

**REPORT OF THE  
VIRGINIA BOARD OF MEDICINE  
DEPARTMENT OF HEALTH PROFESSIONS**

**STUDY OF THE SALE  
OF PRESCRIPTION DRUGS  
VIA THE INTERNET**

**TO THE GOVERNOR AND  
THE GENERAL ASSEMBLY OF VIRGINIA**



**HOUSE DOCUMENT NO. 13**

**COMMONWEALTH OF VIRGINIA  
RICHMOND  
2000**





# COMMONWEALTH of VIRGINIA

## Department of Health Professions

6606 West Broad Street, Fourth Floor  
Richmond, Virginia 23230-1717

<http://www.dhp.state.va.us/>

TEL (804) 662-9900

FAX (804) 662-9943

TDD (804) 662-7197

John W. Hasty  
Director

October 21, 1999

TO: The Honorable James S. Gilmore, III  
Governor of the Commonwealth of Virginia

The Members of the General Assembly of Virginia

It is our privilege to present this report which constitutes the response of the Board of Medicine to the request contained in House Joint Resolution 759 of the 1999 Session of the General Assembly.

The report provides the findings of the board from its Study of the Sale of Prescription Drugs via the Internet. Approximately 125 hours of staff time and \$200 in costs for printing and mailing were expended in the process of conducting this study. The final report is available to the public on the website for the Department of Health Professions at <http://www.dhp.state.va.us/>.

The Board acknowledges the work of the Ad Hoc Committee on Internet Prescribing, the contributions of Elizabeth Scott Russell, Executive Director of the Board of Pharmacy and Faye Lemon, Director of Enforcement and the staff who conducted the research and prepared the final report.

John W. Hasty  
Director  
Department of Health Professions

Warren W. Koqntz, M.D.  
Executive Director  
Board of Medicine



**VIRGINIA BOARD OF MEDICINE  
DEPARTMENT OF HEALTH PROFESSIONS**

**Study of the Sale of Prescription Drugs via the Internet  
Pursuant to HJR 759 (1999)**

**Members of the Board of Medicine  
1999**

Joseph A. Leming, M.D.

\*Harry C. Beaver, M.D.

Brian R. Wright, D.P.M.

James F. Allen, M.D.

J. Kirkwood Allen

Robert J. Bettini, M.D.

Cheryl Jordan, M.D.

Gary P. Miller, M.D.

Richard M. Newton, M.D.

Diane L. Reynolds-Cane, M.D.

\*Cedric B. Rucker

\*Clarke Russ, M.D.

\*Paul M. Spector, D. O.

Connell J. Trimber, M.D.

Virginia Van de Water, Ed.D.

Jeffrey R. Vaughn, M.D.

Jerry R. Willis, D.C.

\*Member of the Study Task Force

**Acknowledgements**

The members of the Board of Medicine gratefully acknowledge the work of the Ad Hoc Committee on Internet Prescribing, chaired by Harry C. Beaver, M.D., for its diligence in studying the issues, hearing testimony and developing a recommendation for the Board's consideration. The Board also acknowledges the contributions of the Board of Pharmacy and the Investigative Division of the Department of Health Professions for providing information and assisting the Ad Hoc Committee in its deliberations.

**Final Recommendations of the Board of Medicine**

The Board has recommended that steps be taken to monitor the prescribing and dispensing of prescription drugs on the Internet and to enhance the ability of the Department to respond to such complaints. In addition, the Board has recommended amendments to the Code of Virginia to further specify the meaning of a bona fide practitioner-patient relationship for the purpose of a valid prescription, to require a non-resident pharmacy to ensure that a prescription results from a bona fide practitioner-patient relationship as specified in the Code, and to provide that a practitioner who practices on a patient in Virginia must abide by the provisions of Chapter 29 of Title 54.1 of the Code of Virginia.



## TABLE OF CONTENTS

	<b>Page</b>
<b>Preface</b>	<b>i</b>
<b>Background and Authority</b>	<b>1</b>
<b>Study Task Force of the Virginia Board of Medicine</b>	<b>1</b>
<b>Review of the Issues</b>	<b>2</b>
<b>A. Summary of the Problem</b>	<b>2</b>
<b>B. Research on the Internet sites offering prescription drugs</b>	<b>3</b>
<b>C. Internet drug sales in Virginia</b>	<b>5</b>
<b>D. Examination of laws and regulations in Virginia</b>	<b>5</b>
<b>Regulation of the practice of medicine across state lines</b>	<b>7</b>
<b>E. Examination of actions taken by other states</b>	<b>8</b>
<b>F. Examination of activity by federal agencies and bodies</b>	<b>11</b>
<b>G. Examination of activity by professional associations</b>	<b>13</b>
<b>Establishment of a national verification system for</b>	
<b>Internet pharmacies by NABP</b>	<b>13</b>
<b>Testimony of the American Medical Association</b>	<b>15</b>
<b>Problem with Internet Prescribing</b>	<b>16</b>
<b>Legitimate Uses for Internet Prescribing</b>	<b>17</b>
<b>Course of Action</b>	<b>17</b>
<b>Policy Recommendations of the Board of Medicine in Response to HJR 759</b>	<b>18</b>
<b>Appendices</b>	





## **EXECUTIVE SUMMARY**

### ***Background and Authority:***

House Joint Resolution 759, patroned by Delegate Jay O'Brien and passed by the 1999 Session of the General Assembly, requested the Virginia Board of Medicine, in consultation with the Board of Pharmacy, to examine the sale of prescription drugs in the Commonwealth over the Internet. Concerns expressed in the body of the resolution refer to the ability of consumers to purchase powerful drugs through the Internet without ever seeing a doctor, the fear that patients in Virginia could be harmed, and the possibly illegal prescribing practices of out-of-state physicians who are not licensed to practice in Virginia. The Board was required to complete its work in time to submit its findings and recommendations to the Governor and the 2000 Session of the General Assembly.

### ***Summary of the Problem***

As noted in the body of the resolution, the Internet is transforming the practice of medicine by offering patients greater accessibility to information and treatment options. Along with that access has come the opportunity for practitioners and drug suppliers with questionable ethics to circumvent or even violate laws and profit from consumer demand for "lifestyle drugs." A summary of the problems with the current practices of many of the Internet drug sites is as follows:

- No physical examination of the patient to determine the appropriateness or need for a particular drug to treat a disease or condition and no valid doctor-patient relationship.
- No evaluation of patient to determine the existence of a condition that might preclude a patient from taking a particular drug or if the drug might have serious side effects.
- No follow-up with the patient or continuity of care.
- No prospective drug utilization review (DUR) by online pharmacy to detect possible drug interactions or counterindications; also, likelihood that a patient would not report use of a drug ordered online to a pharmacist conducting a DUR for another prescription so drug interaction would go undetected.
- No license to dispense drugs in a state; every pharmacy sending drugs to patients in Virginia is required to have a license as a non-resident pharmacy.
- No assurance of drug quality and efficacy or that the drug has been stored and packaged according to manufacturer's specifications; it may have been exposed to heat and light conditions that could lessen its effectiveness.
- No regulation of black market sales from foreign suppliers - both of drugs which are not approved for sale in the United States and those which are approved but may be obtained without even the pretense of a prescription. Drugs sent from foreign sources may not be what the patient has ordered - they may be placebos or worse, adulterated in some manner.

- No assurance of security and confidentiality of patient-prescription information in cyberspace
- Elusiveness of the sites - if investigated, they are quickly closed down and reopened under another name

### ***Policy Recommendations of the Board of Medicine in Response to HJR 759***

1) In addition to other initiatives, the Department of Health Professions should do the following

- Continue to monitor the development of Internet drug sales and the problem of Internet prescribing
- Continue to respond to complaints related to Internet prescribing and dispensing as they are received and investigate cases in the context of the Enforcement Division plan of the Department
- Monitor activities and policies established by federal agencies, the introduction and content of federal legislation, and the outcome of injunctive actions taken by other states

2) In order to effectively and thoroughly pursue investigations of complaints surrounding Internet prescribing and dispensing, the Department should seek additional resources and authority to include

- Limited ability to order certain drugs for investigative purposes through a non-traceable, state credit card The Department should establish a system by which the Director of Enforcement has authority to approve purchases as necessary to secure additional evidence during the investigation of a complaint against a practitioner or pharmacy
- A modest increase in the investigative staff to add a person or persons with specialized knowledge and technical expertise related to the Internet and electronic commerce With an increasing number of investigative cases of billing fraud, prescribing and practicing via the Internet, and dispensing of medications based on such prescribing, the Department needs expertise within the Enforcement Department that it does not currently possess

3) The Department should facilitate and participate in a task force in Virginia comprised of state and federal law enforcement, prosecutors, and regulators to coordinate activities and responses to any problems or illegalities associated with Internet drug sales

4) To provide funding for the activities of the task force, the hiring of staff with specialized expertise and the costs of investigations and training, legislation should be introduced to allow the Department to receive a portion of any fines or assets seized through the course of prosecution of a case.

5) Legislation should be introduced to amend § 54.1-3303 of the Code of Virginia in order to further specify the meaning of a bona fide practitioner-patient relationship. That section of the Code currently provides:

*"The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship.*

*For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. Any practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than medicinally or for therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.*

*B. No prescription shall be filled which does not result from a bona fide practitioner-patient-pharmacist relationship. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription.*

*In order to determine whether a prescription which appears questionable to the pharmacist results from a bona fide practitioner-patient-pharmacist relationship, the pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed. The person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.*

*C. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine authorized to issue such prescription if the prescription complies with the requirements of this chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title, known as the "Drug Control Act," except that out-of-state prescriptions are not required to comply with the provisions of subsection A of § 32.1-87 and subsection C of § 54.1-3408 which establish a prescription blank format accommodating the Virginia Voluntary Formulary."*

Currently the law specifies the following characteristics of a bona fide practitioner-patient relationship:

- The practitioner prescribes and the pharmacist dispenses in good faith to his patient

- The prescription for a controlled substance is prescribed and dispensed for medicinal or therapeutic purpose
- The prescribing by the practitioner and dispensing by the pharmacist is within the course of his professional practice
- A valid prescription must be issued in the usual course of treatment or for authorized research.
- If there is some question about whether the prescription results from a bona fide practitioner-patient relationship, the pharmacist must contact the prescribing practitioner to verify the identifying information.
- A prescription from an out-of-state practitioner may be dispensed provided such prescription complies with the requirements of Chapter 33 (including a bona fide practitioner-patient relationship) and the Drug Control Act.

In addition to provisions of current law, legislation should be introduced to amend § 54.1-3303 to further specify that a bona fide practitioner-patient relationship shall mean that the practitioner must:

- Ensure that a medical or drug history is obtained or is readily available;
- Provide information to the patient about the benefits and risks of a drug being prescribed;
- Perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically. Except for medical emergencies, an examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription.
- Initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects.

6) § 54.1-3434.1 requires that non-resident pharmacies must be registered in Virginia in order to ship or deliver in any manner prescription drugs to a patient in the Commonwealth. Legislation should be introduced to amend the Code to provide that non-resident pharmacies shall not fill or dispense a prescription for a patient in Virginia which does not result from a bona fide practitioner-patient relationship as specified in § 54.1-3303.

7) The addition of language related to a bona fide practitioner-patient relationship in § 54.1-3303 would provide authorization to the Department to seek an injunction against practitioner or a pharmacy, unlicensed in Virginia, who prescribes or dispenses in violation of the law. § 54.1-111 provides that *"It shall be unlawful for any person, partnership, corporation or other entity to engage in any of the following acts... (8) violating any statute or regulation governing the practice of any profession or occupation regulated pursuant to this title... Any person who willfully engages in any unlawful act*

*enumerated in this section shall be guilty of a Class 1 misdemeanor. The third or any subsequent conviction for violating this section during a thirty-six month period shall constitute a Class 6 felony."*

8) The Code of Virginia should be amended to specify that "A practitioner who practices the healing arts on a patient in Virginia, including the prescribing of controlled substances, shall be required to abide by Chapter 29 of Title 54.1 of the Code of Virginia."



**VIRGINIA BOARD OF MEDICINE  
DEPARTMENT OF HEALTH PROFESSIONS**

**Study Report  
Study of the Sale of Prescription Drugs via the Internet  
Pursuant to HJR 759 (1999)**

***Background and Authority:***

House Joint Resolution 759, patroned by Delegate Jay O'Brien and passed by the 1999 Session of the General Assembly, requested the Virginia Board of Medicine, in consultation with the Board of Pharmacy, to examine the sale of prescription drugs in the Commonwealth over the Internet. Concerns expressed in the body of the resolution refer to the ability of consumers to purchase powerful drugs through the Internet without ever seeing a doctor, the fear that patients in Virginia could be harmed, and the possibly illegal prescribing practices of out-of-state physicians who are not licensed to practice in Virginia. The Board was required to complete its work in time to submit its findings and recommendations to the Governor and the 2000 Session of the General Assembly. (A copy of HJR 759 is attached to this report.)

***Study Task Force of the Virginia Board of Medicine***

The Board of Medicine appointed an Ad Hoc Committee on Internet Prescribing for the purpose of reviewing information on the sale of drugs over the Internet, receiving public comment, and bringing recommendations to the Board. For the purpose of this study, the Committee served as the Study Task Force for HJR 759. Draft reports and policy options were also presented to the Board of Pharmacy for their comment and recommendations.

Members of the Ad Hoc Committee on Internet Prescribing are as follows:

Harry C. Beaver, M.D.  
Joseph A. Leming, M.D.  
Cedric B. Rucker

Clarke Russ, M.D.  
Paul M. Spector, D.O.

The Executive Director of the Board of Medicine, Warren K. Koontz, M.D., the Executive Director of the Board of Pharmacy, Elizabeth Scott Russell, and the Regulatory Boards Administrator for the Department of Health Professions, Elaine J. Yeatts, provided staff and research assistance for the Committee.

## *Review of the Issues*

As is stated in an article in The New York Times, "in cyberspace, pharmacies are shipping pills across state lines without the requisite licenses. Doctors are writing prescriptions for people they have never met, a practice the American Medical Association says is unethical, but not illegal. And nobody - not Congress, nor the American Medical Association, or various federal and state agencies - knows quite how to stop it."<sup>1</sup> A statement from Dr. James Winn, Executive Director of the Federation of State Medical Boards has been widely quoted in the popular press as symbolic of the dilemma of Internet drug sales and the mess it has created. Dr. Winn's analogy was that "it is like trying to nail Jello to the wall." Even if an Internet site lists an address, it may not be the location of the pharmacy dispensing the drug, it may be a post office box or the office of a dispensing physician, who is also writing the "prescription". From the consumer or the regulator point of view, it can be very frustrating and sometimes even impossible to pin down the jurisdiction or jurisdictions in which the practice is occurring in order to file a complaint or take legal action.

### **A. Summary of the Problem:**

As noted in the body of the resolution, the Internet is transforming the practice of medicine by offering patients greater accessibility to information and treatment options. Along with that access has come the opportunity for practitioners and drug suppliers with questionable ethics to circumvent or even violate laws and profit from consumer demand for "lifestyle drugs." A summary of the problems with the current practices of many of the Internet drug sites is as follows:

- No physical examination of the patient to determine the appropriateness or need for a particular drug to treat a disease or condition and no valid doctor-patient relationship.
- No evaluation of patient to determine the existence of a condition that might preclude a patient from taking a particular drug or if the drug might have serious side effects.
- No follow-up with the patient or continuity of care.
- No prospective drug utilization review (DUR) by online pharmacy to detect possible drug interactions or counterindications; also, likelihood that a patient would not report use of a drug ordered online to a pharmacist conducting a DUR for another prescription so drug interaction would go undetected.
- No license to dispense drugs in a state; every pharmacy sending drugs to patients in Virginia is required to have a license as a non-resident pharmacy.
- No assurance of drug quality and efficacy or that the drug has been stored and packaged according to manufacturer's specifications; it may have been exposed to heat and light conditions that could lessen its effectiveness.
- No regulation of black market sales from foreign suppliers - both of drugs which are not approved for sale in the United States and those which are approved but may be obtained

---

<sup>1</sup> Stolberg, Sheryl Gay, "In Internet Drug Deals, a Regulation Dilemma, The New York Times on the Web, June 27, 1999.



without even the pretense of a prescription. Drugs sent from foreign sources may not be what the patient has ordered - they may be placebos or worse, adulterated in some manner.

- No assurance of security and confidentiality of patient-prescription information in cyberspace.
- Elusiveness of the sites - if investigated, they are quickly closed down and reopened under another name.

## **B. Research on the Internet sites offering prescription drugs:**

Given the large number of websites which currently offer prescription drugs for sale and the ever-changing and evolving nature of those sites, the purpose of the research on Internet sites was to present an overview of the scope and breadth of the issue. Illustrative of the pervasiveness and availability of drugs on the Internet, an inquiry through the search engine AltaVista found 545,820 Web pages for the impotence drug Viagra. Karen J. Bannan, a writer for Inter@active Week Online wrote that she found thousands of hits when she went on the Web seeking a site for Viagra, but it wasn't even necessary to search any of them because at the top of the page was a banner enticing her to buy Viagra online without the hassle and embarrassment of seeing a doctor. By clicking on the banner, she was able to purchase Viagra without a "prescription" by having a cyberconsultation with Online Physicians for Men, which consisted on a survey with all of the "correct" answers already checked. After a series of screens and giving a credit card number, she was able to purchase the drug.<sup>2</sup>

Numerous other reports have been made of persons who were not examined by a practitioner about the condition for which a drug is prescribed online and for whom the drug is clearly not indicated and could be potentially dangerous. Using a sting operation, the state of Kansas found a Internet company willing to sell Viagra to a 16-year old boy, even though the boy was truthful about his age. A quick check on the Internet will reveal any number of sites at which the viewer is invited to "improve your sex life" to get Viagra online - no doctor, no prescription, no problem. Some proprietors of online pharmacies contend that prescription drugs such as Viagra, Proprecia, Xenical, and Claritin are safe enough to prescribe without a physical examination - a view not shared by the Food and Drug Administration.

It is clear that any medical or pharmacy board would consider a patient's self-assessment, without any direct contact with the prescribing practitioner, to offer no legitimate basis for a bonafide prescription. In an article for USA Today, Dr. James Winn reported that a special Committee on Professional Conduct and Ethics of the Federation of State Medical Boards concluded that "it would be unprofessional to issue a prescription or a recommendation to a patient without conducting an evaluation adequate enough to establish a diagnosis."<sup>3</sup> The Committee is continuing to meet to draw up other policy recommendations and model guidelines for boards to address the situation. In the meantime, there is real concern that the public is at risk. While there have been no known deaths in Virginia attributable to a drug prescribed over the Internet, there have been at least

---

<sup>2</sup> Bannan, Karen J., "Want smokes, booze or drugs? Come to the Web", Inter@active Week Online, May 3, 1999.

<sup>3</sup> Rubin, Rita, "On-line Viagra worries medical boards," USA Today, January 21, 1999, page 1D.

two in Illinois associated with patients who had not seen a doctor but who had been able to order Viagra over the Internet.

The pharmaceutical company that produces Viagra has expressed concern about the proliferation of sites with dubious, if not illegal, prescribing and dispensing practices, and it has encouraged state boards to express their concerns to the Federal Trade Commission. In a letter to the Tennessee Board of Osteopathic Examination dated April 8, 1999 and copied to Richard L. Cleland of the FTC, the legal counsel for Pfizer wrote, "Pfizer recognizes that regulation of 'telemedicine' raises a variety of important and difficult questions. However, the activities that we are concerned about - the indiscriminate 'prescribing' of Rx legend drugs over the Internet without a legitimate underlying doctor-patient relationship - represent clear cases of inappropriate behavior that endangers the public health."<sup>4</sup>

Viagra is by no means the only drug available without a prescription from the patient's physician. Other drugs for which a prescription may be difficult or embarrassing to obtain are also being hawked - such as diet drugs Meridia, Xenical and phentermine, the antihistamine Claritin, and the hair loss drug Propecia. A man in Ohio recently purchased a potentially addictive drug from a Spanish pharmacy that he found on the Internet. Unable to get his local physician to prescribe the drug for his back pain, he sought out a foreign supplier that was willing to ship without a prescription.<sup>5</sup> Many foreign countries do not regulate drugs to the extent it is done in the United States.

Not only is one able to purchase drugs which are legally sold in the United States but illegal drugs are also accessible. While it is illegal for a company to market unapproved drugs, it is not illegal for an individual to order and accept those drugs, as long as the drug is for personal use. The Food and Drug Administration notes however, that those drugs in the mail can be seized by authorities and that it is illegal to receive controlled substances, such as narcotic drugs.

While there is an abundance of research into the practice of prescribing and dispensing prescription drugs via the Internet, both in the popular press and in medical journals such as the Journal of the American Medical Association, there is virtually nothing in the professional literature on any studies or reports of actual patient harm. Though there are anecdotal reports of patient harm, a study to quantify the problem would be virtually impossible because of the privacy sought and given for most Internet drug purchasers. In addition, most of the Internet sites require the buyer to sign an extensive waiver absolving the site and any of its contracted practitioners of any liability for damages or harm to the patient. While some attorneys have discounted the validity of such a waiver in the event a complaint was filed with a disciplinary board or a suit in a civil action, any patient who has suffered may believe that it is truly "buyer beware" and there is no recourse or

---

<sup>4</sup> Friede, Arnold, I., Senior Corporate Counsel for Pfizer, Inc., Letter to Thomas L. Ely, D.O., President, Tennessee Board of Osteopathic Examination, April 8, 1999.

<sup>5</sup> Napoli, Lisa, "Dispensing of Drugs on Internet Stir," The New York Times, April 6, 1999, Section F, page 6.

redress for his problem. In Virginia, there have been no reports of patient harm, but unless a complaint is filed with the Board by someone who ordered online, there would be no record kept.

### **C. Internet drug sales in Virginia**

The Department of Health Professions has recently received several complaints from citizens or reports from licensed bodies in other states about Internet sites and doctors ordering prescriptions without a physical examination.

One complaint came from a person who was solicited by e-mail to order Viagra. Touting "No prescription - No problem!", the sender gave a phone number to call. In checking the information, the investigator reached an automated answering service that offered three options: 1) order for Viagra; 2) a dating game; and 3) mailing services. The investigator left a fictitious name with a private phone number but never received a response. Using a fictitious e-mail address, he also attempted to contact the organization through their e-mail address (goplay.com) but never received any response. That case is now being closed for insufficient information.

The State of Wisconsin has reported a complaint against a pharmacy in Roanoke for operating from an unlicensed location and for dispensing medication without a valid prescription to a person in that state. The complaint also is filed against the doctor (last name only is given) who gave the online order and against the pharmacist who filled the order. The Wisconsin Medical Examining Board takes the position that a valid physician-patient relationship cannot be formed by merely reviewing a questionnaire from an unknown patient. Therefore, it is unprofessional conduct for the doctor to issue the prescription and for the pharmacist to fill such a prescription.

Originally investigated by the Kansas Board of the Healing Arts, there is also a complaint about an online pharmacy site with orders sent to a P.O. box in Midlothian, VA. The site is tied to a doctor being indicted in Ohio on 64 counts of selling dangerous drugs and drug fraud. The P. O. box is registered in his name and that of a partner, who has a business registered with the State Corporation Commission; however, Chesterfield County reports that they have no business license in the county. The Web site (Cybrxpress) through which the drugs may be ordered is still fully operational, although they now say that they are unable to ship drugs to Kansas or Ohio, which have shut down the operation in their states. A check of their Website shows which drugs are available by merely entering identifying information (name, address, etc.) and a credit card number. To order a popular diet drug, the only "medical" history taken was height and weight. Investigators for the Department of Health Professions have been unable to determine who picks up the orders from the box in Midlothian, who supplies the drugs, or from what location the drugs are actually being dispensed. While there may be evidence of unprofessional conduct, it does not appear that any laws have been broken; so even though the State Police have been informed, they are not pursuing any investigation.

### **D. Examination of laws and regulation in Virginia related to Internet drug sales:**

One of the key issues related to prescribing over the Internet is the question of whether a bona fide physician-patient relationship can exist when the practitioner writes a prescription to a patient whom he has "examined" via a questionnaire completed online. While there are no specific laws or regulations governing or defining such a relationship, the Board of Medicine has adopted a guidance document that it has provided to all licensees. Since the Board frequently gets questions on the issue, it reprinted the following guidelines in the August 1999 Board Briefs:

**Virginia law does not directly address this issue, except that the § 54.1-3303 of the Code of Virginia requires that a prescriber have a bona fide practitioner/patient relationship with any person for whom he or she prescribes controlled substances. Therefore, to provide guidance to practitioners, the Board, at its June 1996 meeting, revised its guidelines, which were first adopted in 1985, regarding a bona fide physician/patient relationship. (These guidelines do not carry the force of law and regulation, but are intended as guidelines only.)**

### Documentation

The presence of a medical record is an essential part of a valid practitioner/patient relationship. The medical record shall contain the following:

1. An appropriate history and physical examination (if pain is present and controlled substances prescribed, the assessment of pain, substance abuse history, and co-existing diseases or conditions should be recorded).
2. Diagnostic tests when indicated.
3. A working diagnosis.
4. Treatment plan.
5. Documentation by date of all prescriptions written to include name of medication, strength, dosage, quantity and number of refills. The prescription should be in the format required by law.

Under these guidelines, completion of a questionnaire via the Internet absent any other patient-physician relationship would not be sufficient to establish a valid practitioner/patient relationship. Therefore, a Virginia physician writing prescriptions based on such a questionnaire would possibly be subject to disciplinary action by the Board of Medicine. Likewise, the filling of such a prescription by a pharmacist licensed in Virginia would subject that licensee to disciplinary action by the Board of Pharmacy for a violation of the Drug Control Act.

In addition, an on-line pharmacy that ships drugs into Virginia but is not registered with the Board of Pharmacy would be in violation of Virginia law. § 54.1-3434.1 of the *Code of Virginia* requires any pharmacy that ships, mails, or delivers in any manner scheduled drugs or devices into the Commonwealth be registered as a nonresident pharmacy. The Code further specifies that the nonresident pharmacy 1) disclose the location, names and titles of principal corporate officers and all pharmacists who are dispensing prescription drugs; 2) comply with the laws and regulations of the state in which it resides and be inspected and validly licensed in that state; and 3) maintain records of prescriptions dispensed to patients in Virginia in a form readily retrievable so that information can be provided to an agent of the Commonwealth within seven days. The law further provides that the nonresident pharmacy must provide a toll-free number

and a pharmacist with access to patient records during its regular hours of business for a minimum of forty hours per week.

While there are several on-line pharmacies currently registered in the Commonwealth, it is likely that many are not. There are two problems with enforcement of laws related to nonresident pharmacies and dispensing via the Internet: 1) If an unregistered pharmacy provides prescription drugs to patients in Virginia, the Commonwealth could seek injunctive action to prohibit it from doing business in the state. Such an action would necessitate investigative and legal resources that might be expended on a site which could be easily shut down and reopened with another address. (Other states have had that experience.); and 2) If a nonresident pharmacy that is registered in Virginia provides prescriptions pursuant to a cyberspace "examination", the determination of whether any laws have been broken and possible disciplinary actions would be made by the resident state.

#### Regulation of the Practice of Medicine across State Lines - Issue of Telemedicine

The study resolution states that it is illegal for doctors to prescribe drugs for patients in a state where they are not licensed to practice, that assumes that it is illegal for doctors to practice on patients in Virginia if they are not licensed in Virginia - an assumption which has not been tested and which raises the issue of telemedicine or the practice of medicine across state lines. The Federation of State Medical Boards states that "the practice of medicine across state lines is defined to include any medical act that occurs when the patient is physically located within the state and the physician is located outside the state. Any contact that results in a written or documented medical opinion and that affects the diagnosis or treatment of a patient constitutes the practice of medicine."<sup>6</sup> To address the issue of telemedicine, the Federation has adopted a model act for the regulation of telemedicine or medicine by other means across state lines, which it has recommended to state boards. The Federation model would establish a limited or special license to be obtained in any state in which the physician intends to practice by electronic or other means; such a license could be expedited for a physician who holds a valid, unrestricted license in any state but would not allow the physician to physically practice medicine within another state without full licensure. The physician holding a special license would be subject to the medical practice act of that state, would be subject to disciplinary action by that state, and would be required to maintain patient medical records according to the requirements of the state in which the patient resides.

Realizing that the issue of practice across state lines needed resolution, Virginia Board of Medicine appointed a subcommittee to look at telemedicine and recommend any statutory or regulatory changes needed to address the question of whether licensure is required. After its review of the issue and the actions taken by a number of other states, the Board adopted a policy statement that in its view full licensure in Virginia is required for any physician practices on a patient in the Commonwealth. § 54.1-2900 of the Code of Virginia specifies that the practice of medicine or osteopathic medicine means "the prevention , diagnosis and treatment of human physical or mental

---

<sup>6</sup> "Model Act to Regulate the Practice of Medicine Across State Lines", adopted by the governing body of the Federation of State Medical Boards in April 1996.

ailments, conditions, diseases, pain or infirmities by any means or method." In the opinion of board members, the means and methods would be inclusive of the Internet. To ensure that the law articulates that policy, the Board recommended a statutory change to § 54.1-2903 to clearly state that any person, regardless of location, shall be regarded as practicing the healing arts who actually engages in such practice on an individual located in this Commonwealth, who opens an office for such purpose, or who advertises or announces to the public in any manner a readiness to practice. While that is the position of the Board, the issue has not fully resolved on legal grounds.

#### **E. Examination of actions taken by other states to address the issue of Internet drug sales:**

The resolution notes that laws and regulations were written before the widespread use of the Internet, and in fact Internet prescribing has gotten way out ahead of the regulators whose role it is to protect the efficacy and safety of drugs being sold to the public. In a typical scenario, a drug would be approved for use by the Food and Drug Administration, prescribed by a doctor licensed in a state, and dispensed by a pharmacy also licensed by a state pharmacy board. But now it is possible to purchase drugs from sources that are circumventing or violating the laws and regulations set in place for public protection without the oversight of any of the regulatory bodies.

Therefore, the implication of the study resolution is that Virginia should examine its laws and regulations to determine whether changes are warranted and feasible to address prescribing patterns not contemplated when existing statutes were being written. To provide a basis for consideration of any legislative proposal, the Board has examined actions taken other states in the United States to address the problem of Internet drug sales.

The dilemma faced by state boards in trying to deal with Internet prescribing is that even if jurisdiction can be established, enforcement is another issue entirely. If a prescription is ordered by a physician licensed in Virginia, jurisdiction for the Virginia Board of Medicine is clear and enforceability is feasible. If, however, a patient in Virginia is harmed by a drug following a cyber-consultation (questionnaire) over the Internet and "prescription" from a doctor in another jurisdiction, to whom does the patient seek redress. There is a jurisdictional question as to whether the physician is actually practicing in this state or in his home state. In states that do have clear laws that require licensure for persons who are rendering treatment which includes the transmission of patient data by electronic means, it is still almost impossible to investigate and prosecute those persons outside their jurisdictional borders without the assistance of the federal government.

The state of Kansas has probably been the most aggressive in seeking court orders to prevent Internet pharmacies not licensed in the state from doing business there and taking actions against doctors who are either not licensed in Kansas or who are charged with unprofessional conduct. Petitions to the court seek a permanent injunction against a group of companies and individuals selling prescription drugs over the Internet. They have successfully received temporary injunctions against several defendants, and other companies have chosen to discontinue selling drugs to persons in the state. They have also identified six doctors not properly licensed to practice in Kansas who were providing prescriptions to persons in Kansas without ever seeing the patients; four people

doing business under fictitious names, and three out-of-state pharmacies dispensing drugs in Kansas without being properly registered.

While acknowledging that most states lack the resources to seek injunctions against the many organizations illegally selling or physicians prescribing drugs over the Internet, the Kansas State Board of Healing Arts has actively filed petitions in state court to try and stop the activities of a number of such organizations or individuals located in other states. Suits have been filed against companies and physicians based on prescribing of drugs without a valid physician-patient relationship and on not providing a quality of care.

Since the problem of Internet prescribing is prevalent through the United States, it is unknown how many states are currently investigating or disciplining doctors for prescribing online or pharmacies for distributing in a state without a license. A sampling of actions being taken in other states is as follows:

#### Nevada

The Nevada State Board of Medical Examiners has interpreted its laws to mean that it is considered malpractice for a physician to prescribe medication, such as Viagra, for a new patient without first conducting such physical examination as may be necessary to determine whether the patient has a condition for which a given medication is appropriate. Conducting an "examination" via a questionnaire filled out on the Internet would not satisfy that interpretation. The Nevada Board of Pharmacy has proposed regulation to require that a Nevada pharmacist verify that a bona fide physician-patient relationship exists before filling a prescription for an out-of-state patient by an out-of-state doctor.

#### Colorado

The Colorado Board of Medical Examiners disciplined a Colorado physician, whose name appeared on drug packaging received by a patient in California, for his role in allowing a patient to obtain a prescription without an examination and without follow-up care. The position of that board and of the Board of Pharmacy is that an Internet exchange does not qualify as an initial medical examination and no legitimate patient-physician relationship has been established.

#### Massachusetts

The Board of Registration in Pharmacy has urged the FTC to halt the sale of drugs over the Internet pending an investigation to address the serious and imminent patient risk and the installation of adequate safeguards and medical practices.

#### Illinois

A physician had his license suspended by The Illinois Medical Disciplinary Board for prescribing Viagra over the Internet while acting as a consultant for a pharmacy based in Texas.

#### Iowa

Officials are investigating several Internet sites that offer Viagra and other drugs after only a tertiary, written examination.

#### Wisconsin

The Medical Examining Board regards the prescribing on a drug via the Internet without examining the patient to be clearly unprofessional conduct and has entered an order suspending the license of one Wisconsin physician who has been engaged in the practice. The Board is investigating two organizations, both located outside the state, which are soliciting orders for Viagra, but is concerned about jurisdiction and the effort to seek injunctions.

#### Washington

The Washington Medical Quality Assurance Commission has cited one physician for unprofessional conduct for prescribing to patient he had not physically examined. He was an orthopedic surgeon who signed up to review electronically submitted questionnaires and prescribe Viagra on the Internet. The doctor told investigators that he never signed a prescription for Viagra - which was technically true. The dispensing pharmacy kept a copy of his medical license on file, and according to the contract, orders for a requested drug are assumed approved unless otherwise notified by the physician.

#### Maryland

The Maryland Board of Physician Quality Assurance published in its March, 1999 newsletter a warning that the doctors licensed in that state could expect their on-line prescribing to be subject to peer review and that any doctor, who is not licensed in Maryland and who is providing consultation or prescribing on-line for a patient in the state, could be subject to a \$50,000 fine for practicing without a license.

#### California

The Medical Board of California is investigating a number of cases of Internet prescribing. Its position is that a doctor in California may not approve an order for a prescription drug without ever meeting the patient, even if the person completes a questionnaire online. That would also apply to an out-of-state doctor prescribing a drug for a patient in California.

#### Wyoming

The Board of Medicine took action against one site registered in Cheyenne; they were unable to associate a Wyoming doctor with the site but are prepared to seek an injunction against anyone who is practicing medicine in the state without a license. The Wyoming Web site now lists an address in Nevada under the name of a person in Las Vegas who is not a health care professional.

#### Ohio

The Ohio State Medical Board has proposed rules that would regulate the prescribing of drugs not seen by the physician. With some exceptions, such as on-call situations, it would prohibit a physician from prescribing, dispensing or otherwise providing a controlled substance to a person who the physician has never personally, physically examined and diagnosed. Likewise, the Ohio State Board of Pharmacy has adopted rules for the sale of drugs on-line, which require licensure or registration as a pharmacy and disclosure of such things as a list of all states in which the site is licensed and information about responsible parties. Ohio has also actively pursued investigation and prosecution of doctors, pharmacists and pharmacies engaged in unethical or illegal online prescribing and dispensing practices.

#### Arizona

The Arizona Medical Board is conducting an investigation of at least two Web sites promoting online drugs with consultations by a physician licensed in the state. Once investigators began their



inquiry, the doctor's office telephone was disconnected, even though his Web site remains operational.

#### District of Columbia

The D.C. Board of Medicine has taken the position that prescriptions written without a complete history and physical do not meet the accepted standard of care and are potentially hazardous to public health and safety.

#### New York

The State Health Department, which licenses doctors, has received complaints but has concluded that it lacks the authority to take action against out-of-state doctors. The Office of Professional Discipline, which is required to investigate people practicing medicine in N.Y. without a license, is considering whether prescribing drugs to a New Yorker from out of state qualifies.

### **F. Examination of activity by federal agencies and bodies.**

Since Internet drug sales is a national, indeed an international, enterprise, a number of federal agencies are actively examining the issue and the potential risks for harm and illegal activity, but no agency has explicit authority to take control of the situation. The Federal Food and Drug Administration (FDA), which regulates drug manufacturing, the Drug Enforcement Administration (DEA), which control the sale of narcotics, and the Federal Trade Commission (FTC), which regulates deceptive advertising and unfair trade practices - all play a role. All have been involved in discussions and studies directed at the issues outlined by HJR 759, but the federal agencies do not license or discipline the practitioners and pharmacies involved in possible malpractice or unethical practices.

Many states, however, have urged the FTC to become more involved in this issue. In a letter from the Drug Control Division of the Connecticut Department of Consumer Protection, the Director, William P. Ward urged intervention by the FTC against a growing number of Internet firms that distribute drugs in a manner he considers to be a direct threat to the health and safety of the public. In his letter, Mr. Ward states that "without hesitation that the newly emerging practice of Internet prescribing and subsequent distribution of legend drugs without a bonafide physician-patient relationship, represents one of the most potentially dangerous health related situations our citizens have faced ... the ability of these distributors to change business names and holdings and move and operate between states makes appropriate enforcement actions virtually impossible at the state level." In his estimation and that of many other state regulators, this is a national problem requiring a national effort to be effective.

In response, the FTC is considering a federal rule which would at least require all online pharmacy sites to disclose information about the business selling the drugs and provide identifying information about the doctors writing the prescriptions. That information would be helpful to consumers and regulators, who often find it difficult, if not impossible, to determine the actual location and licensure of the physician and dispensing pharmacy. But jurisdictional issues continue to plague the efforts to address a growing national problem. Despite pressures applied by the

manufacturer of Viagra and state boards to take action, the Federal Trade Commission says it can only go after those Internet sites that make false claims about their goods or services.

Many other federal and state agencies, attorneys general, legislative bodies are seeking to address the problem. In March, the House of Representatives Commerce Committee commissioned the General Accounting Office to conduct a study on the scope of prescription sales online and to find out which federal and state agencies are regulating the industry. Rep. Tom Bliley of Virginia also asked the GAO to evaluate whether NABP's verification program VIPPS is an adequate self-regulatory vehicle.<sup>7</sup> Several congressmen called upon Congress to hold hearings on the issue. Rep. Ron Klink of Pennsylvania, a member of the Commerce Committee, is one who is calling for federal action. In a U. S. News and World Report article he said, "There are hundreds of these sites, thousands internationally, and do state boards have people who can monitor them? [Internet drug marketing] has every kind of potential for every kind of harm ever done to anyone through drug misuse...And it's amazing to me how few people have grasped this."<sup>8</sup>

In September, Rep. Klink introduced legislation to the U. S. House of Representatives to require each website to link to a web page containing the following information: the name, address and phone number of the person or business responsible for the site; the name of the pharmacist or pharmacists and the state or states in which they are authorized to dispense prescription drugs; the name of the individual who provides medical consultation through the site, the health profession for which they are licensed and the state or states in which they are authorized to provide such consultation. If passed, the legislation would not preempt state laws where an enforceable, no less stringent law on Internet prescribing exists.

The Food and Drug Administration (FDA), which has the responsibility for approval of drugs for sale in the United States, acknowledges that the sale of illegal or unapproved products over the Internet is of particular concern. Recently, the agency has taken several steps to address the situations; it has re-deployed several staff members to investigate fraudulent practices online. In addition, the agency believes that prescribing without personal interaction is a significant problem, but contends that it is better handled by state licensing boards. Without a valid physician-patient relationship and the appropriate oversight role of a pharmacy, the usual safeguards that exist with prescription drugs have been by-passed. The situation is tantamount to putting all prescription drugs on a shelf and allowing customers to come in and help themselves.

In February, the FDA invited representatives of the Federation of State Medical Boards, the National Association of Boards of Pharmacy, the American Medical Association, and Pfizer, Inc. to a meeting to discuss online prescribing and the sale of prescription medications. The deputy commissioner admitted that the problem is "too big for any one organization to handle comprehensively, and the FDA doesn't have the staff, the resources, or even the authority to deal

---

<sup>7</sup> Ukens, Carol, "Internet Pharmacies," Drug Topics, May 17, 1999, page 69.

<sup>8</sup> Fischman, Joshua, "Drug bazaar," U. S. News and World Report, June 21, 1999, page 62.

with it."<sup>9</sup> At that meeting, John O'Bannon, III, a Richmond physician reported that the Council on Ethical and Judicial Affairs of the American Medical Association is planning to update their statement of Internet prescribing. At its convention in June, the AMA voted to develop model state legislation to limit Internet prescribing and to encourage states to discipline doctors who participate in cyberconsultations for that purpose.

The problem lies in the nature of the Internet - even if states choose to expend valuable resources pursuing cases involving out-of-state doctors prescribing for in-state patients, it can be difficult locating the physician in cyberspace. One of the big problems is that many of the Internet sites and collaborating doctors are located outside the United States. Clearly, seeking an injunction or getting a "cease and desist" order against shady practitioners doing business on-line from foreign countries would be an exercise in futility. The World Health Organization acknowledges that there is a problem for consumers trying to distinguish between the reputable and disreputable online pharmacies, but WHO supports the accessibility of drugs and medical information worldwide.<sup>10</sup> WHO notes that international action is virtually impossible because of the different prescription standards in each country but has urged its member countries to apply their particular laws to Internet prescribing and to cooperate in stopping illegal sales across national boundaries.

#### **G. Examination of activity by professional associations and organizations.**

##### **Establishment of a national verification system for Internet pharmacies by NABP**

The National Association of Boards of Pharmacy (NABP) recently announced the new program that will verify the licensure of Internet pharmacy practice sites and inform the members of the public of those that hold licensure in good standing in their state. VIPPS was founded because of growing concerns about the mushrooming of such sites and the number of states embroiled in complaints tied to Internet pharmacy practice sites. NABP has stated, "While a growing number of legitimate Web sites are coming on-line to dispense prescription and over-the-counter medications and provide patient care, the medium has attracted a visible band of unlicensed and unscrupulous entrepreneurs who are interested only in a quick profit, often at the patient's expense."<sup>11</sup>

With the assistance of representatives from state boards of pharmacy, government agencies, professional pharmacy organizations, and Internet pharmacy practice sites, NABP has set the criteria for becoming a "qualified" VIPPS pharmacy. Those criteria include such things as:

- Verification of licensure or registration to operate a pharmacy in all applicable jurisdictions and verification of licensure or registration to practice pharmacy for all persons affiliated with the site;

---

<sup>9</sup> Marwick, Charles, "Several Groups Attempting Regulation of Internet Rx," Journal of the American Medical Association, March 17, 1999, Vol. 281, No. 11, page 975.

<sup>10</sup> Herman, Robin, "Drugstore on the Net," The Washington Post, May 4, 1999, page 15.

<sup>11</sup> News release from the National Association of Boards of Pharmacy, February 9, 1999.

- Agreement to comply with all federal and state statutes and regulations, including rules on generic substitutions and prohibition against unauthorized therapeutic substitutions.
- Maintenance and enforcement of procedures to ensure prescription integrity, authenticity and patient confidentiality; maintenance of patient medication profiles in readily accessible format; conduct of a prospective drug use review prior to dispensing.
- Maintenance and enforcement of procedure for reporting drug reactions or prescription errors and for communication of information to the patient.
- Shipment of drugs in a secure and traceable manner; compliance with USP standards for storage and shipment.

Compliance with the criteria will entitle the Internet pharmacy to enter into a licensing agreement with NABP to display the VIPPS seal on the pharmacy site. At the time this report is being written, applications for VIPPS verification are being accepted, and the first listing of VIPPS-approved Internet pharmacies is expected sometime in August, 1999. NABP intends to provide free access for the public to the VIPPS verification system.

Just because a pharmacy offers drugs online, there should not be a presumption that corners have been cut, laws violated, or ethics shaded. Many legitimate companies fill prescription orders online and do so with full licensure in every state in which their customers live and with prescriptions submitted electronically from their personal physicians. A check of online pharmacies listed on the Web will give the browser an almost endless selection, including commercial giants such as Eckerd, Rite Aid and CVS Pharmacies. In response to an inquiry made to Drugstore.com about their licensure status in the Commonwealth of Virginia, we were given the information about their license as a nonresident pharmacy and that of their prescription partner RxAmerica. In addition, we were advised and encouraged to utilize the Verified Internet Pharmacy Practice Sites (VIPPS) program as a means of verifying the licensure status of any online pharmacy. With the introduction of VIPPS, it would appear that consumers wanting assurance that their online pharmacy is meeting certain standards and abiding by applicable laws and regulations will have a place to go to verify that fact.

On July 30, 1999, the National Association of Boards of Pharmacy (NABP) presented testimony before the Subcommittee on Oversight and Investigations, Committee on Commerce, U. S. House of Representatives. Carmen Catizone, Executive Director of NABP reported that they had identified approximately 150 pharmacy-based sites and about the same number of prescribing-based sites currently available to the public. NABP drew a distinction between the two as follows:

Pharmacy-based sites

Pharmacy-based sites are associated with an identifiable pharmacy licensed or registered by a state board of pharmacy; they do not offer prescribing services but do accept prescriptions written by a prescriber for his or her patient. Those sites can be effectively controlled by the state boards empowered to regulate the practice of pharmacy and medicine. Initiatives to circumvent that authority in favor of assigning responsibility to a federal agency are, in the opinion of NABP, unwarranted and unconstitutional.

State boards already have the authority to regulate and inspect online pharmacies that dispense within the state under existing laws and regulations, and 40 jurisdictions require the licensure of out-of-state pharmacies that dispense drugs within the state. States have begun to take action against inappropriate or illegal prescribing and distribution of prescription medication. Some have been successful in obtaining restraining orders to stop the operations of an out-of-state pharmacy. With information sent to the NABP National Disciplinary Clearinghouse and Database, all states where a licensee holds a license will be notified if there is disciplinary action by a state. In the effort to stop illegal and unethical Internet prescribing, it is important that states have the ability to discipline a licensee based on the actions of another state.

### Prescribing-based sites

Prescribing-based sites are outlets for medications utilizing a cyberspace consultation or questionnaire. With regard to the later, the position of the NABP is that the practice of making prescription medications available to consumers without a legitimate patient-prescriber relationship, and thus, without a valid prescription order, is dangerous. Further, it is the position of the NABP that "pharmacists and pharmacies dispensing prescription medications pursuant to an invalid patient-prescriber relationship are acting illegally and are subject to disciplinary action by the appropriate state board of pharmacy."<sup>12</sup>

The prescribing sites are often organized into an arrangement of pages designed for consumer accessibility and for the appearance of legitimacy. NABP found that "The system resembles fraudulent pyramid operations where a primary operation is often supported by a varying number of referral or access portals. To the unknowing consumer, the referral or relocater pages appear to be independent and individual sites. In reality, however, such sites are linked and serve only as a means for the primary site to forward sales into its distribution operations."<sup>13</sup>

In conclusion, the National Association of Boards of Pharmacy testified that existing laws and regulations are sufficient to effectively regulate and monitor U.S.-based online prescribing and pharmacy sites. State boards will need to cooperate with each other and federal agencies and could be assisted by the provision of money to that effort. NABP acknowledges that foreign-based sites may be outside the jurisdiction of state boards, and that federal legislation and efforts to curb their activities are necessary.

### **Testimony of the American Medical Association**

Also at the hearing on July 30, 1999 before the subcommittee of the Committee on Commerce, Dr. Herman Abromowitz, representing the American Medical Association, presented testimony - the

---

<sup>12</sup> Catizone, Carmen A., "Testimony of the National Association of Boards of Pharmacy, U. S. House of Representatives, July 30, 1999, page 3.

<sup>13</sup> Catizone, Carmen A., "Testimony of the National Association of Boards of Pharmacy, U. S. House of Representatives, July 30, 1999, page 3.

subject of which was the benefits and risks of online pharmacies. In his statement, Dr. Abromowitz stated that "The AMA...is gravely concerned about current misuse of the Internet for prescribing purposes. The Food, Drug and Cosmetic Act requires physician involvement in making prescription drugs available. This requirement is part of the safety analysis conducted by the Food and Drug Administration (FDA) prior to the approval of any new drug...Today, our testimony addresses the concerns that must be concerns in connection with misuse of the Internet for prescribing and dispensing prescription drugs. In summary, we believe that before prescribing a medication, a physician must:

- Ensure that a medical history is obtained or readily available;
- Provide information to the patient about the benefits and risks of the prescribed medication;
- Generally perform an examination of the patient to determine a specific diagnosis and whether there actually is a medical problem; and
- Initiate additional interventions and follow-up care, if necessary, especially when the drug in question (e.g., Viagra) may have serious side effects.

These are the requirements that a physician must meet in a setting traditionally used to visit with and treat patients. Treating patients via the Internet is no different, and thus these same requirements must also be met in this context. Web sites that offer a prescription solely on the basis of a simple questionnaire are not sufficient."

#### Problem with Internet Prescribing

Internet prescribing has become more prevalent partially because marketing strategies and buying habits have changed, but also because of the advent of so-called "lifestyle drugs" or those that treat people who are over-weight, balding or have problems with erectile dysfunction. Often the information requested on a brief questionnaire is far from sufficient to warrant writing a prescription. In addition, there is no mechanism to ensure that the consumer has answered the questionnaire accurately or truthfully. Likewise, some terms used in the questionnaire and the liability waiver are likely to be beyond the knowledge of the average consumer. The information provided to the consumer is also non-existent or insufficient in its instructions and warnings of interactions or side effects. Often there is no attempt to warn consumers of potential risks of certain drugs.

The AMA is very concerned that prescription drugs are being ordered without a physical examination, which would serve to evaluate any potential underlying cause for a patient's dysfunction or disease and would offer a basis for the most appropriate intervention. For the most part, Internet prescribing provides no medical assessment or follow-up to determine whether the drug has been effective or if there have been side effects to taking it. To address the concerns about Internet prescribing and avoid some of the problems identified, the AMA recommends that the following minimum standards of care be met:

- There generally must be an examination of the patient to determine a specific diagnosis and whether there actually is a medical problem.

- There must be a dialogue between the physician and patient to discuss treatment alternatives and determine the best course of treatment;
- The physician must establish or have ready access to a reliable medical history;
- The physician must provide information to the patient about the benefits and risks of prescribed medication; and
- The physician must follow-up with the patient to assess the therapeutic outcome.

#### Legitimate Uses for Internet Prescribing and Dispensing

In the process of addressing the problems with Internet prescribing and dispensing, it is important to note that there are some important legitimate uses and a number of appropriately licensed pharmacy practice sites dispensing pursuant to a valid prescription. While the consumer needs to be protected from the inappropriate and illegitimate sites, care must be taken to protect the availability and increasing prevalence of electronic prescribing and dispensing. Some examples of legitimate Internet prescribing would be: (1) computer order entry and on-line transmission of prescriptions which could reduce errors from handwritten prescriptions (under consideration by DEA); (2) ordering of refills, either patient to pharmacy or physician to pharmacy; or (3) electronic consults between physician and patient where the outcome is an ordered prescription. The latter would be a situation in which the physician does not see the patient at the time the drug is ordered, but the patient has recently been under the physician's care and the physician has the his or her medical history and an on-going relationship with the patient.

#### Course of Action

In its testimony before Congress, the AMA agreed that it would continue its involvement and study of the issues, develop principles for appropriate use of the Internet in prescribing medications based on the standards noted above, and work with state medical societies in urging medical licensing boards to investigate and, if necessary, take action against physicians who fail to meet appropriate standards of care when issuing prescriptions over the Internet. The AMA believes that there is a role for state and federal authorities in closing down web sites of companies that are illegally promoting and distributing drugs and disciplining physicians who inappropriately prescribe on such sites. It will also work with the Federation of State Medical Boards to develop and endorse model state legislation to establish appropriate limitations and safeguards for Internet prescribing.

In summary, the AMA "believes the states and their medical boards must carefully develop standards that continue to ensure such good medical practice when the Internet is used to prescribe and/or dispense prescription drugs, without impeding legitimate use of the Internet. State medical boards must also initiate investigative and enforcement efforts of physicians who violate these standards...Finally, the federal government should coordinate with the states to monitor and facilitate enforcement activity with respect to illegal, domestic-based Internet prescribing activity."<sup>14</sup>

---

<sup>14</sup> Abromowitz, Herman I., "Statement of the American Medical Association before the Subcommittee on Oversight and Investigations Committee on Commerce, U. S. House of Representatives, July 30, 1999.

## ***Policy Recommendations of the Board of Medicine in Response to HJR 759***

1) In addition to other initiatives, the Department of Health Professions should do the following:

- Continue to monitor the development of Internet drug sales and the problem of Internet prescribing.
- Continue to respond to complaints related to Internet prescribing and dispensing as they are received and investigate cases in the context of the Enforcement Division plan of the Department.
- Monitor activities and policies established by federal agencies, the introduction and content of federal legislation, and the outcome of injunctive actions taken by other states.

2) In order to effectively and thoroughly pursue investigations of complaints surrounding Internet prescribing and dispensing, the Department should seek additional resources and authority to include:

- Limited ability to order certain drugs for investigative purposes through a non-traceable, state credit card. The Department should establish a system by which the Director of Enforcement has authority to approve purchases as necessary to secure additional evidence during the investigation of a complaint against a practitioner or pharmacy.
- A modest increase in the investigative staff to add a person or persons with specialized knowledge and technical expertise related to the Internet and electronic commerce. With an increasing number of investigative cases of billing fraud, prescribing and practicing via the Internet, and dispensing of medications based on such prescribing, the Department needs expertise within the Enforcement Department that it does not currently possess.

3) The Department should facilitate and participate in a task force in Virginia comprised of state and federal law enforcement, prosecutors, and regulators to coordinate activities and responses to any problems or illegalities associated with Internet drug sales.

4) To provide funding for the activities of the task force, the hiring of staff with specialized expertise and the costs of investigations and training, legislation should be introduced to allow the Department to receive a portion of any fines or assets seized through the course of prosecution of a case.

5) Legislation should be introduced to amend § 54.1-3303 of the Code of Virginia in order to further specify the meaning of a bona fide practitioner-patient relationship. That section of the Code currently provides:



*"The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship.*

*For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. Any practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than medically or for therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.*

*B. No prescription shall be filled which does not result from a bona fide practitioner-patient-pharmacist relationship. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription.*

*In order to determine whether a prescription which appears questionable to the pharmacist results from a bona fide practitioner-patient-pharmacist relationship, the pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed. The person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.*

*C. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine authorized to issue such prescription if the prescription complies with the requirements of this chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title, known as the "Drug Control Act," except that out-of-state prescriptions are not required to comply with the provisions of subsection A of § 32.1-87 and subsection C of § 54.1-3408 which establish a prescription blank format accommodating the Virginia Voluntary Formulary."*

Currently the law specifies the following characteristics of a bona fide practitioner-patient relationship:

- The practitioner prescribes and the pharmacist dispenses in good faith to his patient
- The prescription for a controlled substance is prescribed and dispensed for medicinal or therapeutic purpose
- The prescribing by the practitioner and dispensing by the pharmacist is within the course of his professional practice
- A valid prescription must be issued in the usual course of treatment or for authorized research.
- If there is some question about whether the prescription results from a bona fide practitioner-patient relationship, the pharmacist must contact the prescribing practitioner to verify the identifying information.
- A prescription from an out-of-state practitioner may be dispensed provided such prescription complies with the requirements of Chapter 33 (including a bona fide practitioner-patient relationship) and the Drug Control Act.

In addition to provisions of current law, legislation should be introduced to amend § 54.1-3303 to further specify that a bona fide practitioner-patient relationship shall mean that the practitioner must:

- Ensure that a medical or drug history is obtained or is readily available;
- Provide information to the patient about the benefits and risks of a drug being prescribed;
- Perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically. Except for medical emergencies, an examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription.
- Initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects.

6) § 54.1-3434.1 requires that non-resident pharmacies must be registered in Virginia in order to ship or deliver in any manner prescription drugs to a patient in the Commonwealth. Legislation should be introduced to amend the Code to provide that non-resident pharmacies shall not fill or dispense a prescription for a patient in Virginia which does not result from a bona fide practitioner-patient relationship as specified in § 54.1-3303.

7) The addition of language related to a bona fide practitioner-patient relationship in § 54.1-3303 would provide authorization to the Department to seek an injunction against practitioner or a pharmacy, unlicensed in Virginia, who prescribes or dispenses in violation of the law. *§ 54.1-111 provides that "It shall be unlawful for any person, partnership, corporation or other entity to engage in any of the following acts...(8) violating any statute or regulation governing the practice of any profession or occupation regulated pursuant to this title...Any person who willfully engages in any unlawful act enumerated in this section shall be guilty of a Class 1 misdemeanor. The third or any subsequent conviction for violating this section during a thirty-six month period shall constitute a Class 6 felony."*

8) The Code of Virginia should be amended to specify that "A practitioner who practices the healing arts on a patient in Virginia, including the prescribing of controlled substances, shall be required to abide by Chapter 29 of Title 54.1 of the Code of Virginia."

# GENERAL ASSEMBLY OF VIRGINIA -- 1999 SESSION

## HOUSE JOINT RESOLUTION NO. 759

*Requesting the Board of Medicine, in consultation with the Board of Pharmacy, to study the sale of prescription drugs in the Commonwealth via the Internet.*

Agreed to by the House of Delegates, February 9, 1999

Agreed to by the Senate, February 23, 1999

WHEREAS, among the many huge inroads the Internet is making in medicine, patients can communicate with their doctors through electronic mail, order prescription refills through online pharmacies, and access medical journals 24 hours a day, 7 days a week; and

WHEREAS, despite these and other enhancements to patients' ability to access health care professionals and medical information, the Internet has also made it possible for American consumers to purchase powerful prescription drugs, including some not yet approved for sale in the United States, without ever seeing a doctor; and

WHEREAS, supporters of Internet sales of prescription drugs argue that consumers are knowledgeable enough to buy medicines over the Internet and that patients should be free to purchase certain drugs without the inconvenience or embarrassment of in-person doctor visits; and

WHEREAS, many health care experts and government regulators fear that the growing trend towards purchasing prescription drugs over the Internet could endanger, and even kill, patients; and

WHEREAS, it is illegal for doctors to prescribe for patients in a state where they are not licensed to practice, and licensed doctors must also meet standards of care that in most states require a doctor-patient relationship to prescribe drugs; and

WHEREAS, these laws and regulations were written before widespread use of the Internet; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Board of Medicine, in consultation with the Board of Pharmacy, be requested to study the sale of prescription drugs in the Commonwealth via the Internet.

All agencies of the Commonwealth shall provide assistance to the Board for this study, upon request.

The Board shall complete its work in time to submit its findings and recommendations to the Governor and the 2000 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

