

**Statement of the  
Federation of State Medical Boards**

**Senate Committee on the Judiciary**

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President and Chief Executive Officer**

**Rogue Online Pharmacies: The Growing Problem of Internet Drug  
Trafficking**

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**I. The Federation of State Medical Boards (FSMB)**

The FSMB is a non-profit organization of the 70 state medical licensing and disciplinary boards of the U.S. and its Territories. Established in 1912, the FSMB is a known and authoritative resource on issues related to medical regulation, including research, policy analysis and development, education, and state by state licensing and disciplinary statutes, rules and policy. FSMB's mission is to improve the quality, safety, and integrity of health care by promoting high standards for physician licensure and practice and to support state medical boards in protecting the public. As a collective voice for state medical boards, the FSMB monitors state and federal legislative initiatives, works collaboratively with federal and state regulatory agencies, and offers legislative assistance to and on behalf of our member medical boards.

**II. Model Guidelines and Key Concerns**

The Internet has had a profound impact on society, including the practice of medicine and pharmacy, and offers opportunities for improving the delivery of health care. The appropriate application of technology can enhance medical care by improving patient access to specialty care, facilitating communication with physicians and other health care providers, filling prescriptions, obtaining laboratory results, scheduling appointments, monitoring chronic conditions, providing health care information and clarifying medical advice. At the same time, new technologies can create opportunities for individuals and entities to exploit technological advancements for personal gain without regard for patient safety. The simultaneous increase in telemedicine technologies/applications and "rogue" Internet pharmacies, those that prescribe and dispense medication based on online consultations or questionnaires, have created complex regulatory challenges for state medical boards in protecting the public.

The primary mission of state medical boards is patient protection through the regulation of the practice of medicine, regardless of the treatment modality. Regulation becomes more complicated as patients interact with physicians electronically rather than in a

traditional face-to-face setting. Accordingly, the FSMB has been active in addressing regulatory issues associated with the use of telecommunications and the Internet in the practice of medicine for more than a decade. In 1996, the FSMB published *A Model Act to Regulate the Practice of Medicine Across State Lines*. In 2000, it published guidelines for Internet prescribing. In 2002, it published *Model Guidelines for the Appropriate Use of the Internet in Medical Practice*, one of the first national standards established for Internet medical practice.

Those guidelines, which the FSMB recommends be adopted by all state medical boards, emphasize the key position of the FSMB and its member boards with respect to Internet pharmacies: *An appropriate relationship between the patient and the physician must exist before a prescription is written and medication dispensed*. Failure to have an appropriate physician-patient relationship poses serious health risks including: (1) adverse drug reactions and/or interactions, (2) misdiagnosis or delay in diagnosis, (3) failure to identify complicating conditions, and (4) misuse, abuse and diversion of prescription medications, including controlled substances.

### **III. National Clearinghouse on Internet Prescribing**

In addition to policy development and promulgation, the FSMB has aggressively sought to identify Internet pharmacies that are dispensing drugs on the basis of prescriptions written by health care providers whose relationship with the patient does not appear to meet minimal standards. In September 2000, the FSMB established its National Clearinghouse on Internet Prescribing, to collect and disseminate information on “rogue” Internet sites offering prescribing and dispensing services for prescription drugs to consumers.

The Clearinghouse is uniquely qualified to coordinate information between regulatory and enforcement entities because of its formal relationship with state medical boards. The FSMB has well established lines of communication with state and federal regulatory agencies, including the Department of Justice, the Drug Enforcement Agency, the Food and Drug Administration, Immigration and Customs Enforcement, and the Federal Trade Commission, as well as the National Association of Boards of Pharmacies, the National Association of Drug Diversion Investigators, the National Association of Attorneys General, representatives of the pharmaceutical industry, and the media.

To date, approximately 39 physicians have been disciplined by their licensing board based on Clearinghouse data. The Clearinghouse has supplied information for more than 300 cases on the federal level and more than 600 cases on the state level. Additionally, information regarding Internet prescribing has been shared with the Medical Council of New Zealand and the Ministry of Health in Germany.

### **IV. State Regulation**

The Federation strongly supports state-based regulation of the practice of medicine. With regard to Internet prescribing, state medical boards have the authority to discipline

licensed physicians prescribing and dispensing medications inappropriately. Forty-six (46) boards have taken disciplinary action against licensees, twenty-nine (29) states have adopted rules/policies, and seventeen (17) states have enacted legislation to clarify this authority. An additional nine (9) states have introduced legislation this year to regulate the practice of medicine via the Internet. Further, state medical boards have communicated among themselves regarding physicians licensed in multiple states. These cooperative efforts have been effective in closing several Internet sites and causing a number of physicians to cease their affiliation with questionable operations.

## **V. Federal Legislation – Online Pharmacy Consumer Protection Act**

The FSMB supports the development of federal legislation to protect patients ordering prescriptions over the Internet but cautions against any legislation that would have the unintended consequences of restricting patient access to legitimate telehealth services. The FSMB supports legislation that would strengthen the enforcement authority of state and federal regulators against Internet pharmacies and those associated health care professionals.

S.980, the Online Pharmacy Consumer Protection Act of 2007, would provide significant protection for consumers who utilize the Internet to obtain pharmaceuticals.

S.980 addresses issues crucial to the protection of patients ordering prescriptions over the Internet. First, the bill requires a pharmacy that seeks to deliver, distribute, or dispense by means of the Internet a controlled substance to obtain a registration specifically authorizing such activity from the Attorney General. The pharmacy would be required to disclose information in a visible and clear manner on its homepage, including contact information for the site owner, a list of States in which the pharmacy has any operations, information relating to pharmacies and pharmacists associated with the website, the name, licensing information and contact information for practitioners who provide medical consultations through the website, and a compliance statement. Patients should know with whom they are dealing. Disclosure will not only be beneficial to patients but will allow state medical boards to identify individuals against whom they may take disciplinary action.

Second, S.980 defines the term “qualifying medical relationship” to mean a medical relationship that exists when a practitioner has conducted at least one medical evaluation with the user in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals; or conducts a medical evaluation of the patient as a covering practitioner and is not prescribing a controlled substance in schedule II, III, or IV; and shall not be construed to imply that one medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice. This requirement for conducting at least one in-person physical examination prior to issuance of a prescription is similar to requirements in much of the country. A clear, national standard would greatly support law enforcement and administrative efforts to regulate this burgeoning practice via the Internet. However, vigilance must be maintained to make certain this bill

does not negatively impact the practice of telemedicine. As this legislation moves forward, FSMB would be pleased to work with the Committee and the sponsors to address these concerns.

Third, state attorneys general are not able to enjoin the operations of an Internet pharmacy that affect citizens in their particular states if that pharmacy is operated out of another state. Many of our member boards believe that a number of Internet sites that dispense drugs in an inappropriate manner could be shut down if the attorneys general had nationwide injunctive powers as well as the ability to pursue other civil remedies including damages, restitution or other compensation across state lines. S.B. 980 authorizes those injunctive powers.

## **VI. Model Guidelines on Physician-Patient Electronic Communication**

In its *Model Guidelines for the Appropriate Use of the Internet in Medical Practice*, the FSMB addresses physician use of electronic communications and the Internet in the delivery of patient care. Portions of the guidelines are excerpted below: ***Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings.*** Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care. A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise.

Patient-physician electronic mail should be maintained with written policies and procedures addressing (1) privacy, (2) health-care personnel who will process messages, (3) hours of operation, (4) types of transactions that will be permitted electronically, (5) required patient information to be included in the communication, (6) archival and retrieval, and (7) quality oversight mechanisms.

Sufficient security measures must be in place and documented to assure confidentiality and integrity of patient-identifiable information. All patient-related electronic communications, including patient-physician e-mail, prescriptions, lab results, evaluations and consultations should be stored and filed in the patient's medical record.

Turnaround time should be established for patient-physician e-mail. E-mail systems should be configured to include an automatic reply to acknowledge message delivery and that messages have been read. Patients should be encouraged to confirm that they have received and read messages.

## **VII. Conclusion**

In conclusion, the Internet offers tremendous opportunities for improving the delivery of health care. However, it is the position of the FSMB that the use of the Internet in

providing medical services, including prescribing and dispensing medications, should supplement and enhance, but not replace, crucial interpersonal interactions that create the very basis of the physician-patient relationship. The misuse of the Internet in providing medical services and dispensing dangerous drugs to consumers is risk to the public health, safety and welfare and warrants the passage of federal legislation that can distinguish legitimate telemedicine practice from those associated with “rogue” Internet pharmacies.