



# newsletter

National Association of Boards of Pharmacy®

September 2007 / Volume 36 Number 8

aid to government  
the profession  
the public  
1904 to 2007

## Upcoming Events

**September 16-18, 2007**  
NABP Fall Legislative Conference  
Hyatt Regency Crystal City  
Arlington, VA

**October 3-6, 2007**  
NABP/AACP District 7 and District 8 Meeting  
Ashland Springs Hotel  
Ashland, OR

**October 11-12, 2007**  
NABP/AACP District 2 Meeting  
Hotel DuPont  
Wilmington, DE

**October 25-27, 2007**  
NABP/AACP District 1 Meeting  
Wyndham Burlington Hotel  
Burlington, VT

**November 14-16, 2007**  
NABP/AACP District 4 Meeting  
Omni Severin Hotel  
Indianapolis, IN

## States Begin to Define What Constitutes Legitimate Patient-Prescriber Relationships

A Google search for “Online Pharmacy” produces over 44 million hits. While valid Internet pharmacies are sprinkled in the mix, many search results lead to fly-by-night sites where prescription medications can be purchased with few questions asked – or answered.

Some rogue “pharmacy” sites offer drugs without a prescription of any kind or offer “prescriptions” based on online questionnaires or other insubstantial or false criteria. In addition, legitimate brick-and-mortar pharmacies in many states are being actively solicited to fill illegitimate prescriptions or release medications without a prescription at all.

With the explosion of these shadowy sites,

state boards of pharmacy are often asked by their licensees to clarify points of ethics and law in regard to what constitutes a legitimate prescription. More and more boards are providing this answer: to legitimately obtain prescription medication, a patient must produce a legitimate prescription based on a bona fide patient-prescriber relationship.

In general, state boards of pharmacy use the following criteria to determine if a prescription is legitimate:

- A patient has a medical complaint
- A medical history has been taken
- A physical examination has been performed
- Some logical connection exists between the medical complaint, the



physical examination, and the drug prescribed. Developed to help patients distinguish between legitimate and illegitimate Internet pharmacies as well as to assist state boards of pharmacy in regulating online pharmacies, the Verified Internet Pharmacy Practice Sites™ (VIPPS®) program was launched by NABP in the spring of 1999. Internet pharmacies that display the VIPPS seal must meet several professional practice criteria, including having procedures in place to ensure that only valid prescriptions are dispensed.

(continued on page 130)

## In This Issue. . . .

**Legal Briefs:**  
IA Confidential

132

**Feature News:**  
Pharmacies, State Boards, Others Take Steps to Lessen Impact of Avian Influenza Pandemic

134

**Association News:**  
OIG Exclusion List Raises Concerns for State Boards of Pharmacy

138

**State Board News:**  
North Carolina Board Requires VIPPS Accreditation for Internet Pharmacies

140

**Professional Affairs Update:**  
Death in Canada Tied to Counterfeit Drugs Bought via Internet

141

The NABP Newsletter (ISSN 8756-4483) is published 10 times a year by the National Association of Boards of Pharmacy (NABP) to educate, to inform, and to communicate the objectives and programs of the Association and its 66 member boards of pharmacy to the profession and the public. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABP or any board unless expressly so stated. The subscription rate is \$35 per year.

National Association of Boards of Pharmacy  
1600 Feehanville Drive  
Mount Prospect, IL 60056  
847/391-4406  
www.nabp.net  
custserv@nabp.net

Carmen A. Catizone  
Executive Director/  
Secretary

Larissa Doucette  
Editorial Manager

©2007 National Association of Boards of Pharmacy. All rights reserved. No part of this publication may be reproduced in any manner without the written permission of the executive director/secretary of the National Association of Boards of Pharmacy.

## Patient-Prescriber

(continued from page 129)

VIPPS criteria require qualifying pharmacies to maintain and enforce policies and procedures to ensure that prescription medications are not prescribed or dispensed based upon telephonic, electronic, or online medical consultations without a pre-existing patient-prescriber relationship that has included an in-person physical examination.

In addition, Article III of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* encourages the state boards of pharmacy to adopt regulations specifically to address Internet and out-of-state pharmacies conducting business in their respective states. The *Model Act* states that any out-of-state pharmacy offering care to a state resident – including by telephone or other technology – is subject to the state’s laws and regulations and must register with the state.

Several states have incorporated into their laws and rules the stipulations defined in the VIPPS program and in the *Model Act* regarding Internet pharmacies. In March of 2005, Kentucky became one of the first states in the nation to pass a law regulating Internet

pharmacies. The law requires any pharmacy conducting business, “primarily or exclusively within the Commonwealth by use of the Internet,” to obtain a Kentucky pharmacy permit and become VIPPS accredited. The law defines a legitimate patient-prescriber relationship as one in which the prescriber has performed a physical examination within the preceding six months.

The North Carolina Board of Pharmacy aggressively attacks the problem of illegal Internet pharmacies by educating its licensees and sending cease and desist letters to offending companies. The letters, under the signature of Jack W. Campbell, IV, executive director of the North Carolina Board of Pharmacy, inform the offending companies that it is illegal in North Carolina to fill a prescription that a pharmacist knows, or should reasonably know, was written without benefit of a physical examination and an ongoing patient-prescriber relationship. The letters state that the Board will help local and federal law enforcement in shutting down the illegal pharmacies.

Campbell says pharmacists need to look for the same red flags with electronic prescriptions as they would with paper prescriptions. Clues that should raise suspicions that a prescriber may not be

engaged legitimately with patients include:

- Large numbers of geographically dispersed patients
- Quantities of prescriptions above the norm
- Refills written at an excessive rate
- Abundance of prescriptions for “lifestyle” medications for such medical conditions as erectile dysfunction, anxiety, obesity, and pain

Almost all illegal prescriptions and medications dispensed without a prescription involve pain or lifestyle medications. The difficulty in writing guidelines and laws, says Campbell, is that “you need to write a rule broad enough to capture the illegitimate prescriptions, but not so broad to make it difficult to get legitimate pain medication.”

Campbell urges state boards to develop and implement additional licensing procedures for Internet and out-of-state pharmacies. Two measures that Campbell recommends are (1) requiring every pharmacy that does business in a given state to be licensed in that state, and (2) requiring Internet pharmacies to be VIPPS accredited. Campbell advises boards to be aggressive in confronting problems that come to their attention, and to communicate with law enforcement, other state

boards, and NABP when concerns over suspected illegal pharmacies arise.

In 2007, Arkansas passed a law addressing Internet prescriptions, which states that a prescription may not be dispensed if the patient has not consulted a prescribing practitioner, or had a proper relationship with a practitioner. No prescription may be dispensed if the pharmacist knows – or should have known – that the prescription was written based upon an Internet questionnaire or a cyber or telephonic consultation. A “proper relationship” is defined as one where the practitioner takes a history and performs a physical examination, knows the patient and his or her general health, provides accepted follow-up care, or treats a patient in consultation with another provider who has a proper relationship with the patient.

The Kansas State Board of Pharmacy recently sent a warning to its licensees via its January 2007 newsletter stating it had come to the Board’s attention that several pharmacies had been filling prescriptions for Internet sites that did not appear to be legitimate. The warning advised pharmacists to be aware that several prescriptions written by the same prescriber for many patients in different areas of the country is a red flag that a legitimate patient-prescriber relationship may not exist.

The Colorado State Board of Pharmacy passed a rule requiring pharmacists to make a reasonable effort in determining the legitimacy of a prescription, which includes the existence of a proper patient-prescriber relationship. A pharmacy and pharmacist sued the Board, stating the rule was too vague, too burdensome, and that the Board had overstepped its authority (see “Legal Briefs” in the August 2007 issue of the *NABP Newsletter*). The Colorado Court of Appeals heard the case and determined that the Board of Pharmacy had legitimately promulgated the rules and had not overstepped its authority in requiring a proper patient-prescriber relationship to be in place. The court determined that it was not unreasonable for a pharmacist to know the definition of a proper patient-prescriber relationship, as determined by the Board of Pharmacy.

During the NABP 103<sup>rd</sup> Annual Meeting held in May 2007, NABP passed a resolution bolstering its commitment to encourage and assist the state boards in adopting uniform standards to protect patients from illegitimate Internet sites in their respective states. In adopting resolution No. 103-2-07, “Valid, Ongoing Patient-Prescriber Relationships,” NABP resolves to work with the Federation of State Medical Boards, Food and Drug Administration, Drug Enforcement Administration,

and other stakeholders to assess and, if necessary, revise the *Model Act* to explicitly prohibit the dispensing of medications based on prescriptions generated solely from Internet-based questionnaires or otherwise invalid patient-prescriber relationships. The resolution also encourages the state boards of pharmacy to review their existing regulations and, if necessary, update them to reflect the amended *Model Act* and/or communicate such concerns to the state legislature.

So, what is the consensus on the definition of a legitimate patient-prescriber relationship? In the end, the constant in NABP guidelines and in the states’ rules is this: a legitimate patient-prescriber relationship cannot exist without the provider performing a physical examination at some point in the relationship or consulting with a provider who has done so and who has a proper relationship with the patient. A medical relationship established by an Internet questionnaire or by cyber or telephonic consultation is not legitimate because it lacks this key component. State boards of pharmacy are encouraged to communicate this distinction to their licensees and to advise them that disciplinary action may be taken against pharmacists and pharmacies that dispense prescriptions written outside of such a relationship. Ⓢ

## Executive Committee

**Lawrence H. “Larry” Mokhiber**  
*Chairperson*  
One-year term

**Oren M. Peacock, Jr**  
*President*  
One-year term

**Richard A. “Rich” Palombo**  
*President-elect*  
One-year term

**Gary A. Schnabel**  
*Treasurer*  
One-year term

**Karen M. Ryle**  
*Member, District 1*  
Serving first year of a three-year term

**Elizabeth Scott “Scotti” Russell**  
*Member, District 2*  
Serving first year of a three-year term

**Reginald B. “Reggie” Dilliard**  
*Member, District 3*  
Serving third year of a three-year term

**William T. “Bill” Winsley**  
*Member, District 4*  
Serving third year of a three-year term

**Lloyd K. Jessen**  
*Member, District 5*  
Serving first year of a three-year term

**Malcolm J. Broussard**  
*Member, District 6*  
Serving second year of a three-year term

**Cathryn J. Lew**  
*Member, District 7*  
Serving first year of a two-year term

**Patricia F. Harris**  
*Member, District 8*  
Serving third year of a three-year term

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

## IA Confidential

By Dale J. Atkinson, JD

**Boards of pharmacy collect and maintain numerous data and information regarding applicants, licensees, and facilities. The information within the possession of the board may or may not be subject to disclosure depending upon the freedom of information or open records laws that apply within each respective jurisdiction (generally referred to in this article as FOIA laws).**

Data including demographics, examination attempts, contact information, licensure status, and personal history are some of the information voluntarily provided by a licensee/applicant and maintained within the board records. Additional information regarding an applicant/licensee may also be in the possession of the board, yet provided by parties other than the professional. FOIA laws are enacted to ensure government operates in the sunshine, and the laws usually require disclosure of information held by the board with the exception consisting of nondisclosure and maintenance of confidentiality. Of course, each jurisdiction must comply with the laws applicable to each particular circumstance. Consider the following:

An individual maintained a license as a physician issued in 1979 by the Iowa Board of Medical Examiners. In 2000, he relocated to Massachusetts and applied for licensure as a physician. His application for licensure was denied by the Massachusetts board based, in part, on the disclosure by the Iowa board of the existence of three pending investigations in Iowa at the time of his attempt to licensure transfer. The disclosure of these pending investigations from the Iowa board was based upon a request by the Massachusetts board for such information.

In May 2001, the licensee filed a complaint with the Iowa State Appeal Board alleging that the Iowa board unlawfully disclosed confidential information to the Massachusetts board. The

State Appeal Board denied his claim. The licensee appealed the denial to the district court, which, prior to the hearing, granted the licensee's request to amend his complaint to include a claim for damages and attorney's fees. However, the court affirmed the decision of the State Appeal Board denying the complaint. The licensee appealed the decision of the district court denying his complaint and the board appealed the grant of the amended complaint for damages and attorney's fees. The issues were consolidated for purposes of the appeal.

The Iowa Supreme Court enumerated the standard of review noting that under these circumstances the court examined whether the agency committed an error of law or acted unreasonably, capriciously, or arbitrarily. The statute at issue states, in pertinent part,

In order to assure a free flow of information for accomplishing the purposes of this section, . . . all complaint files, investigation files, other investigation reports, and other investigative information in the possession of a licensing

board . . . which relates to licensee discipline are privileged and confidential, and are not subject to discovery, subpoena, or other means of legal compulsion for their release to a person other than the licensee and the boards, their employees and agents involved in licensee discipline, and are not admissible in evidence in a judicial or administrative proceeding other than the proceeding involving licensee discipline. *However, investigative information in the possession of a licensing board . . . which relates to licensee discipline may be disclosed to appropriate licensing authorities within this state, [or] the appropriate licensing authority in another state . . . in which the licensee is licensed or has applied for a license [emphasis added].*

The court engaged in an analysis of the language and legislative history of the law. It noted the technical meanings of the words and phrases used in the statute, as well as the amendments to the law adopted clarifying certain applications of

the law to circumstances. The court referred to a previous opinion and the amendments to the law whereby two additional exceptions were enacted. These exceptions authorized the release of investigative information “which relates to licensee discipline” to other states’ licensing authorities and to law enforcement when information indicates a crime has been committed.

Interpreting the initial exception, the licensee argued that the relevant statute only allows the disclosure of investigative information after formal disciplinary proceedings have been initiated. In addressing this argument, the court analyzed the phrase “relates to licensee discipline.” Consistent with a previous Iowa Supreme Court opinion, the court held that

[i]n stating that ‘all complaint files and investigative data are confidential,’ we implicitly concluded that all complaint files and investigative information relate to licensee discipline regardless of whether that information leads to the filing of formal disciplinary charges. [citation omitted] This

conclusion is logical given the legislature’s use of the broad phrase ‘relates to.’

The court held that the statute in question was intended to ensure broad confidentiality of all complaint and investigative information pertaining to licensee discipline. By using the same language in the statute to describe information that may be shared with states’ licensing authorities, the legislature indicated its intent to provide for broad disclosure to such authorities as well.

The licensee argued that the statute was intended to protect both the complainant and the licensee and that disclosure defeated such protections. However, the court disagreed stating that such an argument did not change the analyses. It held that the disclosure was not to the general public, but to another state’s licensing authority which, “presumably, keeps this information confidential and uses it solely for purposes of determining whether to issue [applicant] a medical license.” It also noted that the licensee’s reputation among the general public or among his colleagues was not influenced due to

(continued on page 143)



Attorney Dale J. Atkinson is a partner in the law firm of Atkinson & Atkinson, counsel for NABP.

## Pharmacies, State Boards, Others Take Steps to Lessen Impact of Avian Influenza Pandemic

The question driving the Centers for Disease Control and Prevention (CDC) is not, *will an avian influenza pandemic strike the human population, but when will it strike.*

While humans thus far have contracted the Influenza A (H5N1) virus almost exclusively from direct or close contact with H5N1-infected poultry or H5N1-contaminated surfaces, experts are wary that the virus may one day mutate to become better able to infect humans and spread easily from one person to another. Given the lack of, or little, immune protection against H5N1 virus in humans, if the virus does gain the capacity to spread easily from person to person, an influenza pandemic could begin.

With this watchful approach, vaccine manufacturers, government agencies, corporate employers, and community pharmacies are preparing for such an event in an effort to lessen its impact.

### Pharmacists Positioned to Help

Pharmacists are uniquely positioned to lessen the impact of avian influenza pandemic by increasing the rates of pneumococcal and seasonal influenza immunizations

in vulnerable populations. These immunizations would reduce the likelihood of severe influenza complications, such as invasive pneumococcal disease, in the event of a pandemic. Given their advisory role, pharmacists have the opportunity to communicate risks and advocate immunization to their patients.

Consistent with state laws, pharmacists can also become immunizers and assume an active role in protecting the public health. All but a handful of states allow pharmacists to administer vaccinations. Such efforts would be especially valuable during mass immunization programs during a pandemic. In addition, pharmacists are advised to protect themselves and those with whom they come in contact by being appropriately immunized themselves.

### Disaster Plans to Address Pandemic

The boards of pharmacy are taking steps to prepare for a pandemic and the strain it would place on

health care resources. As with any catastrophe, having a disaster preparedness plan in place is critical to an organization's ability to weather the storm. A comprehensive model disaster preparedness guide, *Emergency and Disaster Preparedness and Response Planning: A Guide for Boards of Pharmacy*, is available on the NABP Web site under News/Press, Committee and Task Force Reports.

Issued by NABP as a culmination of the Task Force on Emergency Preparedness, Response, and the US Drug Distribution System, the guide offers recommendations regarding forging partnerships between the boards of pharmacy and the public and private sectors in coordinating emergency preparedness and response efforts. Among other sections, the guide provides for boards "Recommendations for Preparing and Responding to an Emergency or Disaster," a "Model Emergency and Disaster Preparedness Response Plan," and "Model Rules for Public Health Emergencies," as well as emergency and disaster resources that NABP provides to assist boards in their efforts.

As part of an international disaster preparedness plan, the World Health Organization (WHO) announced on June 13, 2007, that it is working with vaccine manufacturers to move ahead on plans to create a global stockpile of vaccine for the H5N1 virus to protect against the threat of an avian flu pandemic. Several major manufacturers have pledged millions of doses of H5N1 vaccine for WHO's global stockpiling scheme.

### **Firms Take Controversial Steps to Protect Staff**

At the same time, manufacturers may encourage companies to stockpile H5N1 vaccine or Tamiflu® for distribution to their employees. Tamiflu manufacturer Roche Holdings, for instance, which provides the medication to its own employees, has been contacted by many firms eager to acquire the drug. While corporate efforts to protect their employees – as well as their bottom line and the economy as a whole – from a pandemic are well-founded, firms must be sure to follow established safeguards to protect the health of those receiving the medications.

Corporate or private stockpiling raises concerns for two primary reasons: (1) it may deplete supplies that would otherwise go into government stockpiles, and (2) by skirting the normal relationship between physician, patient, and pharmacist, the vaccine or medication may inadvertently be stored, transported, and/or dispensed inappropriately.

In November 2006, the California Department of Health Services strongly discouraged doctors from writing prescriptions that would allow individuals to keep a supply of Tamiflu in their own medicine cabinets. It based its advisory on federal warnings that the practice could create a shortage of the drug when it is needed.

To protect the health of their employees, companies that do choose to provide the vaccine or medication for their employees must ensure that the drugs are prescribed and distributed only by those properly authorized to do so, and only after the employees have been examined by the prescriber and screened to ensure the medication is appropriate for them. Patients should also receive printed

information that includes instructions for taking the medication. Additionally, the manufacturers, wholesalers, or pharmacies distributing or dispensing the medications should be licensed in the applicable states and must sell only to other licensed entities or persons (ie, pharmacies, physicians, or other prescribers).

The boards of pharmacy are encouraged to ensure that companies distributing medications to their employees have an appropriate structure in place and that the medications are being dispensed by appropriately licensed individuals.

### **FDA Issues Guidance Documents**

For its part, Food and Drug Administration (FDA) recently issued final recommendations to increase the supply of safe and effective influenza vaccines for both seasonal and pandemic use.

The two guidance documents – one for seasonal influenza vaccines and another for pandemic influenza vaccines – outline the regulatory pathways for rapid development and approval of these

(continued on page 137)

## Fall Legislative Conference

nabp newsletter

**September 16-18, 2007**

**Hyatt Regency Crystal City**

**Arlington, VA**

### Sunday, September 16

**7:30 AM - 5 PM**

Registration/Information Desk Open

**8 - 9 AM**

Continental Breakfast

**9 - 9:15 AM**

Welcome Remarks

**9:15 - 10:15 AM**

Keynote Address

United States Representative Marion Berry, AR-01 (Invited)

**10:30 AM - noon**

Legislative and Regulatory Update

*Sponsored by Medco Health Solutions, Inc*

*Program #205-000-07-006-L03P*

*(0.15 CEUs – 1.5 contact hours)*

Speakers: Eileen M. Lewalski, Professional Affairs Manager, NABP

Joshua M. Bolin, Board Liaison, NABP

**Noon - 1:15 PM**

Buffet Luncheon

**1:15 - 2:45 PM**

The Federal Legislative Process: Understanding the Beltway

Speakers: Catherine Polley, Chief Policy Officer and Senior

Vice President of Government & Professional

Affairs, American Pharmacists Association

Kristina Lunner, Senior Director, Government

Affairs, American Pharmacists Association

**3 - 4:30 PM**

Meeting Your Congressional Leadership: Tools for a Successful Encounter

Speaker: John Coster, Vice President, Federal Affairs and Public Policy, Rite Aid Corp

**6:30 - 8:30 PM**

Welcome Reception

*(Buffet dinner will be served.)*

### Monday, September 17

**7 - 9 AM**

Registration/Information Desk Open

**7 - 8 AM**

Continental Breakfast

**8 - 8:45 AM**

Remarks of FDA Representative

Speaker: Andrew C. von Eschenbach, Commissioner, Food and Drug Administration

**9 - 11 AM**

Roundtable Discussion: Political Platforms Meet Current

Issues in Pharmacy Regulation

*Sponsored by Abbott Laboratories*

*Program #205-000-07-007-L03P*

*(0.2 CEUs – 2 contact hours)*

**11:15 AM - 12:15 PM**

Moving Forward with Emergency Preparedness

**12:15 PM - 5 PM**

Open time to meet with Congressional Leadership

### Tuesday, September 18

**7 - 8 AM**

Registration/Information Desk Open

**7 - 8 AM**

Continental Breakfast

**8 - 8:45 AM**

Remarks of DEA Representative

Speaker: Karen P. Tandy, JD, Administrator, Drug Enforcement Administration

**8:45 - 9:45 AM**

Building the Infrastructure for Health Information Exchange

*Program #205-000-07-08-L03P*

*(0.1 CEUs – 1 contact hour)*

Speaker: Brent I. Fox, Assistant to the Dean for Educational Technology, Auburn University – Harrison School of Pharmacy

**10 - 11 AM**

111<sup>th</sup> Congress and the New Administration: What to Expect

**11 AM - noon**

FDA Discussion on Compounding

**Noon- 12:15 PM**

Closing Remarks

**12:15- 5 PM**

Open time to meet with Congressional Leadership

Program Subject to Change



NABP and the NABP Foundation are approved by the Accreditation Council for Pharmacy Education (ACPE) as providers of continuing pharmacy education. ACPE Provider Number: 205. Participants may earn up to 4.5 hours of ACPE-approved continuing education credit from NABP. Participants in continuing pharmacy education programs will receive credit by completing a "Statement of Continuing Pharmacy Education Participation" and submitting it to NABP. A validated Statement of Continuing Pharmacy Education Credit will be sent as proof of participation within approximately six weeks. Full attendance and completion of a program evaluation form for each session are required to receive continuing pharmacy education credit and a Statement of Continuing Pharmacy Education Credit.

**Continuing Legal Education (CLE) Policy:** NABP staff will be available to assist attendees on an individual basis to apply for CLE credit for attending conference CE sessions. To apply for CLE credit, attendees must initiate the program approval process in their own states by completing and submitting the appropriate application materials and forms. NABP will provide documentation as necessary.

## 2007 Fall Legislative Conference Online Registration Available


Online registration is available for the NABP 2007 Fall Legislative Conference, which will be held September 16-18, 2007, at the Hyatt Regency Crystal City in Arlington, VA. The Conference will provide attendees with the opportunity to further educate themselves on issues of importance as well as develop their ability to effectively speak with senators and representatives. In addition, up to 4.5 Accreditation Council for Pharmacy Education-approved

continuing education credits may be earned.

Online registration is available on the NABP Web site at [www.nabp.net](http://www.nabp.net). Quick and easy online registration also offers three payment options: (1) mailing in payment, (2) using a credit card, or (3) paying on site.

Attendees may make their Hyatt Regency Crystal City reservations online through the group room reservation rate link located in the Meetings section of the NABP Web site or call the hotel at 703/418-1234

or 1-888/591-1234. Attendees are asked to mention that they are attending the NABP Fall Legislative Conference.

Special air travel and rental car rates are available through the NABP designated travel agency Options Travel at 1-800/544-8785. When calling Options Travel, it is recommended that attendees identify themselves as registrants of the NABP Fall Legislative Conference and mention the NABP meeting code number, FLC07. 

## Avian Influenza Pandemic

(continued from page 135)

products. By encouraging the manufacture of licensed influenza vaccines, FDA aims to enhance the industry's capacity to produce more doses of seasonal influenza vaccines and, by extension, to contribute to the nation's pandemic preparedness.

Both guidances recommend using recent technologies such as cell culture and recombinant manufacturing to enhance the development and evaluation of vaccines. They also recommend adding substances that improve the immune response from the vaccine (novel adjuvants).


The guidances describe conventional and accelerated approval pathways to vaccine licensure. Companies selecting the conventional pathway must provide clinical evidence that the vaccine prevents influenza. Adequate and well-controlled clinical trials are also required for accelerated approval but companies may use a biological indicator – such as immune response to the vaccine – to predict effectiveness, an approach that may reduce the vaccine's development time. Further clinical studies are then required to verify the vaccine's clinical benefit.

The guidances direct manufacturers to submit a new Biologics License

Application (BLA) for the initial licensure of a pandemic or seasonal influenza vaccine to ensure that each pandemic and seasonal vaccine has its own trade name and labeling.

For companies with United States-licensed seasonal influenza vaccines, the pandemic guidance outlines the regulatory pathway for obtaining licensure for a new pandemic vaccine for which the manufacturing process is the same as for the seasonal vaccine. For manufacturers developing vaccines using a new manufacturing process, both guidance documents explain the process for obtaining licensure using the accelerated approval pathway.

The guidance documents represent FDA's ongoing efforts under its Critical Path Initiative to translate scientific advances, such as cell-culture derived and recombinant vaccine technologies, into new medical products with shorter approval time frames.

The two documents are available on the FDA Web site: "Guidance for Industry: Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines" at [www.fda.gov/cber/gdlns/trifluvac.htm](http://www.fda.gov/cber/gdlns/trifluvac.htm), and "Guidance for Industry: Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines" at [www.fda.gov/cber/gdlns/panfluvac.htm](http://www.fda.gov/cber/gdlns/panfluvac.htm). 

## OIG Exclusion List Raises Concerns for State Boards of Pharmacy

**NABP will soon put forth efforts to work with the Office of the Inspector General (OIG) to prevent pharmacists disciplined and reinstated by their respective state boards of pharmacy from being further penalized by OIG.**

At the 103<sup>rd</sup> Annual Meeting in Portland, OR, NABP passed Resolution No. 103-1-07, "OIG Exclusion Programs and Board of Pharmacy Disciplinary Actions," in an effort to distinguish the authority of the state boards of pharmacy from that of OIG in regard to disciplinary matters.

### LEIE Ties States' Hands

Title XI of the Social Security Act authorizes OIG to exclude entities convicted of program-related crimes, patient abuse or neglect, and other felonies from participation in any federal health care program, including Medicare and Medicaid. OIG maintains a List of Excluded Individuals/Entities (LEIE), barring those listed from participation in federal health care programs.

As a result, pharmacists who have been disciplined by boards of pharmacy for violations unrelated to fraud or abuse of federal

health care programs, and who have complied with conditions mandated by boards, have been subsequently barred by OIG from participating in federal health care programs for those same violations by means of inclusion on the LEIE. Inclusion on the LEIE may subject pharmacists to additional punitive actions beyond those imposed by the boards and, in effect, restricts them from practice after the boards have reinstated their licenses.

### NABP Addresses Question of Authority

As stated in the resolution, "NABP and boards of pharmacy are concerned that these actions overall demonstrate a lack of recognition by the OIG of the pharmacy boards' role in protecting the public health and the authority of boards of pharmacy to regulate pharmacists."

The NABP Executive Committee and the

2005-2006 Committee on Law Enforcement/Legislation previously submitted a formal recommendation to OIG to defer disciplinary matters unrelated to federal program abuse to the state boards. As no policy change ensued, NABP intends to follow up and pursue a dialogue with OIG and with state and national pharmacy stakeholders, congressional representatives, and other constituencies.

If deemed necessary, NABP resolves to work with these entities to develop legislation amending applicable provisions of the Social Security Act to support collaboration between the state boards of pharmacy and OIG. The objective of NABP in this effort is to ensure that pharmacists disciplined by boards of pharmacy for certain violations are not automatically subject to OIG exclusionary actions.

### OIG Holds Employment, Reinstatement Strings

Individuals and entities named to the LEIE are ineligible for reimbursement from federal health care

programs. If they do submit such claims, they may be subject to fines of \$10,000 for each item or service furnished during the period of exclusion. Further, health care providers that employ or enter into contracts with excluded individuals or entities to provide items or services to federal program beneficiaries are also subject to fines. In effect, OIG exclusion often precludes employment of excluded individuals in any capacity by a health care provider that receives reimbursement from any federal health care program.

Once excluded, individuals and entities must apply for reinstatement and receive authorized notice from the OIG that reinstatement has been granted before they are eligible to again participate in Medicare, Medicaid, or other federal health care programs.

To request reinstatement, excluded parties may write to OIG within 90 days of the expiration of the minimum period of exclusion to request statement and authorization forms, which must be completed,

notarized, and returned to OIG. OIG then evaluates the information provided in the forms and sends written

If deemed necessary, NABP resolves to work with these entities to develop legislation amending applicable provisions of the Social Security Act to support collaboration between the state boards of pharmacy and OIG.


notification indicating its final decision on the reinstatement request. If reinstatement is denied, excluded parties are eligible to reapply after one year.

### LEIE Accessible on OIG Web Site

OIG maintains the LEIE in two formats: the online database enables users to search by the name of an individual or business and indicates whether an exclusion is currently in effect. If a match is made on an individual, the database can verify with an individual's Social Security number (SSN) that the match is unique. Employer Identification

Numbers (EIN) (also known as Taxpayer Identification Numbers [TIN]) are included for recently excluded entities. The online searchable database contains all individuals and entities currently excluded. Individuals and entities who have been reinstated are removed from the LEIE.

The second format, the downloadable database file, enables users to copy the LEIE file to a personal computer. It includes all individuals and entities that were excluded as of the date the file was produced. Further exclusions are posted on the Web site on a monthly basis, as are reinstatement data files. Supplements list all individuals and entities excluded or reinstated during each month subsequent to the original LEIE. A continuously updated file is also available. The downloadable database file does not contain SSNs or EINs; only the online searchable database can verify specific individuals or businesses by SSN or EIN.

The LEIE and more information on the OIG Exclusion Program are available on the OIG Web site at [oig.hhs.gov/fraud/exclusions.html](http://oig.hhs.gov/fraud/exclusions.html). 

nabp newsletter

## North Carolina Board Requires VIPPS Accreditation for Internet Pharmacies

Internet pharmacies in North Carolina must comply with substantial new requirements, as described in 21 NCAC 46.1601, to receive or renew pharmacy permits. The rule took effect April 1, 2007.

In addition to all of the other requirements for issuance and renewal of a pharmacy permit imposed by statute and rules of the Board, the Board shall not issue any original or annual renewal pharmacy permit to any Internet pharmacy until the Board is satisfied that:

1. the Internet pharmacy is accredited by the NABP Verified Internet Pharmacy Practice Sites™ (VIPPS®) program;
2. the Internet pharmacy has certified the percentage of its annual business conducted via the Internet on a form required by the Board, when it applies for permit or renewal; and
3. the Internet pharmacy has provided the Board with the names, addresses, Social Security numbers, phone numbers, facsimile numbers, e-mail addresses, and titles of all principal

corporate officers of the Internet pharmacy; of all principal officers of any company, partnership, association, or other business entity holding any ownership interest in the Internet pharmacy; and of any individual holding any ownership interest in the Internet pharmacy.

More information on the VIPPS accreditation program is available on the NABP Web site, [www.nabp.net](http://www.nabp.net).

*The above information was taken from the North Carolina Board of Pharmacy News, Volume 29, Number 1, July 2007.*

## States Adopt Legislation to Tighten Licensing Requirements for Wholesalers

● **Colorado:** Senate Bill (SB) 217, Prescription Drug Wholesalers, was signed by the governor on May 25, 2007. The legislation states that prior to issuing a wholesaler license to an applicant, the Colorado State Board of Pharmacy or a Board-approved accreditation body may conduct a physical inspection of the wholesale distribution facility at the business address provided by the applicant. Nothing in this subsection would preclude the Board

from inspecting a wholesaler.

● **Kansas:** SB 11 was adopted on May 10, 2007. The legislation provides the Kansas State Board of Pharmacy with the authority to establish more stringent licensing requirements for wholesale distributors seeking to conduct business in Kansas. It also gives the Board the authority to recognize a third party to inspect and accredit wholesale distributors. While the language does have definitions that relate to the normal distribution channel concept, the bill does not explicitly require pedigrees.

## North Carolina Board Investigates Compounding Violations

The North Carolina Board of Pharmacy holds pharmacists accountable for taking affirmative steps to determine whether compounded medications are being resold.

The Board is investigating several pharmacies, both in-state and out-of-state, that regularly compound prescription veterinary drug products for resale. This practice violates North Carolina law 21 NCAC 46.1810(1), which states that “[c]ompounded

drug products shall not be offered to other entities for resale.”

In a recent disciplinary action concerning the resale of compounded prescription drugs, the Board ruled that negligence in the practice of pharmacy can result from a pharmacist’s failure to take affirmative steps to determine whether compounded products are being resold. The Board further stated that it “recognized that compounding pharmacists can, and do, provide valuable services to patients. But with the ability to compound medications for patients comes a tremendous responsibility to ensure that these products are safe and used appropriately.”

The Board also is investigating a handful of out-of-state pharmacies lacking North Carolina permits that have been regularly shipping compounded products (for human and veterinary use) into the state. A recent investigation of one such pharmacy resulted in its discontinuing business in North Carolina. State law 21 NCAC 46.1607(a) mandates that out-of-state pharmacies that send prescription medications into North Carolina must have an out-of-state pharmacy permit. Shipping compounded products into the state may also violate statutes and regulations pertaining to wholesale drug distributors. ⓘ

## Death in Canada Tied to Counterfeit Drugs Bought via Internet

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA) about the risks involved in buying medications over the Internet, the association states in a July 6, 2007 press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites™ program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

## FDA Sets Standards for Dietary Supplements

Food and Drug Administration (FDA) recently issued a final rule requiring current

good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients

used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredient.

FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at [www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments).

The final CGMP and the interim final rule are effective as of August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at [www.cfsan.fda.gov/~dms/dscgmps7.html](http://www.cfsan.fda.gov/~dms/dscgmps7.html) and a fact sheet at [www.cfsan.fda.gov/~dms/dscgmps6.html](http://www.cfsan.fda.gov/~dms/dscgmps6.html).

## FDA, EC, EMEA to Expand Regulatory Cooperation

FDA, the European Commission (EC), and the European Medicines Agency (EMA) have agreed to expand their

current cooperative activities in several areas.

At a meeting June 14-15, 2007, FDA and EC reviewed the past year's activities under the existing Implementation Plan for the confidentiality arrangement. The goals of the initiative are to promote and protect public health, reduce regulatory burden and costs, and bring innovative products to patients in a timely manner. The initiative also promotes sharing of important safety information about medicinal products among the parties.

Building upon previous collaborative achievements in vaccines, oncology, and pharmacogenomics, the agencies agreed to collaborate further in the areas of pediatrics and medicinal products for rare diseases ("orphan drugs"). Furthermore, scientific dialogue has been widened to include extensions of therapeutic indications and risk management plans.

Based upon the newly adopted pediatric legislation in the EC, a "Principles of Interactions" document that will facilitate the timely exchange of information on scientific and ethical issues for pediatric therapeutics has been finalized and is available on the FDA Web site at [www.fda.gov/oia/pediatricsIP.htm](http://www.fda.gov/oia/pediatricsIP.htm).

(continued on page 142)

**Around the Association**

**Executive Director Changes**

**David E. Potters, JD**, has been appointed executive director of the West Virginia Board of Pharmacy. Potters received a bachelor of arts degree in psychology from West Virginia University and a doctor of jurisprudence degree from Ohio State College of Law. He has practiced law in Charleston, WV, since 1998. Potters filled the vacant position left by William T. Douglass, Jr, in June 2007.

**ACE Member Honored**

On June 21, 2007, **Stephen M. Gross, EdD, MA**, dean of the Long Island University Arnold & Marie Schwartz College of Pharmacy and Health Sciences, was honored at a benefit dinner that launched the Stephen M. Gross Endowment Fund for Pharmacy Policy. Gross was largely responsible for the development of the Pharmacy College Admissions Test. He has been involved with several advisory boards and committees including the NABP Advisory Committee on Examinations. A nationally recognized pharmacy educator, Gross earned


(continued on page 143)

**Date and Locations Announced for December FPGEE Administration**

The next Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) will be administered on Saturday, December 1, 2007, at three testing sites: Brooklyn (New York City), NY; Northlake (Chicago), IL; and San Jose, CA. The deadline to register

for the December 1 FPGEE is October 19, 2007; however, please note that seating for the examination is limited and registration will be closed once all test sites have reached capacity.

Additional information regarding the FPGEE and

the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) is available in the FPGEC Application Bulletin and in the frequently asked questions section of the NABP Web site at [www.nabp.net](http://www.nabp.net). 

**Professional Affairs Update**

(continued from page 141)

**Canadian Researchers Seeking Input from US Pharmacists**

Just as the role of the pharmacist has evolved in the United States in recent years, the role of the Canadian pharmacist is now shifting from that of pharmaceutical product expert to pharmacy care expert. As such, Canadian pharmacists are now assuming even more complex roles as members of primary health care teams. In addition, new legislation, new technology, and a better informed public are affecting how pharmacists deliver services to their patients.

As innovative models of pharmacy practice are emerging to support pharmacists in their new roles, the Canadian government is funding Moving Forward: Pharmacy

Human Resources for the Future, an in-depth examination of the factors contributing to change and the future challenges for pharmacy human resources in Canada. The identification of future models in both Canadian and international health care systems, along with an understanding of their supports and facilitators, are critical components of this study; therefore, the Moving Forward research team is seeking US pharmacists who are delivering pharmacy services in new ways, or playing new roles in patient care in any practice setting. Innovations could include:

- Broadening the pharmacist's role,
- Initiatives in continuity of care (eg post-discharge from a health facility),
- Cognitive services outside the pharmacy,
- New uses of information/communication technology,

- Medication reconciliation,
- New initiatives in chronic disease management,
- Health Promotion/Disease Prevention,
- Broadening the role of pharmacy technicians,
- Training of pharmacists for new roles, or
- Other practice innovations.

These innovations might be pilot projects, academic studies, or established local practices – the common thread will be that they use pharmacists' skills in new ways.

If you are participating in, or know of an innovative practice model, the Canadian research group would like to hear from you. Please send a short description and contact information to either Barbara Wells ([info@bawellshealthcare.ca](mailto:info@bawellshealthcare.ca); tel: 613/233-0348) or Jim Blackburn ([jblackburn@sasktel.net](mailto:jblackburn@sasktel.net); tel: 306/374-6327). Please respond by Friday, September 14. 

## Around the Association

(continued from page 142)

his bachelor of science, master of arts, and doctor of education degrees from Columbia University.

### Board Member Appointments

**DeeAnn Wedemeyer-Oleson, RPh**, was appointed a member of the Iowa Board of Pharmacy. Her term expires on April 30, 2010. Wedemeyer-Oleson replaces Michael J. Seifert.

**Margaret “Peggy” Whitworth** was appointed a public member of the Iowa Board of Pharmacy. Her term expires on April 30, 2010. Whitworth replaces Kathleen Halloran.

**Barbara A. Bilek, PharmD**, was appointed a member of the Missouri

Board of Pharmacy. Her term expires on June 1, 2012. Bilek replaces Douglas Lang.

**James D. Riddle, RPh**, was appointed a member of the Missouri Board of Pharmacy. His term expires on April 25, 2012. Riddle replaces Timothy Kock.

### Board Officer Changes

The **Alaska Board of Pharmacy** elected the following officers to the Board:

- **Gary Givens**, Chairperson
- **Mary Mundell**, Vice Chairperson
- **Cindy Bueler**, Secretary

The **Arizona State Board of Pharmacy** elected the following officers to the Board:

- **Thomas J. Vanhassel, RPh**, President
- **Zina S. Berry, PharmD, RPh**, Vice President

The **California State Board of Pharmacy** elected the following officers to the Board:

- **William Powers** (Public Member), President
- **Ruth M. Conroy, PharmD**, Vice President
- **D. Timothy Dazé** (Public Member), Treasurer

The **Iowa Board of Pharmacy** elected the following officers to the Board:

- **Paul Abramowitz, PharmD**, Chairperson
- **Leman Olson, RPh**, Vice Chairperson

The **Maine Board of Pharmacy** elected the following officer to the Board:

- **Lori McKeown, RPh**, President

The **Michigan Board of Pharmacy** elected the following officers to the Board:

- **Laura A. Shaw, RPh**, Chairperson
- **David S. Bach, RPh**, Vice Chairperson

The **Minnesota Board of Pharmacy** elected the following officers to the Board:

- **Betty L. Johnson, RPh**, President
- **Gary S. Schneider, RPh**, Vice President

The **Missouri Board of Pharmacy** elected the following officers to the Board:

- **Gary Sobocinski, RPh**, President
- **Elaina Wolzak, RPh**, Vice President

The **Nebraska Board of Pharmacy** elected the following officers to the Board:

- **Kevin Borcher, RP**, Chairperson
- **Roger Kaczmarek, RP**, Vice Chairperson (®)

## Legal Briefs

(continued from page 133)

the limited disclosure to the Massachusetts board.

Finally, the licensee argued that many complaints filed against physicians are unsubstantiated, may take years to investigate, and do not ultimately result in administrative discipline. He argued that it may take years to inform another state licensing authority whether formal administrative disciplinary

proceedings arose out of such complaints due to the complexity of voluminous medical records and procedures. The court not only noted these arguments, but held that such arguments provided further justification for its holding that complaints are subject to disclosure. In doing so, the court emphasized the public protection nature of the board and the necessity to ensure competence in those wishing to practice medicine. It also recognized that many

practitioners seek licensure in multiple jurisdictions and that the Iowa legislature acknowledged board responsibilities to disclose information to other states' licensing authorities that may aid them in making licensure eligibility determinations.

Accordingly, the court held that complaints pending investigations relate to licensee discipline and are subject to disclosure to other state licensing authorities under circumstances where such

licensees seek licensure in another jurisdiction. Boards of pharmacy are encouraged to understand the application of confidentiality laws for purposes of disclosure. In this case, disclosure to other states' licensing authorities was justified under the law. Indeed, disclosure was not merely allowed under law, but referenced as a responsibility of the board.

*Doe v Iowa Board of Medical Examiners*, 2007 WL 1792495 (IA 2007) (®)

### NEWLY ACCREDITED VAWD FACILITIES

The following facilities were recently accredited through the NABP Verified-Accredited Wholesale Distributors® (VAWD®) program:

**AmerisourceBergen Drug Corporation**  
Romeoville, IL  
Paducah, KY  
Lockbourne, OH  
Accredited July 16, 2007

**Cardinal Health 200, Inc dba Cardinal Health**  
Ontario, CA  
Accredited July 11, 2007

**Drogueria Central, Inc**  
Monroe, OH  
Accredited June 21, 2007

**Integrated Commercialization Solutions dba ICS**  
Brook, KY  
Accredited June 12, 2007

**McGuff Company, Inc**  
Santa Ana, CA  
Accredited July 2, 2007

**McKesson Corporation**  
Memphis, TN  
Accredited May 24, 2007

**McKesson Corporation dba McKesson Drug Company**  
Carol Stream, IL  
Accredited May 24, 2007

**McKesson Packaging Services**  
Concord, NC  
Accredited July 11, 2007

**McKesson Specialty Distribution, LLC**  
Memphis, TN  
Accredited May 24, 2007

**Patterson Logistics Services, Inc**  
Mt Joy, PA  
Accredited July 11, 2007

**PharmPak, Inc**  
San Rafael, CA  
Accredited June 28, 2007

**Rite Aid of Maryland, Inc dba Rite Aid Mid-Atlantic Customer Support Center**  
Perryman, MD  
Accredited July 11, 2007

**RxC Acquisition Company dba RxCrossroads Third Party Logistics Division**  
Louisville, KY  
Accredited June 21, 2007



**Sentry Logistic Solutions, Inc**  
Indianapolis, IN  
Accredited May 24, 2007

**STAT Pharmaceuticals, Inc**  
Santee, CA  
Accredited July 11, 2007

**Theracom, Inc dba Theracom**  
Rockville, MD  
Accredited June 12, 2007

**VWR International, Inc**  
Batavia, IL  
Accredited July 11, 2007

A full listing of accredited VAWD facilities is available on the NABP Web site at [www.nabp.net](http://www.nabp.net).



## nabp newsletter

National Association of Boards of Pharmacy  
1600 Feehanville Drive  
Mount Prospect, IL 60056

### FALL LEGISLATIVE CONFERENCE

Registration available at [www.nabp.net](http://www.nabp.net).