



newsletter

National Association of Boards of Pharmacy®

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aid to government
the profession
the public
1904 to 2008

State, Federal Regulatory Authorities Combat Rogue Internet Drug Distributors

Upcoming Events

May 17-20, 2008
NABP 104th Annual Meeting
Baltimore Marriott Waterfront
Baltimore, MD

June 5-6, 2008
MPJE Item-writing Workshop
NABP Headquarters
Mount Prospect, IL

June 28, 2008
FPGEE Administration
New York City, NY
Northlake, IL
San Mateo, CA

July 30-31, 2008
NABP Program Review and Training Session
NABP Headquarters
Mount Prospect, IL

The public health risk posed by Internet drug distributors that operate in unapproved, unsafe, and illegal manners has continued to grow over the last couple of years. (See “Internet Drug Distributors Posing New Concerns” in the March 2008 issue of the *NABP Newsletter*.) Combating this epidemic has been a challenge for the state boards of pharmacy and law enforcement agencies as well as federal regulatory agencies. The fluidity and anonymity offered by the Internet and the prevalence of foreign-operated sites that lie outside the United States regulatory jurisdiction provide a barrier behind which these rogue operations hide.

Nonetheless, those in charge of safeguarding the public health and enforcing compliance with state

and federal laws continue the fight. The most effective approaches generally have been multi-pronged and have involved communication and collaboration between various entities.

State Actions

While some states have taken legislative action specifically targeting illicit drug distributors operating on the Internet, others apply existing laws to address the issue. States generally have taken one of three approaches to regulating Internet drug distributors: out-of-state pharmacy licensing requirements, valid patient-practitioner relationships, and state controlled substance laws.

Not every state specifically addresses Internet drug distributors in its regulations. But the vast majority require out-of-



state drug distributors that dispense medications to state residents to be registered or licensed in that state – a requirement that encompasses Internet pharmacies.

The Wisconsin Pharmacy Examining Board’s description of its requirements for out-of-state drug distributors is fairly standard: “No pharmacy that is in another state may ship, mail, or otherwise deliver a prescribed drug or device to

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Rogue Internet Drug Distributors

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persons in Wisconsin unless the pharmacy is licensed in Wisconsin.” While the requirements for this license are not identical to those for in-state drug distributors (“An out-of-state pharmacy . . . is not required to comply with Wisconsin law relating to the professional service area of a pharmacy or the minimum equipment requirements . . .”), the requirement allows the state to weed out rogue drug distributors and provides a mechanism to sanction drug distributors that dispense without a license.

Other states find it useful to cite Internet drug distributors in their regulations. Kentucky and North Carolina, for example, specifically require Internet drug distributors dispensing in those states to hold the NABP Verified Internet Pharmacy Practice Sites™ (VIPPS®) accreditation.

Meanwhile, out-of-state pharmacy regulations are supplemented with state requirements concerning the patient-practitioner relationship for a prescription to be considered legitimate by the pharmacist. (See “States Begin to Define What Constitutes Legitimate Patient-Practitioner Relationships” in the September 2007 issue of the *NABP Newsletter*.) In general, that relationship includes at least the following elements: a medical history; a physical examination; and some logical connection between the patient’s medi-

cal complaint, the medical history, the physical examination, and the drug prescribed. State boards of pharmacy in Arkansas, North Carolina, West Virginia, and Colorado, for example, emphasize the need for a legitimate patient-practitioner relationship in determining the validity of a prescription that may be dispensed. California, in another example, specifies the need for such a relationship particularly in relation to controlled substances available via the Internet (“No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices . . . on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination.”) The many rogue Internet drug distributors that sell prescription medications based solely on an online questionnaire do not meet these legitimacy requirements.

Last, many rogue Internet drug distribution sites offer would-be patients easy access to controlled substances and, in doing so, run afoul of numerous state and federal laws and regulations. In his May 2007 testimony during a US Senate Judiciary Committee hearing, Joseph T. Rannaz-

zisi, JD, deputy assistant administrator at the Drug Enforcement Administration’s Office of Diversion Control, stated that, in particular, Schedule III and IV drugs, such as anti-anxiety medications, hydrocodone combination products, and anabolic steroids, “are increasingly accessible and often illegally purchased through the Internet.” The process violates both federal and state laws addressing controlled substances.

Doubtless, states will continue to draft legislation that ever more specifically addresses the problem of rogue Internet drug distributors. The difficulty in combating the rogue operations, however, often seems to be one more of enforcement than of having the appropriate regulations on the books. Often, determining if a site has violated the law is glaringly obvious, while information for shutting down or prosecuting the operation is not. The Internet often yields few clues as to the identity of the site’s operators, or even the country in which they live. Fortunately, drugs are tangible products that have to be purchased from manufacturers and shipped to customers. It is attacking these physical steps where law enforcement has had its greatest impact.

Laws and regulations calling for a legitimate patient-practitioner relationship and limiting access to controlled substances often give state regulators another potent tool in combating rogue Internet

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NABP Launches PCOA to Assist Schools, Colleges of Pharmacy in Curriculum Assessment

NABP is pleased to announce that 24 schools and colleges of pharmacy participated in the first administration of the Pharmacy Curriculum Outcomes Assessment™ (PCOA)®, which took place in April 2008. The PCOA is a comprehensive assessment tool developed by NABP and key stakeholders in response to the need expressed by the United States schools and colleges of pharmacy requesting assistance with curriculum development and measurement of student performance and growth.

Earlier this year NABP provided all schools and colleges of pharmacy with PCOA information kits, encouraging each school and college to select an assessment date within the two-week period of April 7-18, to administer the PCOA to their students. As an added benefit, those schools and colleges that chose to participate in the April 2008 assessment did so at no charge. After this first administration, the PCOA will be administered annually by participating schools and colleges of pharmacy during a designated window of time at a cost of \$75 per student.

“Assessment is necessary in all areas, not just pharmacy,” states Stephen M. Gross, MA, EdD, professor of pharmacy administration and dean, Long Island University, Arnold and

Marie Schwartz College of Pharmacy and Health Sciences. “It is important to have measures that will evaluate the effectiveness of curricula.” The college of pharmacy set up an assessment day this spring for students to take the PCOA as well as a series of objective structured clinical examinations. Along with participating in the administration of the PCOA, the college also took part in the beta testing of the PCOA.

Developing a Reliable and Valid Tool

In the spring of 2007, with the assistance of eight schools and colleges of pharmacy from various regions of the United States, NABP administered a beta test of the PCOA. The beta test was conducted as a follow up to the initial pilot studies in 2005 and 2006.

As an active participant in both the pilot studies and beta tests, “The University of Utah College of Pharmacy remains committed to development of a nationwide, standardized, validated examination for curricula assessment to the benefit of our students, the academy, and the profession,” states Mark A. Munger, PharmD, FCCP, professor and associate dean for academic affairs at the university. The university was one of the key stakeholders in initiating development of the PCOA.

With the cooperation from the University of Utah College of Pharmacy, the Long Island University, Arnold and Marie Schwartz College of Pharmacy and Health Sciences, and six other schools and colleges of pharmacy, the beta test was successfully administered as a 200-item multiple choice paper-and-pencil assessment to a total of 1,307 P1 through P4 students and upon completion, an independent psychometric consultant performed a thorough analysis of the PCOA data. The results of this analysis not only supported the PCOA’s reliability and validity, but were used by NABP to further fine-tune the assessment tool. The assessment will continue to undergo annual revisions by subject-matter experts, regular item analyses, reliability and validity studies, and annual statistical equating in accordance with an ongoing assessment validation process set in place by NABP.

The construct of the PCOA was influenced by ACPE’s *Accreditation Standards and Guidelines for the Professional Program Leading to the Doctor of Pharmacy Degree*, and consists of four major pharmacy content areas, including: basic biomedical sciences, pharmaceutical sciences, social/behavioral/administrative pharmacy sciences, and clinical sciences. Each of these four areas is further broken down into additional competencies.

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The NABP Executive Committee is elected each year at the Association’s Annual Meeting.

TAP Dance Revisited

By Dale J. Atkinson, JD

Boards of pharmacy may, under certain circumstances, be impacted by decisions of other entities that may also share jurisdiction or authority over licensees, whether pharmacists or pharmacies. Judicial decisions also impact future board actions in the administrative arena should they reverse a particular matter or interpret a statute or regulation in a manner inconsistent with previous board interpretations. As discussed in “Legal Briefs” in the February 2007 issue of the *NABP Newsletter*, the impact of a settlement agreement in a criminal investigation related to the Prescription Drug Marketing Act (PDMA) was addressed by the Missouri Appellate Court, which recognized the authority of the Missouri Board of Pharmacy to place a facilities permit holder (licensee) on probation based upon the settlement agreement, rejecting arguments of the licensee that the settlement precluded any further action by the state (including the board of pharmacy).

A recap of the relevant facts identifies settlement of criminal and civil investigations instigated in 1996 and 1997 by the United States Attorney’s Office in Boston and the US Department of Justice in Washington, DC. The investigations involved inflated prices and improper sales and marketing practices designed to induce physicians to prescribe a particu-

lar product. In addition, the licensee was accused of filing false claims with the Medicare and Medicaid programs. The licensee settled with the federal government, all 50 states, and the District of Columbia regarding the Medicare and Medicaid allegations. The settlement involved the licensee pleading guilty to felony conspiracy to violate the PDMA and

conspiracy to violate sections 331(t) and 333(b) of title 21 of the US Code by causing billing for free drug samples.

As part of the resolution with Missouri, the licensee and the state entered into a settlement agreement whereby the state, received monetary consideration and, in exchange, agreed to release any civil claims against the licensee relating to its conduct in the underlying guilty plea. The US District Court for the Western District of Massachusetts accepted the guilty plea in December 2001. The settlement agreement with the state of Missouri was also executed in December 2001.

Thereafter, in January 2003, the attorney representing the Missouri Board of Pharmacy filed an administrative complaint with the Board related to the felony conviction. After a hearing, the Board placed the licensee on probation for a three-year period with an effective date of February 25, 2005. The circuit court reversed the Board order, and the court of appeals reversed the circuit court, thus upholding the Board of Pharmacy sanction. The licensee appealed the matter to the Missouri Supreme Court.

On appeal, the licensee argued that the Board’s actions did not comport with due process based upon insufficient notice and that the Board was not a fair and impartial tribunal under applicable constitutional

