legal and regulatory issues on topics such as reimbursement, licensure, telecommunications, FDA regulations, privacy, and accreditation.

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"The technology has developed faster than the rules of operation."

-Greg Bell

Abstract

This paper will focus on telemedicine as it relates to prescribing. It will distinguish between telemedical prescribing, e-prescribing, and the forms of internet prescribing that have often led to legal sanctions and fines. It will examine recent and significant legal cases involving internet prescribing, as well as newly-implemented federal legislation. Finally, it will conclude with prescribing guidelines for physicians and considerations of the future of 21st century prescribing.

Introduction

The increased use of technology in our society has naturally led to an increase in use among the medical community. Technology has been employed successfully to improve the privacy, expediency, availability, and effectiveness of healthcare. It has significantly changed the way medicine is being practiced. But, the nature of the Internet - its speed, its anonymity, and its fluidity of location - has sparked a need for re-evaluation among the medical community of state statutes and guidelines regarding prescription-writing by licensed physicians, as well as a critical look at the realistic enforcement of these statutes.
21st Century Prescribing: An Overview

“[The American Telemedicine Association] has historically considered telemedicine and telehealth to be interchangeable terms, encompassing a wide definition of remote healthcare.”¹ In much the same way, the term “internet prescribing” has been used to describe a wide variety of actions, some generally accepted by the medical community while others spark storms of controversy. In order to effectively discuss prescribing, it is important to distinguish between the different forms of prescribing physicians engage in while employing telecommunications, and more specifically, the internet.

21st century prescribing can be divided into three areas: telemedical prescribing, e-prescribing, and internet prescribing.² Each of these forms can be characterized generally as “telemedicine” as it is defined by the American Telemedicine Association.³ However, the doctor-patient relationship and the role of telecommunications in each form varies. It is those variances that often determine whether an action falls outside the guidelines of state medical boards and federal legislative acts or remains safely within the bounds of generally accepted standards of care.


² These terms are not concretely and uniformly used in the telemedicine community. They are being employed in this paper for the sake of clarity and effective discussion.

³ ATA describes telemedicine as “the use of medical information exchanged from one site to another via electronic communications to improve patients' health status.”
Telemedical Prescribing

Prescribing that falls under the first category, *telemedical prescribing*, takes place after an authentic telemedicine encounter. These encounters often occur in hospitals or clinics that have implemented an established telemedicine program. Programs might utilize video conferencing, high-resolution cameras, or tele-robotics. The patient will be under the immediate care of a licensed physician. What distinguishes this type of prescribing from traditional prescribing is that the issuing physician is at a different location than the patient.

The Partners Telestroke Center at Massachusetts General Hospital and Brigham and Women’s Hospital illustrates the use of telemedical prescribing. With this national program, hospitals can provide a heightened standard of care to their stroke patients, and in many cases, can actually save lives and reduce disabilities by engaging in video conferencing and image transferring with a remote stroke specialist.

Because stroke specialists may not be readily available in smaller hospitals or rural areas, telemedicine programs like that of Partners Telestroke Center can be an especially significant leap in the delivery of advanced medical care. This particular telemedicine

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4 For the purposes of this paper, an “authentic telemedicine encounter” will be an interaction that meets the guidelines set forth in California’s “Telemedicine Development Act of 1996.” Specifically, a telemedicine encounter is “neither a telephone conversation nor an electronic mail message between a health care practitioner and patient” and telemedicine must use interactive communications, with “interactive” being defined as “an audio, video, or data communication involving a real time (synchronous) or near real time (asynchronous) two-way transfer of medical data and information.”

program illustrates the importance of prescription-writing within these programs. Specifically, a doctor specializing in strokes would be able to identify an ischemic stroke and immediately prescribe the FDA-approved drug, tissue plasminogen activator (tPA). This drug has been shown to dramatically reduce the disabling effects of ischemic strokes.\(^6\) Physicians must administer tPA within three hours of a stroke occurrence. However, emergency room doctors are often hesitant to prescribe tPA because of the risks\(^7\) associated with the drug and their inexperience in its use.\(^8\) Telemedicine programs alleviate these concerns by placing the responsibility for diagnosis, treatment, and the prescribing of tPA on the telemedicine doctor, thereby reducing risk and improving the chances of recovery among patients.

The legal obstacles entangling this form of prescribing are rooted in licensure concerns. Almost every state medical board has statutes prohibiting the practice of medicine within the state by physicians not licensed by the state’s medical board. For example, California’s Medical Board could sanction a doctor in Maryland if that doctor attempts to diagnose or treat a California resident. Because of these restrictions, telemedical prescribing by practitioners lacking the appropriate medical licenses often does not

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\(^7\) If tPA is prescribed too late or for hemorrhagic stroke, further damage could occur. Ischemic strokes are caused by a blood clot. TPA contains a clot-dissolving agent. If the tPA is prescribed too late it could cause hemorrhaging. If it is prescribed for a hemorrhagic stroke, the bleeding could worsen and symptoms would become more severe.

meet accepted standards of care. Violation of medical board licensure guidelines by telemedically prescribing could result in license suspensions or revocations.

**e-Prescribing**

The second category of prescribing is *e-prescribing*. Under this form of prescribing, the physician issues prescriptions electronically to a pharmacy. This form is different from other forms of internet prescribing because the prescription is not issued in response to an internet encounter. It is also not necessarily a result of telemedicine. Rather, this process operates similarly to a traditional doctor-patient encounter: a patient visits their physician, undergoes a physical examination, and receives an appropriate prescription as treatment. Tradition ends when the doctor, instead of writing the prescription and giving it to the patient, instead “generate[s] the prescription through an automated data-entry process using e-prescribing software.”

Federal Telemedicine News reports that “e-prescribing has more than doubled from 68 to 190 million e-prescriptions in 2009 with the adoption of the technology by prescribers going from 74,000 in 2008 to 150,000 by the end of 2009.”

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This form of prescribing has been heralded as a way to reduce healthcare costs.\textsuperscript{11} E-prescribing has also been attributed to a decrease in medical errors. Researchers at Weill College in New York conducted a study on e-prescribing by examining 7,500 prescriptions from 12 medical practices. “Practices that used electronic prescribing for a year cut their error rate to 6.6% on average from 42.5% before they began e-prescribing, the researchers found. The error rate at medical practices that continued to use paper prescriptions rose slightly to 38% on average from 37%.”\textsuperscript{12}

Legally, e-prescribing has encountered little resistance or concern.

\textit{Internet Prescribing}

The final category of prescribing, \textit{internet prescribing}, is distinguished by the primary role the internet plays in the issuance of the prescription. Arguably, the most defining characteristic of internet prescribing is that the entire doctor-patient relationship is rooted in, sustained by, and concludes with internet communications. The relationship is initiated by the patient through a website. The “examination” is commonly a completed online questionnaire. The prescriptions are issued, authorized, and sent electronically.

\begin{flushright} \textsuperscript{11} Surescripts CEO and President Harry Totonis explained that the company anticipates “reducing the costs for e-prescribing by 10 to 20 percent because Surescripts has achieved operational efficiency and also as a result of the benefits from the company’s merger with RxHub.” \\
\textsuperscript{12} Martin, Timothy. “More Doctors Are Prescribing Medicines Online.” \textit{Wall Street Journal}. 20 Apr. 2010. Print. \end{flushright}
This form of prescribing can further be divided into two categories.

**Website Prescribing**

The first category of internet prescribing takes place through a website after a telecommunication evaluation by a physician and is offered as a complement to the treatment of a primary care physician. It is not meant to supplant the traditional doctor-patient relationship or to treat major health issues. These websites promote their convenience and privacy, factors that may not be as easily acquired through traditional healthcare. The website acts as an alternative to traditional medicine and seeks to claim a legitimate place in the telehealth world, evidenced by a sincere attempt to adhere to governing rules and guidelines.

An example of this type of website is TelaDoc. Patients can use Teladoc when they encounter an issue after normal business hours or if they are in a different location than their primary care physician. Once a patient requests care, they are assigned a doctor that is licensed in the state in which the patient is currently located. The doctor may rely on online video conferencing and/or telephone conversations to diagnose illnesses.

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15 This is an important consideration undertaken by telemedicine websites that wish to legitimize themselves in the community because of medical board guidelines requiring doctors be licensed by the state in which they are practicing.
and recommend treatment. Teladoc’s prescription-writing does not include any drugs classified as “controlled substances” by the Drug Enforcement Agency.

Teladoc recently received $9 million in venture capital to grow its business, signaling a growing acceptance of this form of healthcare. Because it reduces costs and increases convenience, Teladoc has struck a chord with employers and insurance companies looking to reduce healthcare expenses. CEO Jason Gorevic explains, “There’s no question that we have to increase health care coverage in this country. The challenge is that increasing coverage exacerbates primary care overload. We help to alleviate that issue by providing an outlet when someone can’t access their primary care physician. We’re not a substitution for a primary care physician. We see ourselves as a complement to it.”

Teladoc has been able to steer clear of legal pitfalls by ensuring doctors are licensed in the states they “practice” and avoiding the prescribing of controlled substances. A typical Teladoc-patient encounter takes place after the physician has reviewed the patient’s medical history. The physician will then telephone the patient to discuss his or her medical concerns and ask follow-up questions. If a prescription is deemed necessary, it will be issued. According to Teladoc’s Prescription Policy, “Teladoc

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physicians do not issue prescriptions for substances controlled by the DEA, lifestyle, and/or those which may be harmful (potential for abuse or addiction).”

Another website-prescribing service is Kwikmed. Kwikmed offers five lifestyle drugs: Propecia (for baldness), Viagra, Cialis, and Levitra (for impotency), and Chantix (for smoking cessation). Though they are licensed and regulated in Utah, national laboratories service Kwikmed patients. Patients can access their laboratory test results and medical history through the website. They are required to complete an online questionnaire about their medical history which the website ensures is reviewed extensively by licensed physicians. The website’s method of operation was recently reviewed by the University of Utah and The Mayo Clinic and was found to be comparable to traditional medical practices and, in the case of prescriptions and care for erectile dysfunction, actually exceeded traditional medicine in medication counseling.

Kwikmed was originally shut down in 2002 when it was indicted on 198 counts by an Arizona federal court accusing the operating pharmacists and doctors of selling drugs

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without valid prescriptions.\textsuperscript{20} It was purchased in 2001 by Peter Ax, and since then has worked with Utah’s state legislature to achieve legitimacy and operating legally.\textsuperscript{21} Their legal protections come from transparency, extensive efforts at regulation, and strict adherence to Utah’s policies and guidelines.\textsuperscript{22} However, Kwikmed still encounters legal push-back from states where the drugs are shipped and professional organizations hesitant to endorse their operations.\textsuperscript{23}

\textit{Rogue Site Prescribing}

The second category of internet prescribing involves what is commonly referred to as a “rogue site.” The doctor-patient relationship is initiated when the patient visits the rogue site and requests a consultation. In lieu of a physical medical exam, the patient will complete an online questionnaire that is then reviewed by a physician contracted or employed by the website. The physician will prescribe medication that is then shipped directly to the patient. Generally, these website have few restrictions over the drugs they are willing to prescribe. Pain killers, weight-loss drugs, lifestyle drugs, and anti-depressants are some of the most commonly issued prescriptions.

It is the legality of rogue sites and their prescribing physicians that is most often called to attention. Medical boards express concern over the fact that doctors are issuing

\textsuperscript{23} “In 2007, the state of Arkansas threatened the company with a lawsuit for sending medicine there...The American Pharmacists Association, a trade group of professional pharmacists, maintains that doctors should examine their patients in person before prescribing drugs and considers companies that do not require that to be “rogue online pharmacies.” - Voiland
prescriptions over the internet to patients they have never met and to whom they may never have spoken. The sheer quantity of prescriptions that are written by physicians working in conjunction with these websites is alarming, as well. Some doctors issue hundreds of prescriptions a day. In order to reach this number, precautions taken before prescribing are minimal (if any are taken at all) and an acceptable doctor-patient relationship is never established.

Case Analyses

Each form of prescribing presents its own challenges and questions. However, it is the last form, internet prescribing, that has come under the most scrutiny and has encountered the most legal resistance. By examining several recent cases, this paper will seek to more clearly illustrate the primary legal issues involved in prescribing in the 21st century. The cases will be divided into three sections based on resulting sanctions - fines, license suspensions or revocations, and imprisonment.

Fines

In February of 2003, the Medical Board of California fined six out-of-state physicians for issuing prescriptions to California residents without performing a prior good faith exam.24 The case garnered nationwide publicity because of its precedence and the substantial amount of the sanction - $48 million.25 Pursuant to California’s Business and

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Professions Code section 2242.1, the Board imposed the maximum fine of $25,000 per incident involving a California resident. Carlos Levy of Florida incurred the largest fine - more than $39 million - for writing 1,567 prescriptions. The cases were then referred to each physician’s respective state for further disciplinary actions, including fines and suspensions or revocations of licenses.

Jose Crespin of Miami, Florida was one of the physicians sanctioned by California. Seven months after the California sanctions were issued, Florida’s Department of Health filed a separate administrative complaint against Dr. Crespin. The complaint included three charges: standard of care violation, inappropriate prescribing, and inadequate medical records. These charges stemmed from Dr. Crespin’s relationship with Impact Healthcare and a patient located in Texas.

While working for Impact Healthcare, Dr. Crespin prescribed the Schedule IV controlled substance Phentermine to a patient referred to as “CH” in the complaint issued by the Department of Health. About a month after CH received the prescription, CH issued an Authorization for Release of Patient Information. The Department of Health forwarded this request to Dr. Crespin. Dr. Crespin failed to release any medical records to CH, prompting suspicions that Dr. Crespin was not maintaining adequate

27 http://www.doh.state.fl.us/mqa/FinalOrders/1-07-04/DOH-03-1506.pdf
patient records. Further investigation into CH’s relationship with Dr. Crespin revealed that Crespin had not performed a valid medical examination on CH before prescribing the medication, had not issued the necessary diagnosis to necessitate the prescription, and had also not developed a treatment plan for patient CH.28

Ultimately, Dr. Crespin was sanctioned with fines, community service and education credits, and court costs.29 Upon a second hearing, the Board accepted the voluntary relinquishment of his license, as well.30

Suspension of License

Dr. Deborah S. Golob of Tempe, Arizona was censured on April 14, 2005 for writing prescriptions to internet patients without conducting prior physical examinations. Specifically, it was alleged that Dr. Golob violated Arizona Revised Statutes § 32-1401(27), which defines “unprofessional conduct” as “prescribing, dispensing or furnishing a prescription medication... to a person unless the licensee first conducts a physical examination of that person or has previously established a doctor-patient relationship.”31 Her license was also suspended, she was fined $10,000, and she was placed on probation for five-years during which she would be required to complete

28 http://www.doh.state.fl.us/mqa/FinalOrders/1-07-04/DOH-03-1506.pdf
29 http://www.doh.state.fl.us/mqa/enforcement/discipline_reports/FO_01-07-04.pdf
30 http://www.doh.state.fl.us/mqa/medical/min_10-06-07.pdf
twenty hours of medical ethics coursework. In response to these sanctions, Dr. Golob sued the Arizona Medical Board, citing the state medical board’s lack of subject-matter jurisdiction, lack of evidence, and the unconstitutionality of A.R.S. § 32-1401(27).

Dr. Golob’s appeal illuminates the common complaints and defenses of those practicing internet prescribing.

Ultimately, the Arizona Court of Appeals ruled against Dr. Golob, dismissing each of her allegations. Regarding subject-matter jurisdiction, Dr. Golob herself admitted that she prescribed to Arizona residents by stating during her initial trial that she prescribed to patients “from all fifty states.” The court pointed out that Golob lived in Arizona, was licensed in Arizona, and worked in Arizona. Her licensure, place of practice, and the fact that she issued prescriptions to Arizonans gave the Arizona Medical Board enough authority to claim jurisdiction.

Concerning the lack of evidence to support the claim that Dr. Golob had not established relationships with her patients, the court found Dr. Golob’s arguments meritless. Dr. Golob’s attorney, Adam Palmer, defended her actions by employing the Arizona License will be renewed upon completion of 20 hours of medical ethics education. Source: Riske, Phil. “Suspended Doctor Sues State of Arizona Over Internet Prescriptions.” BNET: The CBS Interactive Business Network. Arizona Capitol Times/Dolan Media Newswires, 22 Apr. 2005. Web. 7 Aug. 2010.

Supreme Court ruling in *Stanley v. McCarver Jr., M.D.* Palmer asserts the court’s conclusion in *Stanley v. McCarver Jr., M.D.* is indicative of a changing interpretation of doctor-patient relationships. Golob’s relationship with her patients, though never affirmed through a physical exam, could still be considered legal since online questionnaires and the consultation fee are evidence of an established “doctor-patient relationship.” Citing *Jones v. N.D. State Bd. of Med. Examiners*, the appellate court held that online questionnaires, Dr. Golob’s primary method of examination, were insufficient to establish a doctor-patient relationship. The court further expounded on this point by illustrating the potential harm of accepting online questionnaires as accurate records of patient histories and symptoms since patients can divulge misleading and blatantly false information, especially if they are seeking drugs to fuel an addiction. Dr. Golob conceded this point, and the court dismissed her claim of having established legitimate relationships with her patients.

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34 In *Stanley v. McCarver Jr., M.D.*, Dr. McCarver failed to report abnormalities in a chest x-ray to nurse Christine Stanley. However, Dr. McCarver had never met Stanley and was contracted only to review the x-rays for tuberculosis, of which he found no trace. Months later, Stanley was diagnosed with lung cancer. The court concluded that McCarver acted negligently, even though no formal doctor-patient relationship had existed between he and Stanley. Source: Stanley v. McCarver, 208 Ariz. 219, 92 P.3d 849 (2004).

35 “‘Unprofessional conduct’ includes the following, whether occurring in this state or elsewhere: Prescribing, dispensing or furnishing a prescription medication or a prescription-only device as defined in section 32-1901 to a person unless the licensee first conducts a physical examination of that person or has previously established a doctor-patient relationship.” Source: Jones v. North Dakota State Bd. of Med. Examiners, 2005 ND 22, 691 N.W.2d 251
Finally, with regard to the unconstitutionality of A.R.S. § 32-1401(27), the Court referenced *Brighton Pharmacy, Inc. v. Colorado State Pharmacy Board*, which concluded that “trained professionals...should reasonably be expected to be knowledgeable as to their profession and the environment in which it is practiced.”\(^{36}\) Dr. Golob contends that the vagueness of the statute violates the Due Process clause of the 14th amendment because “it is so vague and standardless that it leaves the public uncertain as to the conduct it prohibits...”\(^{37}\) In response, the court explained that because these statutes were written for a trained professional, the expectation existed that these individuals in the course of their practice should have developed a clear understanding of what is permissible and within the bounds of professional and appropriate practice, or if they lack understanding, have the duty to inquire further to alleviate those misunderstandings. Dr. Golob herself admitted knowing of other practitioners who had been sanctioned for actions similar to hers. The court found it “untenable” that she not be informed enough by the statute to effectively determine the legality of her actions.

Having rebutted each of Golob’s defenses, the court upheld the Arizona Medical Board’s sanctions, leaving Dr. Golob’s actions to remain categorized as “unprofessional conduct” under Arizona’s Revised Statutes.\(^{38}\)

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\(^{38}\) Arizona Revised Statutes, Title 32, Chapter 13, Article 1, Definitions
In 2005, Christian Hagaseth III of Colorado endured criminal and civil court cases, seeking to determine what role and to what extent his actions played in the suicide of 19-year-old Stanford student John McKay.

Hagaseth’s relationship with McKay began when McKay initiated a prescription drug request through the website www.usanetrx.com in June 2005. Hagaseth received an online questionnaire completed by McKay and wrote a prescription for fluoxetine, a generic form of Prozac. The prescription was then filled by a pharmacy in Mississippi. Two months later, McKay committed suicide.\(^{39}\)

The San Mateo County District Attorney’s Office continued the investigation of Dr. Hagaseth’s actions after the Medical Board of California concluded Dr. Hagaseth was not legally able to practice medicine in California since his medical license was valid in Colorado only. The California Medical Board determined Hagaseth’s actions did not qualify as telemedicine since it did not meet their designated criteria.\(^{40}\) The California Business and Professional Code Section 2290.5 explicitly states that telemedicine is “neither a telephone conversation nor an electronic mail message between a health care


\(^{40}\) The California Medical Board website states, “Physicians using Telemedicine technologies to provide care to patients located in California must be licensed in California and must provide an appropriate prior exam to diagnose and/or treat the patient. Physicians practicing via telemedicine are held to the same standard of care, and retain the same responsibilities of providing informed consent (Business & Professions Code Section 2290.5).
practitioner and patient.” Further, Hagaseth did not perform a face-to-face evaluation of McKay, did not obtain an accurate medical history, and did not follow-up with McKay after the prescription had been filled.  

Hagaseth’s argument rested on the fact that he performed all medical actions relating to the case in the state of Colorado. Because he never physically practiced medicine in California, he charged that the state did not have the jurisdiction to prosecute him.

Ultimately, the California Court of Appeals applied the “detrimental effects” theory of extraterritorial criminal jurisdiction, which states that “acts done outside a jurisdiction, but intended to produce and producing detrimental effects within it, justify a State in punishing the cause of the harm as if he had been present at the effect.” They charged him with a single felony count of practicing medicine without a valid California license.

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42 Hagaseth pleaded “no contest” to the charge and was sentenced to nine months in prison and three years of probation. He served his sentence in Colorado. He also was required to reimburse the California Medical Board $4000 for investigation costs. Source: Green & Associates. “Telemedicine Internet Prescribing Case - Colorado Doctor Sentenced To 9 Months Jail Sentence In California.” greenandassociates.blogspot.com. Green & Associates, 3 June 2009. Web. 7 Aug. 2010.

43 Hagaseth was also subjected to a civil case brought by McKay’s parents, but this case was dismissed after the U.S. District Court for the Northern District of California found that the antidepressant prescribed by Hagaseth played no part in the McKay’s suicide. Source: Green & Associates
In a different case, Stephen L. Ancier’s history with internet prescribing garnered him a 5-year federal prison sentence, a $7500 fine, and a forfeiture of $465,000 of his prescribing profits.\textsuperscript{44}

In March of 2010, Ancier pleaded guilty to writing more than 100,000 prescriptions online from 2002-2004, earning more than $1.5 million for his work. He never performed a physical examination on any of his online patients and rarely declined a request for a prescription. During his trial, prosecutors linked a patient overdose and an attempted suicide to Ancier’s cavalier prescribing methods.\textsuperscript{45} Illustrating the difficulty of overseeing the actions of online prescribers is the fact that Ancier’s license had already been revoked by several states\textsuperscript{46} by the time he was indicted in 2008 by a federal grand jury for drug conspiracy and illegal distribution of controlled substances.\textsuperscript{47}

Similarly alarming, by the time Dr. Robert Ogle prescribed the Schedule III painkiller hydrocodone to Ryan Haight over the internet, he had been imprisoned twice and lost his license to practice medicine in Texas.\textsuperscript{48} The rogue site Main Street Pharmacy employed Dr. Ogle anyway, and during his time with the pharmacy, he was able to


\textsuperscript{46} License suspended by Pennsylvania when they discovered he omitted fraud convictions and marijuana charges on his licensure application; congressional inquiry in 2004, license revoked in New Jersey; Washington license revoked in 2005 (Ryan).

\textsuperscript{47} In February 2009, Ancier pleaded guilty in Iowa to conspiring to dispense controlled substances outside the usual course of professional practice. He was transferred to New Jersey for sentencing. \textit{Source:} Ryan.

issue 5,866 prescriptions from August 2000 to Feb. 8, 2000, earning more than $250,000.49

His medical career ended however when, on February 12, 2001, 18-year old Ryan Haight was found dead in his home, a victim of a drug overdose. Investigators were able to trace the prescription back to Dr. Ogle when they found the empty bottle in Haight’s room with a label for Main Street Pharmacy. A few weeks later, Main Street Pharmacy was closed and the prescribing physicians working with the pharmacy lost their licenses.

Dr. Ogle was ordered to pay $2 million to Ryan’s parents by the San Diego Superior Court and he was sentenced to 24 months in prison.50 The United States District Court for the Northern District of Texas indicted Dr. Ogle and his co-workers for “conspiring to distribute controlled substance outside the usual course of professional practice, in violation of 21 U.S.C. § 846 of the Controlled Substances Act (“CSA”), and conspiring to launder money, in violation of 18 U.S.C. §§ 1956, 1957.”51

**Ryan Haight Consumer Protection Act**

Ryan Haight’s story resulted in one of the most significant steps toward legal clarity in internet prescribing in the past decade. Through the diligence of Senators Diane

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50 “Online Pharmacy Prosecutions.”
51 United States v. Fuchs, 467 F.3d 889, 898 (5th Cir.2006)
Feinstein (D-CA) and Norm Coleman (R-MN), and with the support of various agencies and associations, Congress passed the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, an amendment to the Federal Food, Drug, and Cosmetic Consumer Protection Act of 1938,\(^52\) that directly targets physicians and pharmacists engaged in internet prescribing. It is designed to respect legitimate telemedicine practices while closing the loopholes that physicians often embrace when defending controversial prescribing practices.

Key provisions of the Ryan Haight Consumer Protection Act include:

- Amend the Controlled Substances Act to prohibit the delivery, distribution, or dispensing of a controlled substance that is a prescription drug over the Internet without a valid prescription. It exempts telemedicine practitioners.

- Define “valid prescription” as a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of a patient.\(^53\)

- Impose registration and reporting requirements on online pharmacies that dispense 100 or more prescriptions or 5,000 or more dosage units of all controlled substances combined in one month.

- Require an online pharmacy to: (1) display specified information on its Internet home page, including a statement that it complies with the requirements of this Act, its name, address, and telephone number, the qualifications of its pharmacist-in-charge, and a certification of its registration under this Act; (2) comply with state laws for the licensure of pharmacies in each state in which it operates or sells controlled substances; and (3)

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\(^{53}\) A practical benefit of the act is the explicit defining of commonly used terms in regulations and statutes. Physicians (see Golob v. Arizona Medical Board) are expressly denied the argument of vagueness or misunderstanding. This provision, in effect, closes one of the most commonly-used loopholes.
notify the Attorney General and applicable state boards of pharmacy 30 days prior to offering to sell, deliver, distribute, or dispense controlled substances over the Internet.

- Increase criminal penalties involving controlled substances in Schedules III, IV, and V of the Controlled Substances Act.
- Authorize states to apply for injunctions or obtain damages and other civil remedies against online pharmacies that are deemed a threat to state residents.\(^\text{54}\)

**Summary: 21st Century Prescribing Legal Guidelines**

Recent legislation, like the Ryan Haight Consumer Protection Act, along with a broad case analysis can provide general guidelines for physicians to use when engaging in 21\(^\text{st}\) century prescribing.

First, online questionnaires do not establish a doctor-patient relationship. Though some states may allow for telecommunications to be used to establish a doctor-patient relationships,\(^\text{55}\) online questionnaires are not equivalent to real-time video examinations, electronically-sent vital signs, or consultation with a doctor who is performing a physical examination. The veracity of online questionnaires is often questioned, and the reliance on patient’s self-examination has proven unacceptable in assessing patient conditions and medical needs.

Second, if a prescription is administered to a patient, records must be kept and a follow-up visit should be scheduled. Physicians who prescribe medication to patients who

\(^{54}\) This summary of provisions was taken directly from the Global Legal Information Network at www.glin.gov.

\(^{55}\) Some statutes employ the language “face-to-face” when discussing the establishment of the doctor-patient relationship; however, this does not necessarily occur in telemedicine encounters involving video conferencing or image scans. This leaves the legality of these encounters in question until statutes are revised to include all forms of legitimate doctor-patient relationships.
would have no way of contacting them after they receive the medication are not delivering an acceptable standard of care. Physicians who prescribe medication, but offer no medical record of this interaction are not delivering an acceptable standard of care.\textsuperscript{56} Physicians who do not guarantee privacy of patient records also open themselves up to legal action.

Third, though some state statutes may not yet be specific enough in directly regulating use of the internet in prescribing, they are not vague enough to call into question their constitutionality. All doctors will be assumed to be knowledgeable about their practice and able to discern what an “acceptable standard of care is” and what a “bona-fide” doctor-patient relationship looks like. Feigning uncertainty or confusion regarding either of these guidelines will not be seen as an excuse for actions deemed “unprofessional” by a medical board.\textsuperscript{57}

Fourth, physicians should determine what licensure requirements apply before prescribing any medication to a patient residing outside of the physician’s state of licensure. “Some states require a license to be obtained in each state the physician provides services and others issue special licenses to out-of-state physicians to practice


\textsuperscript{57} Golob v. Arizona Medical Board, 217 Ariz. 505, 176 P.3d 703 (App.2008)
in their state. These requirements can significantly limit a physician’s ability to prescribe medication over the Internet.”

Looking Ahead

Prescription-writing is a necessary component of a physician’s medical practice because prescription drugs are an important element of healthcare. Whether it is a simple antibiotic, powerful pain-killer, or common weight-loss drug, physicians need to be able to evaluate patients and then prescribe medications to treat symptoms and cure illnesses. With the introduction of technology into the medical practice, physicians have the opportunity to extend their reach, and thus provide healthcare and treatment to patients all over the United States and world.

Telecommunications, especially the internet, have increased the autonomy of patients and have already revolutionized the prescribing within our healthcare system. Patients can enjoy levels of convenience and privacy in obtaining medication unavailable twenty years ago. Patients in rural or remote areas can now access advanced medical care through telecommunications. However, these benefits can easily become overshadowed by stories of drug overdoses, addictions, and accidents caused by casual internet prescribing and the lack of significant and consistent enforcement of new statutes.

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The legality of 21st century prescribing itself is no longer as ambiguous as it once was; however, the question of who will be responsible for overseeing the enforcement of the laws that protect citizens from possible channels of professional misconduct and providing guidance to physicians about those laws remains to be answered completely or adequately. Continued efforts to clarify prescribing guidelines and regulations will be only as effective as the agencies deemed responsible for enforcing them. Further, traditional licensure practices should be evaluated in light of our transitioning society to ensure that current policies do not infringe upon the benefits of future medical technological advancements.
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