NABP Names Internet Drug Outlets Operating in Conflict with Patient Safety and Pharmacy Practice Standards

On May 16, 2008, NABP launched the Internet Pharmacies section of its Web site, empowering patients to make informed choices and educating them on the potential dangers of buying medicine online. As of July 21, the site lists 400 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby putting those who use these sites in danger of purchasing drugs that could cause patients serious harm or even death.

NABP developed these standards for its new Internet Drug Outlet Identification™ program with input from its member boards of pharmacy, interested stakeholders, and regulatory agencies, including the US Food and Drug Administration (FDA) and the US Drug Enforcement Administration. Internet drug outlets that appear to be operating in conflict with these criteria are listed on the NABP Web site as “not recommended.” NABP has identified another 330 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the “not recommended” list.

In July, NABP added a mid-level group to its categorization of Web sites selling prescription medicine called the Reviewed Internet Pharmacy Practice Sites™. These sites appear to comply with state and federal laws and NABP patient safety and pharmacy practice standards based on a review of the public information available.

NABP advises patients to use these Reviewed Internet Pharmacy Practice Sites with caution, as information needed to conclusively determine the legitimacy and legality of these sites may not have been available.

The Association asks patients to immediately report to NABP, via its online Report-a-Site feature, any activity indicating that the sites do not comply with state and federal laws or NABP criteria, for example, if the sites dispense

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Drug Outlets Operating in Conflict

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• medication without a valid prescription or dispense non-FDA approved medicine. NABP will continue to monitor the activity of these sites to determine continued inclusion on this list.

NABP continues to recommend that patients buying medicine online use only Internet pharmacies accredited through the Verified Internet Pharmacy Practice Sites™ (VIPPS®) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as “recommended.”

Of the 400 Internet drug outlets currently listed as “not recommended”:

• 369 do not require a valid prescription – a valid prescription is a legal requirement for dispensing prescription drugs in the US;

• 234 offer foreign or non-FDA-approved drugs – (which includes those from Canadian sources) – it is illegal to sell such drugs in the US. Though some Canadian Internet drug outlets may be reputable sites, NABP does not recognize these because the drugs they sell are not FDA approved. In addition, some Internet outlets appearing to be located in Canada and shipping from Canadian sources may, in fact, be shipping from foreign sources.

• 158 have a physical address located outside of the US – to sell prescription drugs legally in the US, a pharmacy must be licensed in each state where it practices pharmacy.

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2008 Annual Report on NABP Legal Affairs

The following report was distributed at the 104th Annual Meeting, held May 17-20, 2008, in Baltimore, MD.

In 2006, NABP established a Legal Affairs Department to manage the day-to-day legal activities and coordinate projects with outside legal counsel, Atkinson & Atkinson. The Legal Affairs Department is overseen by Moira Gibbons, PharmD, JD, legal affairs senior manager, and manages a variety of legal matters including program and vendor contracts, trademark and copyright management, and other similar matters.

NABP staff personally registers the North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), and Pharmacy Curriculum Outcomes Assessment® (PCOA®) mechanism with the United States Copyright Office. Legal Affairs staff is also managing and revising, where applicable, nondisclosure agreements required for staff, committee members, and examination candidates and managing the development and execution of contracts with the states for NABP services such as the competency assessment examinations and state newsletter program. As a result of these efforts, all states in the United States, the district of Columbia, Puerto Rico, Guam, and the Virgin Islands are currently under contract for the provision of the NAPLEX and, for those jurisdictions utilizing it, the MPJE.

NABP continues to protect its program trademarks through cease and desist letters and other legal means. The Association targeted organizations that are holding out their products or services as being affiliated with or endorsed by NABP, and has successfully halted a number of Web sites claiming accreditation through the Association’s Verified Internet Pharmacy Practice Sites™ (VIPPS®) program. Working jointly with the boards of pharmacy enables NABP to share information with pharmacy regulators and make sound decisions regarding accreditation, which most recently resulted in NABP denying accreditation and disqualifying from accreditation wholesale drug distributors that did not meet the Association’s Verified-Accredited Wholesale Distributors® (VAWD®) program standards.

Litigation and Other Legal Matters

NABP successfully secured the reinstatement of its tax exempt status from the Illinois Department of Revenue in regard to property taxes for the Association’s headquarters. NABP earned 501 (c)(3) status as a charitable and educational organization in August 1985. The state of Illinois also recognized this determination and has applied it to exempt NABP from state sales tax.

As reported to the member boards, NABP initiated litigation directed against the Board of Regents of the University System of Georgia and affiliated individuals, as well as two professors. The litigation was initiated because NABP maintains that the integrity of the NAPLEX and MPJE were compromised. On April 18, 2008, the United States District Court for the Middle District of Georgia granted the Board of Regents the request to dismiss NABP’s copyright infringement claims against the Board of Regents, stating the court lacked jurisdiction over the Board of Regents; however, the court denied the same request filed by the individual professors. Accordingly, the injunction prohibiting the professors from engaging in copyright infringement remains in place, and NABP’s case against the professors, which seeks damages for such conduct, will continue in District Court. NABP will file a motion asking the court to reconsider its decision regarding the Board of

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Boards of pharmacy can benefit from the legal analyses of certain criminal and/or civil matters that have relevance to the regulatory mandates imposed on such boards. Of course, the differences between criminal prosecutions and administrative prosecutions are quite pronounced. Criminal prosecutions involve allegations of a violation or violations of the criminal code and convictions may result in loss of liberty. Thus, criminal proceedings require adherence to strict procedural and substantive rules designed to protect the rights of those accused of violating applicable criminal statutes. Successful criminal prosecutions of serious matters usually establish the necessary grounds for subsequent administrative sanctions by regulatory boards against licensees. Similarly, the board must follow the appropriate procedures in pursuing the disciplinary action. Communication and coordination between the entities involved in criminal and administrative investigations may be essential to ensure successful outcomes.

Communication regarding ongoing investigations may also involve communications between additional impacted regulatory boards. Complex schemes involving drug diversion and the use of the Internet not only may involve differing professions, they will likely involve differing states and, perhaps, countries. For example, communications among allied boards (medicine, pharmacy, nursing, veterinary medicine, and others) are essential in this technologically advanced global society. On many occasions, multiple boards of differing professions from the same state are involved. Further, boards from other states or jurisdictions may also be required for a successful conclusion to the matter.

Whether the issues relate to interpreting overlapping scopes of practice and the need for ancillary boards to regulate in unison, or the necessity of boards that regulate in the “chain” of events to coordinate licensure and investigative information, the public protection mission of the regulatory community must be paramount. One place to start such a dialogue of coordinated efforts and a continued public protection focus is a more thorough understanding of ancillary processes that may provide a basis for informed action, and perhaps inaction, on the part of pharmacy boards.

At times, the criminal sector and the administrative proceedings must coordinate their efforts to ensure that one does not impede the other. In order for boards of pharmacy to better understand the nuances of a criminal prosecution, the 2008 NABP Report of Counsel will focus on criminal indictments related to activities that may also subject the accused physicians, pharmacists, pharmacy owners, and others to administrative consequences. The
defenses propounded by these criminally accused defendants may be enlightening to NABP members and provide insight into potential defenses that may be argued in administrative proceedings.

Twenty-one defendants were indicted on numerous counts related to conspiracy to distribute Schedule III and IV controlled substances in connection with sales over the Internet. Specifically, the defendants included three physicians, three pharmacists, eight business owners, and seven corporations who were charged, in various combinations of defendants, with distribution of controlled substances in violation of Title 21 USC section 841 and section 821 of the Controlled Substances Act (CSA). Section 841 provides in pertinent part:

(a) Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally –

(1) to manufacture, distribute, or dispense, or possess with intent to distribute, or dispense, a controlled substance.

The method used for distribution of the controlled substances involved interaction via the Internet. Once the customer found an Internet site offering the diet and/or sleeping pills for sale (of which more than 400 such sites were connected to the defendants), the customer was redirected to another site (operated by one of the defendants) to fill out a “Patients Questions” page. This page was also controlled by one of the defendants, and customers complete a questionnaire about their date of birth, height, weight, and sex. Thereafter, the customer completed 14 additional questions related to medical conditions, allergies, other medications and/or conditions, blood pressure conditions, pregnancy, and acknowledged the existence of the Patient Responsibility Statement, Waiver and Consent Agreement, and Privacy Statement.

The purpose of the height and weight questions was to determine the customer’s body mass index. Customers were provided with the opportunity to change the responses to the height and weight questions until they achieved a body mass index accepted by the Web site. The answers to the questions were never checked for accuracy by anyone, specifically the physicians reviewing the questionnaires.

Upon completion of the questions, the customer was directed to another Web site whereby the payment options were presented and processed. Once payment was received, a licensed physician (not licensed in Florida) employed by one of the corporate defendants was purported to have reviewed the questionnaire and either approved or disapproved the order. Within hours of approval, the order was filled by a pharmacist located and licensed in Florida and shipped to the address indicated by the customer. Throughout the course of these events, there was no direct contact between the physician approving the request and the customer. In fact, the physicians approving the orders did so by logging onto a Web site where such orders were queued. Further, there was no direct contact between the customer and pharmacy/pharmacist filling the order.

The indictment alleges that during a two-year period between May 2002 and May 2004, a total of 122,194 prescriptions were written for more than nine million pills. For varying reasons, the defendants filed motions to dismiss the indictments that were addressed by the United States District Court for the Southern District of Florida.

Certain corporate defendants that operated the Web sites argued that section 841, which formed the basis for some of the criminal charges, was
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unconstitutional as applied to them because that portion of the CSA did not preclude the sale of prescription drugs over the Internet and where the physician and patient never meet face to face.

A licensed physician defendant argued that he could not be charged with illegal distribution based upon invalid prescriptions because physicians are legally able to dispense drugs. Also, the physician argued that the indictment failed to state an offense because the CSA does not permit a charge of “drug dealing” through the medical practice of prescribing controlled substances over the Internet without face-to-face encounters absent proof that the substances were distributed to addicts or abusers, citing a recent United States Supreme Court decision, Gonzalez v Oregon.

A pharmacist defendant argued for dismissal of the indictment based upon the fact that Congress did not intend to impose criminal sanctions based upon federal regulations for which there are no standards, also citing the Gonzalez decision.

The pharmacy owner defendants argued several issues in support of the motions to dismiss the indictments alleging that the prosecution’s conclusion that an online physician questionnaire does not amount to a legitimate physician-patient relationship was arbitrary. Specifically, these defendants argued that the matters at issue involved the practice of medicine, which are regulated and should be determined by the states, that the reliance upon online questionnaires does not amount to a breach of professional conduct, that the United States Attorney General cannot regulate the practice of medicine, and that the indictments fail to allege that the conduct of the defendants was “outside the course of professional practice” and “not for a legitimate medical purpose.”

Several other allegations regarding defense to the indictments were also made by certain defendants. Various defendants joined other defendants’ motions in an attempt to extract themselves from the indictments.

In addressing the myriad motions, the court began by summarizing the general rule related to criminal indictments and the fact that a criminal conviction cannot be upheld if the indictment upon which it is based does not set forth the essential elements of the offense. For purposes of a motion to dismiss, all allegations in the indictment are taken as true.

Citing the CSA, section 821, the court noted the requirement that persons (such as doctors and pharmacists) wishing to lawfully dispense or distribute controlled substances must register with the Attorney General. Authorization to dispense or distribute must be consistent with the individual’s registration. Under section 829, Schedule I, II, III, and IV controlled substances may be dispensed only by prescription, except when dispensed by a practitioner (other than a pharmacist).

In addressing the defendants’ motion to dismiss the indictments, the court turned its attention to the issue of whether a registered medical professional was subject to prosecution under section 841. Certain defendants argued that because registered physicians are legally able to dispense controlled substances, they cannot be guilty of violating section 841. The court summarized a previous United States Supreme Court ruling, Moore v U.S., which addressed this issue and held that Congress was concerned with the drug transaction, rather than the status of the defendant.

As noted and quoting the Moore decision, “Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels,” and that “registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.” Therefore, the Court held that there was “nothing in the statutory scheme or the legislative history [of the Controlled Substances Act] which justifies a conclusion that a registrant . . . is thereby exempted from prosecution under § 841 for the significantly greater offense of acting as a drug pusher.”

In the instant matter, the court held that the CSA contemplated the intent of limiting a registered physician’s dispensing authority to the course of a professional practice. It noted, since the Moore decision, additional case law has held that medical professionals, pharmacists, and lay persons can conspire with physicians to dispense or distribute drugs in violation of the CSA. In order for successful prosecutions under section 841, the government must prove three elements: (1) that the defendant distributed a controlled substance, (2) that he or she acted intentionally and (3) that he or she prescribed the drug without a legitimate medical purpose and outside the course of professional practice.

The court held that the determination of what conduct is outside the bounds of professional practice is left to the judge or jury. Further, the court also noted that an indictment need not necessarily specify the precise dates, locations, drug amounts, and purchasers to be valid.

Finally, the court noted that other judicial decisions dealing with prosecutions of physicians and pharmacists under section 841 have referred to an interpretive regulation promulgated by the Attorney General, which requires that every prescription for a controlled substance “be issued for a legitimate medical purpose by an individual practi-
tioner acting in the usual course of his professional practice.” However, several defendants cited Gonzalez v Oregon in support of the proposition that the Attorney General cannot undertake such interpretive regulations.

In Gonzalez, the Supreme Court held that the Attorney General’s interpretation of the CSA was not entitled to deference and that “the CSA’s prescription requirement does not authorize the Attorney General to bar dispensing controlled substances for assisted suicide in the face of a state medical regime permitting such conduct.” Accordingly, the court concluded that the Attorney General lacks the power to decide what the CSA says, but is charged with evaluating compliance with the statute in determining registration requirements and who to prosecute for alleged violations. Certain defendants in the instant case attempted to use Gonzalez in support of their motions to dismiss, arguing that the interpretive regulation addressing the legitimate medical purpose requirement for every prescription was also not entitled to deference.

With that background and foundation, the court turned its attention to the application of the referenced legal analyses to the motions to dismiss propounded by the defendants. Regarding the arguments that there is no law prohibiting the sale of drugs over the Internet, the court stated that such arguments ignore the fact that the indictments are premised upon the theory that the drugs were prescribed and distributed outside the bounds of professional medical practice, rather than any statute or rule that prohibits Internet sales. Because the issue of determining the bounds of professional practice is subject to decision by the jury, the court held that such is not ripe for a motion to dismiss the indictments.

Regarding the arguments by certain licensees that they cannot be charged with illegal distribution of drugs, but must be charged with illegally dispensing drugs, the court again rejected these arguments. It stated that such an argument was not ripe for decision at this time, but may be made at the conclusion of the government’s case. The court also agreed with the government’s argument that under this fact situation no lawful prescriptions were issued, thus allowing for the physician to be charged with illegally distributing (rather than dispensing) drugs.

The court also rejected the defendants’ argument that Gonzalez stands for the proposition that in order for the government to find the defendants were “drug dealing” it must prove that the substances were distributed to addicts or abusers. To the contrary, the court noted that Gonzalez, citing the CSA, held that the “prescription requirement is designed to ensure that patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse and preclude doctors from peddling to patients who crave the drugs for those uses.” Thus, the court held that the Gonzalez decision has no bearing on the indictments in the instant case and provides no basis for defendants’ motions.

Various other arguments by defendants were also rejected resulting in the denial of all motions to dismiss the indictments. Short of a plea, the defendants will stand criminal trial for the alleged wrongdoings related to the distribution of controlled substances via the Internet.

The complexities of the criminal process and the interpretation of statutory language are illustrated in this opinion. The proliferation of Internet activities subject to the administrative regulatory schemes of the states requires board members and staff to acquire a basic understanding of the application of the laws, both state and federal, to the state processes. The interplay between state and federal law both adds to the complexities of the process, while at the same time assisting in the interpretation of similar language. It is hopeful that aggressive administrative and criminal pursuit of illegitimate marketing, dispensing, and distribution of drugs will provide patients with a safe means of pursuing medical care.

United States v Hernandez, 2007 WL 2915854 (DC So District FL 2007) ③

Legal Briefs

Executive Director Changes

Mary K. Walker, RPh, has been appointed executive director of the Wyoming State Board of Pharmacy. Walker began her appointment on April 1, 2008. Prior to assuming this position, she was the director of pharmacy at Cheyenne Regional Medical Center for the past 20 years. In addition, she was a member of the Wyoming Board from 2005 to 2008 and is a past president of the Wyoming Pharmacy Association and Wyoming Society of Health-System Pharmacy. Walker has also served on the NABP Committee on Constitution and Bylaws and the Committee on Law Enforcement/Legislation. She has received numerous awards including the Bowl of Hygeia in 2004 and the Hospital Pharmacist of the Year in 1995. Walker obtained her bachelor of science degree in pharmacy from the University of Wyoming School of Pharmacy.

Board Member Appointments

- Robert Young, PharmD, MBA, FACHE, has been appointed a member of the Alaska Board of Pharmacy. Young’s appointment will expire on March 1, 2012.

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nabp newsletter

FDA’s ANDA Review Process Designed to Ensure Safety and Efficacy of New Generic Medications

The recent NABP article “Generic Substitution Raises Questions, Concerns for Some Patient Groups” concerning activities in the states and certain classes of medications created some controversy and was misinterpreted by some groups as NABP’s rejection of the process utilized by Food and Drug Administration (FDA) to approve generic medications. This was not the intent of the article nor is it the position of the Executive Committee and NABP. Quite the contrary, NABP firmly supports the drug approval process of FDA for innovator and generic products. The official position of NABP in regard to medication therapy decisions for all medications is that any decision to select or change a medication should be made in the best interest of the patient and take into account all of the critical factors relevant to such a decision including, but not limited to, the patient’s current medication therapy and the success and stability of the therapy, as well as patient factors such as allergies, contraindications, lifestyle, and costs.

The following article provides information on the FDA Office of Generic Drugs (OGD) and the Approved Drug Products with Therapeutic Equivalence Evaluations (or the Orange Book).

FDA Employs Rigorous Approval Criteria

The OGD’s review process begins when a manufacturer submits an Abbreviated New Drug Application (ANDA) to FDA (see chart on page 101). Reviewers must substantiate that the drug is chemically equivalent and bioequivalent. Chemically, the drug must contain the same active ingredients as the innovator drug; be identical in strength, dosage form, and route of administration; and have the same use indications. The generic drug also must meet the same batch requirements for identity, strength, purity, and quality as the innovator drug.

Performance of the drug is measured through bioequivalence data. Statistical analysis is performed to determine whether or not there are significant differences between the generic drug’s rate and extent of absorption and the branded drug’s rate and extent of absorption. In addition to tests on the generic drug’s formulation, its manufacturing, packaging, and testing sites must pass the same quality standards used to evaluate the innovator’s. Since costly preclinical and clinical studies were completed and documented when the innovator drug was approved, they are not required for the generic equivalent.

Based on this review process, generic drug products approved by FDA are determined to be therapeutically equivalent to the branded product. Therapeutically equivalent drugs generally may be substituted for each other with the expectation that the substituted product will produce the same clinical effect and safety profile when used according to the labeling.

FDA’s Generic Approval Process Developed With Expert Scrutiny

As seasoned practitioners will remember, FDA’s current generic drug approval process was developed in the late 1970s/early 1980s in response to the need for an authoritative reference on drug substitution. To begin meeting these needs, FDA developed the Orange Book. The Orange Book, first published in 1980 after extensive review and public commentary, includes definitions of the criteria used by FDA in evaluating therapeutic equivalence. At the initial publication, the ANDA was used to approve generic versions of drugs that had been approved for market between 1938-1962. Drugs approved after 1962 required a New Drug Application to demonstrate safety and efficacy.

The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) made the use of ANDAs for approval of all generic drugs possible. In addition, it required that a list of approved drug products be available to the public, and the Orange Book satisfies that requirement.

A three-day public hearing in 1986 revisited FDA’s method of determining bioequivalence for immediate release, solid oral dosage forms. With over 50 speakers, 800 participants, expert consultants, and special-topic forums, the hearing held the standards to high scrutiny. Expert participants found no need to modify the bioequivalence criteria used in the ANDA review process.

More Generic Medications on the Horizon

In October of 2007, FDA launched an initiative aimed at increasing the OGD’s review efficiency in order to bring more generic drugs to market more quickly. The Generic Initiative for Value and Efficiency (GIVE) is intended to “modernize and streamline the generic drug approval process” using existing resources, FDA states on its Web site. GIVE’s efforts are expected to result in more generic drugs approved in fiscal year 2008 and thus more options for consumers.
FDA's Generic Drug Review Process

With increasing numbers of generic drugs submitted for approval each year, review scientists, physicians, and pharmacists at the Food and Drug Administration’s (FDA) Office of Generic Drugs (OGD) are busier than ever, evaluating the drugs against rigorous criteria before approving their release to market. Due to such standards, generics, which now account for about half the prescriptions in the United States, come with FDA's assurance that they are as effective and safe as their branded equivalents. FDA’s review process is displayed in the above chart and begins when a manufacturer submits an Abbreviated New Drug Application.
Task Force Issues Recommendations to Curb Prescription Drug Diversion from Common Carriers

Truckloads of prescription medications are finding their way onto the black market due to carriers’ insufficient security measures, an NABP task force found. Communication among the boards of pharmacy and further data collection regarding drug cargo thefts are the first steps to grasping the scope of the problem, and subsequently identifying and implementing solutions, the task force advised.

Established in response to member state board of pharmacy approval of NABP Resolution No. 103-4-07, Prescription Drug Diversion from Common Carriers, in May 2007, the Task Force on Prescription Drug Diversion from Common Carriers met on November 8-9, 2007, at NABP Headquarters in Mount Prospect, IL, and again on April 21-22, 2008, at the Northbrook Hilton in Northbrook, IL. The task force issued several recommendations, which the NABP Executive Committee has approved, to address the problem.

The task force recommended that NABP partner with appropriate stakeholders to serve as a clearinghouse for reports of any theft, suspected theft, diversion, or significant loss of any prescription drug and that NABP develop a process that encourages the reporting of such incidents. Task force members felt that NABP would be an excellent resource to serve as a national clearinghouse for this type of data, which could then be made available to the appropriate entities to better protect the public. The task force recommended that NABP make the data available to the state boards of pharmacy and, when appropriate and applicable, to federal agencies and pharmacies in order to provide information and alerts on products that may be stolen or diverted and other diversion/theft activities.

The task force acknowledged that many prescription drug and controlled substance thefts go unreported. Even though DEA requires the reporting of all significant losses of controlled substances via DEA Form 106, many losses remain unreported due to the ambiguity of the term significant loss. Task force members identified several other reasons that licensees may not report losses, including fear of punitive action; confusion about which party in the wholesale chain of custody actually sustained the loss and at what point; confusion about which party is then responsible for reporting; and considering the loss a non-loss if it is covered by insurance, and not realizing it should be reported.

The task force further recommended amending the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) to more clearly define the roles and responsibilities of pharmacists and wholesale drug distributors in regard to diversion. Recommended were new definitions for the terms common carrier and significant loss and new language pertaining to reporting and recordkeeping requirements for pharmacists-in-charge and wholesale distributors when losses occur. The new reporting and record-keeping language mirrors language
in the federal regulations (21 CFR 1301.74), including the requirement that a theft or loss be reported “within one business day of discovery.” It was agreed that record-keeping provisions for wholesale distributors should be consistent with those for pharmacies. Task force members also discussed the relative merits of requiring licensure or registration of common carriers but concluded that it was inappropriate at this time.

The task force members also advised that NABP amend the wholesale distributor security provisions in the Model Act to incorporate a requirement that such distributors use common carriers that have a verifiable security system or that have been certified via a board-approved certification or accreditation program such as NABP’s Verified-Accredited Wholesale Distributors® (VAWD®) program.

The task force further recommended strengthening accreditation requirements for the VAWD program agreeing that VAWD criteria should be reviewed and revised to reflect amendments made to the Model Act regarding common carriers – specifically, that wholesale distributors must include in their contractual agreements with common carriers requirements that common carrier employees who handle prescription drugs undergo criminal background checks, initial and random toxicology screening, and security training.

The task force recommended that NABP partner with appropriate stakeholders to serve as a clearinghouse for reports of any theft, suspected theft, diversion, or significant loss of any prescription drug and that NABP develop a process that encourages the reporting of such incidents.

DEA Form 106 Now Available Online

Registrants may now electronically submit Drug Enforcement Administration (DEA) Form 106 online through the DEA Office of Diversion Control Web site to report the loss or theft of controlled substances.

To submit the form online, users must be registered with DEA and be authenticated by entering their DEA Number and registered last name or business name. Users then can provide background information and can choose from a list of common names of controlled substances to report the loss or theft.

Prior to submitting the electronic form, users must review it to ensure the information is correct. Upon submitting the form, they receive information on how to amend it if necessary. Users then print a copy of the submitted form that must be kept at the registered location to satisfy the federal two-year retaining period.

The electronic DEA Form 106 is available on the DEA Web site at https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp.

The following guest participants joined the task force for the follow-up meeting: Paul Arnold and Steve Hutter, United Parcel Service of America, Inc; Demetra Ashley, DEA; Dan Bellingham and Brian Cherico, Healthcare Distribution Management Association; Barry Boudreaux, RPh, Medco Health Solutions, Inc; Frank Devlin, CVS Caremark Corporation; Robert P. Giacalone, RPh, JD, and Carolyn Mcpherson, Cardinal Health; Bruce Gundy, AmerisourceBergen Corporation; Connie T. Jung, RPh, PhD, FDA; and Ronald Koziol, Federal Bureau of Investigation.

The task force report is available under News/Press on the NABP Web site at www.nabp.net.

The initial task force comprised the following individuals: Howard C. Anderson, Jr, RPh, North Dakota State Board of Pharmacy, chair; Wendy L. Anderson, RPh, Colorado State Board of Pharmacy; John R. Dorvee, Jr, PharmD, Vermont Board of Pharmacy; Edith G. Goodmaster, Connecticut Commission of Pharmacy; Edward G. McGinley, RPh, New Jersey Board of Pharmacy; Peter J. Orzali, Jr, RPh, Kentucky Board of Pharmacy; Frank A. Whitchurc, RPh, Kansas State Board of Pharmacy; Jack W. “Jay” Campbell IV, RPh, JD, North Carolina Board of Pharmacy; and Lloyd K. Jessen, RPh, JD, Iowa Board of Pharmacy, Executive Committee liaison.

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The task force report is available under News/Press on the NABP Web site at www.nabp.net.
Several state boards of pharmacy require pharmacies to implement continuous quality improvement (CQI) and peer review programs. Few boards, however, have the resources to inspect pharmacies to ensure that the programs are in place and operating as intended. To address this and other obstacles impeding the full potential benefits of CQI and peer review programs, an NABP task force recommends that the Association consider establishing an accreditation program to assist the boards in upholding pharmacy CQI standards in their jurisdictions.

The Task Force on Continuous Quality Improvement, Peer Review, and Inspecting for Patient Safety met December 6-7, 2007, at NABP Headquarters in Mount Prospect, IL. The task force was established in response to Resolution 103-5-07, Medication Error Reporting, which was approved by NABP membership at the Association’s 103rd Annual Meeting in May 2007. The four recommendations outlined in the task force report and approved by the NABP Executive Committee focus on establishing and maintaining uniform standards for pharmacy CQI and peer review programs.

The first recommendation of the task force is to modify the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) to revise certain definitions and to clarify guidelines pertaining to pharmacy CQI and peer review programs. The task force recommends expanding the definition of the practice of pharmacy to include “continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training” to reflect the expectation of forward progress to improve pharmacy operations in the interest of protecting the public health. Other recommended revisions included the addition or revision of the following definitions:

- **Peer review**: part of an outcome-based, CQI process that involves setting and periodically re-evaluating quality standards, identifying when those standards are not being met and for what reasons, recommending quality improvements, and ensuring improvements in patient care. Peer review “should not be a punitive activity or a performance evaluation.”

- **Peer review committee**: a group “that is authorized to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care.”

- **Quality-related event (QRE)**: “any departure from the appropriate dispensing of a prescribed medication,” regardless of whether it is corrected prior to delivery and/or administration of the medication, including a variation from the prescriber’s prescription drug order or a failure to identify and manage medication-related risks.

- **Quality self-audit**: an internal evaluation at a pharmacy to assess the effectiveness of the CQI program. The task force also recommends revisions to Section 3(j), Continuous Quality Improvement.
Program, to provide that “[c]ompliance with this section may be considered by the Board as a mitigating factor in the investigation and evaluation of a [QRE], (2) each pharmacy shall establish a CQI program for the purpose of detecting, documenting, assessing, and preventing QREs.” Minimum program provisions are specified in the report. Additionally, the revisions provide that “appropriately blinded” incidents of QREs shall be reported to a board-designated, nationally recognized error reporting program. The revisions also clarify the provisions pertaining to subsections (5) Quality Self-Audit, (6) Consumer Survey, and (7) Protection from Discovery, and adds subsection (8) Compliance with Subpoena.

The second recommendation offers a potential solution to task force members’ concerns regarding the boards’ limited resources to inspect pharmacies for adherence to CQI standards. It calls for NABP to “explore the possibility of developing and implementing a pharmacy accreditation program, in conjunction with the state boards of pharmacy, that will ensure pharmacies are operating in a manner consistent with CQI standards, decreasing the occurrence of [QREs] and ultimately increasing patient safety.”

A lengthy discussion ensued during the task force meeting on the topic of pharmacy accreditation for CQI. Some of the task force members noted increasing media attention on the prevalence of medication errors and mounting pressure on the boards of pharmacy to address the problem. Several participants felt that accreditation would eventually become a requirement of third-party payers, eg, pharmacy benefit management (PBM) organizations and/or Centers for Medicare and Medicaid Services (CMS). Many expressed concern that accrediting bodies whose focus is outside or much broader than the realm of pharmacy might step in to implement a pharmacy accreditation program, overstepping the regulatory authority of the state boards of pharmacy, if the boards themselves do not take on that task first.

“People want to be assured that there is a process in place to protect against medication errors,” said Rich Palombo, RPh, who served as Executive Committee liaison on the task force. “As we see the landscape changing, someone may step in and accredit pharmacies for medication therapy management or CQI more so for business interests than patient safety. If NABP and the boards don’t step in, other organizations are going to do it, and the boards are going to have very little input into this process.”

Task force members discussed the advantages of taking part in – and influencing the direction of – these changes on the professional and regulatory horizon. According to the members, accreditation of quality improvement processes in community pharmacy is inevitable. Consumers and payers are going to demand it and a leadership role should be taken before other organizations begin to define the standards, the members stated.

The task force members agreed that NABP would be the “optimal entity” to develop and implement such a program based on the successes of its durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation program; Verified-Accredit ed Wholesale Distributors® (VAWD®) program, and Verified Internet Pharmacy Practice Sites™ (VIPPS®) program. Members also cited the Association’s experience and knowledge of both chain and independent pharmacies, its available resources, its recognition by entities such as CMS and PBMs that may soon require pharmacy accreditation, and its reputation in the public eye as an independent and trustworthy, safety-oriented organization.

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**NABP Accreditation Program**
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As the cost of accreditation would fall to the pharmacies, task force member Amy Buesing, RPh, of New Mexico expressed concern that independent pharmacies may have difficulty meeting the standards and expenses. In response, Palombo noted that the Association’s DMEPOS accreditation program is the least expensive of all of the CMS-recognized accrediting bodies.

Following this discussion, the task force members voted unanimously in favor of NABP developing a nationwide pharmacy accreditation program to incorporate a standardized CQI program with the goal of minimizing QREs and improving patient safety.

The third recommendation of the task force advises NABP to consult with medication safety organizations such as the Institute for Safe Medication Practices (ISMP) to assist in developing a pharmacy accreditation program.

During the meeting, former NABP President Donna Horn, currently ISMP’s director of patient safety in community pharmacy, addressed the task force telephonically with a proposal involving the use of specially trained state inspectors to educate pharmacists in using the Ten Key Elements of the Medication Use System™. ISMP developed the Ten Key Elements to identify system components that must be addressed to ensure medication safety. The proposed program would involve the state boards of pharmacy, NABP, and ISMP working together to develop materials for inspectors to identify and evaluate safe practices in the community pharmacy setting and corresponding training workshops. It would also involve the development of educational modules for community pharmacies based on the ISMP Ten Key Elements and input from other pharmacy organizations, such as the National Association of Chain Drug Stores.

In response to Horn’s discussion, task force members noted that inspectors currently are and should continue to be used as educators. The members agreed that ISMP’s efforts to evaluate safe practices in the community pharmacy setting would be an asset to NABP in the development of a pharmacy accreditation program.

The fourth recommendation of the task force provides for the development of model documents to assist pharmacies in assessing their own CQI programs and to assist boards of pharmacy in inspecting for such programs. The documents were drafted and submitted to the NABP Committee on Law Enforcement/Legislation for review. Upon review the Committee on Law Enforcement/Legislation provided revisions, which included the recommendation that the forms be more generalized and community-practice-setting based. Subsequent to this, three forms were submitted to the NABP Executive Committee, which approved the three model documents entitled Community Pharmacy QRE Data Collection Form, the Community Pharmacy CQI Program Inspection Form, and the Community Pharmacy Quality Self-Audit form. These forms are available online in the Report of the 2007-2008 Committee on Law Enforcement/Legislation and are being incorporated into the Model Act, which will be available in August 2008.

The complete task force report is available under News/Press on the NABP Web site at [www.nabp.net](http://www.nabp.net).

The task force comprised the following individuals: Kim A. Caldwell, RPh, Texas State Board of Pharmacy, chair; Joseph L. Adams, Louisiana Board of Pharmacy; Vernon H. Benjamin, Iowa Board of Pharmacy; Amy Buesing, RPh, New Mexico Board of Pharmacy; James T. DeVita, RPh, Massachusetts Board of Registration in Pharmacy; Randall Knutsen, RPh, Colorado State Board of Pharmacy; Paul N. Limbergis, RPh, Colorado State Board of Pharmacy; Alice G. Mendoza, RPh, Texas State Board of Pharmacy; Kevin J. Mitchell, RPh, Ohio State Board of Pharmacy; Rebecca R. Poston, RPh, Florida Board of Pharmacy; W. Benjamin Fry, RPh, FACP, FACA, Texas State Board of Pharmacy; Rich Palombo, RPh, New Jersey Board of Pharmacy, executive committee liaison; and Charles R. “Chuck” Young, RPh, CFE, ex officio member.

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**Around the Association**
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- **Joanne M. Trifone, RPh**, has been appointed a member of the Massachusetts Board of Registration in Pharmacy. Trifone’s appointment will expire on November 29, 2012.
- **Stacey Jassey, PharmD**, has been appointed a member of the Minnesota Board of Pharmacy. Jassey’s appointment will expire on January 1, 2012.
- **Cynthia Bamberg, PharmD**, has been appointed a member of the Mississippi Board of Pharmacy. Bamberg’s appointment will expire on June 30, 2012.
- **Susan Hagan** has been appointed a public member to the Montana Board of Pharmacy. Hagan’s appointment will expire on July 1, 2012.
- **Albert J. Linggi, RPh, MBA**, has been appointed a member of the Washington State Board of Pharmacy. Linggi’s appointment will expire on January 19, 2012.
- **Rebekah Cookman, RPh**, has been appointed a member of the West Virginia Board of Pharmacy. Cookman’s appointment will expire on June 30, 2012.
- **Amy Mattila, PharmD**, has been appointed a member of the Wisconsin Board of Pharmacy. Mattila’s appointment will expire on November 29, 2012.

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NABP Inaugurates Three New Members into Executive Committee to Serve Three-Year Terms Representing Districts 3, 4, and 8

Three new Executive Committee members were inaugurated during the NABP 104th Annual Meeting, May 17-20, 2008, in Baltimore, MD. Michael A. Burleson, RPh, executive director of the Kentucky Board of Pharmacy, was elected to a three-year member term representing District 3; Gregory Braylock, Sr, RPh, member of the Ohio State Board of Pharmacy, was elected to a three-year member term representing District 4; and Hal Wand, MBA, RPh, executive director of the Arizona State Board of Pharmacy, was elected to a three-year member term representing District 8.

The newly elected officers of the NABP Executive Committee are President-elect Gary A. Schnabel, RPh, RN, executive director of the Oregon State Board of Pharmacy, and Treasurer William T. “Bill” Winsley, MS, RPh, executive director of the Ohio State Board of Pharmacy. Rich Palombo, RPh, member of the New Jersey Board of Pharmacy, assumed the office of NABP president, and Oren M. Peacock, Jr, RPh, assumed the position of chairperson at the conclusion of the Annual Meeting.

In addition, the following members are continuing to fulfill their terms on the 2008-2009 NABP Executive Committee: Karen M. Ryle, MS, RPh, of Massachusetts (District 1); Elizabeth Scott “Scotti” Russell, RPh, executive director of the Virginia Board of Pharmacy (District 2); Lloyd K. Jessen, RPh, JD, executive director/secretary of the Iowa Board of Pharmacy (District 5); Malcolm J. Broussard, RPh, executive director of the Louisiana Board of Pharmacy (District 6); and Cathryn J. Lew, RPh, member of the Oregon State Board of Pharmacy (District 7).

**Michael A. Burleson, RPh**

Michael A. Burleson has been an active member of NABP, serving on the Teller Committee at the NABP 103rd Annual Meeting and as the chairperson of the Committee on Resolutions during the NABP 102nd Annual Meeting. In addition, he served as chair for the 2007-2008 Committee on Law Enforcement/Legislation. He was named executive director of the Kentucky Board in 2004. Prior to joining the Board, Burleson held positions including pharmacy manager with Walgreen Co, director of pharmacy at Muhlenberg Community Hospital, and he was co-owner of three pharmacies. Burleson has received numerous awards including the Bowl of Hygeia in 1991. A graduate of the University of Kentucky College of Pharmacy, Burleson earned his bachelor of science degree in pharmacy.

**Gregory Braylock, Sr, RPh**

Gregory Braylock, Sr, has been an active member of NABP and the Ohio State Board of Pharmacy, serving on the NABP Committee on Law Enforcement/Legislation and as the committee chairperson of the Ohio State Board of Pharmacy Rules Review in 2006. Braylock has been a member of the Ohio Board since 2001. In addition, he is a member of the Ohio Pharmacists Association, and was the president of the Cleveland Chapter of the National Pharmaceutical Association from 2001 to 2004 and vice president from 1998 to 2001. He is currently a pharmacy manager for Walgreen Co. Prior to this, Braylock held positions including pharmacy manager for Rite Aid and staff pharmacist for Walgreen Co. Braylock earned his bachelor of science degree in pharmacy from the University of Cincinnati.

**Hal Wand, MBA, RPh**

An active member of NABP, Hal Wand participated in both meetings of the Task Force on Telepharmacy and the Implementation of the Medicare Drug Benefit Medication Therapy Management Provisions. In addition, he developed and reviewed questions for the NABP Multistate Pharmacy Jurisprudence Examination. Wand began his career with the Arizona Board as a compliance officer in 1989 and then as a deputy director in 1994 before being named executive director in 2003. Prior to joining the Board, he worked as a hospital pharmacist, long-term care pharmacist, and community pharmacist. He earned his bachelor of science degree in pharmacy from the University of Arizona and his master in business administration degree from the University of Phoenix.
Eugene L. “Gene” Argo, NABP Past President, Passes

Eugene L. “Gene” Argo, BS, passed away suddenly as result of a fall on May 28, 2008, at the age of 75. An active member of NABP, Argo served on the Executive Committee from 1979 to 1987, serving as president of NABP from 1986 to 1987. He was also appointed by Governors George Busbee and Joe Frank Harris to terms on the Georgia State Board of Pharmacy.

A native of DeKalb County, GA, Argo served in the Korean War with the United States Coast Guard. He attended Emory University and graduated from Mercer University Southern School of Pharmacy in 1958 with a bachelor of science degree in pharmacy. While attending college, Argo worked at Stacy’s Pharmacy in Decatur. In 1960, he became vice president and co-owner of the pharmacy and in 1967, he became president and owner. Argo also opened a second pharmacy, Stacy’s Pharmacy at Emory Village, in 1973.

In 1998, Argo opened Stacy’s Compound Pharmacy where he worked until his retirement. He was also a member of the Georgia Pharmacy Association and the American Pharmacists Association. Argo became president and owner of Medical Therapies Inc Home Health Care in 1984 and won many awards during his career, including the Bowl of Hygeia award.

NABP is deeply saddened by Gene Argo’s sudden and unexpected death. He will be greatly missed as he continued to be an active member of the Association well after his presidency. His many contributions helped to build NABP into what it is today. He is survived by his wife of 52 years, Sue; son, Pete; daughter, Catherine; granddaughter, Cali; grandson, Cash; and son-in-law, Cal Callaway.

NABP Appoints Wall to ACPE Board

NABP is pleased to announce that Donna S. Wall, PharmD, has been appointed by the Association to the Accreditation Council for Pharmacy Education (ACPE) Board of Directors for a six-year term ending in 2014. As an active member of NABP, Wall served two years as an Executive Committee member from 1999 to 2001 as well as one-year terms as the Association’s treasurer, president-elect, president, and chairperson spanning the years 2001 to 2005. Wall has also been involved in numerous NABP committees and task forces, serving as the 2006 chair of the Committee on Constitution and Bylaws and as Executive Committee liaison to both the Task Force on Privacy and Confidentiality and the Task Force on Drug Diversion Through Institutional Outlets.

Currently, Wall is the manager of drug use policy, quality improvement and regulatory compliance at Clarian Health Partners. Her professional experience also includes serving as a member of the Indiana Board of Pharmacy as well as several other professional societies including the Indiana Society of Hospital Pharmacists, the Indiana Pharmacists Alliance, the American Society of Health-System Pharmacists, the American College of Clinical Pharmacy, and the Society of Critical Care Medicine. Wall received her bachelor of science degree in pharmacy from Butler University College of Pharmacy and her doctor of pharmacy degree from Purdue University School of Pharmacy.

Wall replaces David E. Holmstrom, RPh, JD, former executive director, Minnesota Board of Pharmacy, who completed his term as ACPE vice president this year, as an NABP appointee to the ACPE Board of Directors. She joins two other ACPE board members appointed by NABP: Michael A. Moné, BS, JD, FAPhA, vice president anti-diversion and senior regulatory counsel, Cardinal Health, whose term covers 2006 to 2012; and current ACPE Secretary/Treasurer Donald H. Williams, RPh, FASHP, affiliate professor, University of Washington School of Pharmacy, whose term covers 2004 to 2010. Wall was an appointment-designee until July 1, 2008, when she became a voting member of the board.

NABP, the American Association of Colleges of Pharmacy, and the American Pharmacists Association each appoint three members to the ACPE Board of Directors.
NABP Welcomes Newly Appointed 2008-2009 ACE Members

To continue safeguarding the integrity and validity of NABP examinations, the following individuals have been appointed to serve as members of the 2008-2009 Advisory Committee on Examinations (ACE).

ACE oversees the development and administration of all of the Association’s examination and certification programs. ACE also considers policy matters, evaluates long-range planning strategies, and recommends appropriate action to the NABP Executive Committee.

ACE typically meets three to four times a year and its members include representatives from boards of pharmacy as well as faculty and/or staff who represent the diversity in pharmacy practice.

The new members of ACE began their terms on June 1, 2008.

Chair .............................................................. Tom Houchens
London, KY

Member .......................................................... Judy Gardner
Atlanta, GA

Member .......................................................... David Todd Bess
Cane Ridge, TN

Member .......................................................... Arthur I. Jacknowitz
Morgantown, WV

Member .......................................................... Kendall M. Lynch
Nashville, TN

Member .......................................................... Richard K. “Mick” Markuson
Boise, ID

Member .......................................................... Michael Duteau
Baldwinsville, NY

Ex Officio Member ........................................ Betty J. Dong
San Francisco, CA

Ex Officio Member ......................................... Kevin O. Rynn
Piscataway, NJ

Ex Officio Member ........................................ Richard Morrison
Kirkland, WA

Executive Committee Liaison .......................... Cathryn J. Lew

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Around the Association

Pharmacy Examining Board. Mattila’s appointment will expire on July 1, 2011.

Board Member Reappointments

- Ronnie Norris, PD, has been reappointed a member of the Arkansas State Board of Pharmacy. Norris’s appointment will expire on June 30, 2013.

- Dwayne Sheffler, RPh, has been reappointed a member to the Idaho Board of Pharmacy. Sheffler’s appointment will expire on June 30, 2012.

- Vernon Benjamin, RPh, has been reappointed a member of the Iowa Board of Pharmacy. Benjamin’s appointment will expire on April 30, 2011.

- Shirley Arck, PharmD, has been reappointed a member of the Kansas State Board of Pharmacy. Arck’s appointment will expire on April 30, 2011.

- Michael Coast, RPh, has been reappointed a member of the Kansas State Board of Pharmacy. Coast’s appointment will expire on April 30, 2011.

- Lee Howard, has been reappointed a public member of the Oregon State Board of Pharmacy. Howard’s appointment will expire on June 1, 2011.

- Linda Howrey, RPh, has been appointed a member of the Oregon State Board of Pharmacy. Howrey’s appointment will expire on June 30, 2011.

Board Officer Changes

The Idaho Board of Pharmacy has elected the following officers to the Board:

- Berk Frazer, RPh, Chairperson
- Dwayne Sheffler, RPh, Vice Chairperson

The Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy has elected the following officers to the Board:

- Philip Burgess, RPh, Chairperson
- Sudhir Manek, RPh, Vice Chairperson

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CPE Standards Revised to Better Meet the Needs of Pharmacists and Pharmacy Technicians

In addition to its recent adoption of Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (Standards 2007), the Accreditation Council for Pharmacy Education (ACPE) has revised its ACPE Criteria for Quality and Interpretive Guidelines. Now titled ACPE Standards for Continuing Pharmacy Education, the new standards are designed to support the development of the pharmacist as a lifelong learner. The Standards for Continuing Pharmacy Education are designed to ensure the quality of continuing education that practicing pharmacists and pharmacy technicians need to be current in their field. The new continuing education accreditation standards will be effective January 1, 2009.

ACPE defines continuing pharmacy education (CPE) as a structured educational activity designed or intended to support the continuing development of pharmacists and/or pharmacy technicians to maintain and enhance their competence. CPE should promote problem solving and critical thinking as applicable to the practice of pharmacy.

The decision to revise the CPE standards was made in part as a response to feedback received from pharmacists in focus groups about their opportunities for continuing education. According to ACPE’s Dimitra V. Travlos, PharmD, BCPS, assistant executive director and director, Continuing Pharmacy Education Provider Accreditation, “the participants in the focus groups most frequently indicated that the programs they needed for education were not available, or that they desired hands-on help as opposed to lectures. We realized that we needed to revise the standards in order to better meet the needs of pharmacists and pharmacy technicians.”

As a result of the revision, the current CPE standards include significant changes. Three types of CPE activities have been identified. They emphasize practice-based courses, and hourly requirements vary.

- **Knowledge-based CPE activity:** Such activities should be designed primarily for pharmacists and/or technicians to acquire factual knowledge. The minimum amount of credit is 15 minutes or 0.25 credit hours.
- **Application-based CPE activity:** These activities should be designed for pharmacists and/or technicians to apply information learned in the time frame allotted. It must be case study-based. The minimum amount of credit is 60 minutes, or one contact hour.
- **Practice-based CPE activity:** These activities are more complex and require skill development. They should be designed for pharmacists, technicians, or both to acquire specific knowledge, skills, attitudes, and performance behaviors that expand or enhance competencies. Practice-based continuing education activities were previously addressed under ACPE standards for certificate programs. The requirements for practice-based CPE activities are the same as certificate programs. Although providers may choose to continue to use the term “certificate program” for market place reasons, the term no longer appears in the new CPE standards. The format for practice-based CPE activities should include a didactic and practice component, with assessment of the learner. The minimum amount of credit is 15 contact hours.

Standards 2007 emphasize that pharmacists and pharmacy technicians should identify their educational needs; pursue educational activities that will produce and sustain a proficiency in knowledge, skills, and attitudes learned to their application of knowledge, skills, and attitudes in practice; and continue self-directed learning throughout the progression of their careers.

As Travlos states, “We want to meet the needs of pharmacists by improving the quality of continuing education. By taking practice-based courses to fulfill their CPE requirements, pharmacists and pharmacy technicians will enhance their lifelong learning experience.”

Because the new standards signify a great change from previous standards, ACPE will offer explanatory workshops throughout 2008, continuing into 2009.

For more information on the changes to CPE standards, contact ceinfo@acpe-accredit.org, or call 312/664-3575.

**Drug Outlets Operating in Conflict**

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Many of these Internet drug outlets do not offer consultation with a pharmacist, do not secure patients’ personal or financial information, and do not provide a physical address for their base of operations. The World Health Organization estimates that medicines purchased over the Internet from outlets that conceal their actual physical address are counterfeit in over 50% of cases. Those patients who receive counterfeits are in danger of taking products without the active ingredient, with an insufficient or excessive quantity of the active ingredient, with the wrong active ingredient, or even a product that contains hazardous ingre-
Ongoing studies performed by NABP show that candidates who utilize the Pre-NAPLEX® can use their results as a reliable predictor of their North American Pharmacist Licensure Examination™ (NAPLEX®) score. Since the Pre-NAPLEX was launched, NABP has routinely evaluated the results from the NAPLEX and the Pre-NAPLEX, and performs analyses comparing individuals’ outcomes on each of the respective examinations.

Studies conducted between 2005 (the year the NAPLEX blueprint was updated) and 2007 have consistently supported a strong relationship between the NAPLEX and the Pre-NAPLEX. A correlation analysis was conducted on 9,868 individuals who took the Pre-NAPLEX and NAPLEX and the results showed the scores of the two examinations to be closely linked at a highly significant level. In addition to the correlation analyses, regression analyses have shown the Pre-NAPLEX to be a good predictor, at a highly significant level, of an individual’s expected results on the NAPLEX.

The results of the analyses conducted on the Pre-NAPLEX and NAPLEX included only those candidates who could be identified by their Social Security number. Providing a Social Security number is an optional, self-reported field in the Pre-NAPLEX registration process, not all individuals who have taken the Pre-NAPLEX over the years were included in the analyses.

The Pre-NAPLEX is the only NAPLEX practice examination written and developed by NABP to familiarize candidates with the NAPLEX testing experience. The Pre-NAPLEX is a 50-item, Internet-based examination composed of actual items that have previously appeared on the NAPLEX. The Pre-NAPLEX is available in two forms that are updated each year in May. A candidate may take one or both of the forms at any time or any day of the week. Candidates completing the Pre-NAPLEX will receive an immediate estimated scaled score that corresponds to what might be an expected result for the NAPLEX at that time.

For additional information on the Pre-NAPLEX visit www.prenaplex.com or www.nabp.net.

NABP is seeking item writers for the North American Pharmacist Licensure Examination™ (NAPLEX®) and the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). The NAPLEX consists of 185 multiple-choice test questions, the majority of which are asked in a scenario-based format, and the FPGEE is a comprehensive examination measuring four major pharmacy content areas: basic biomedical sciences, pharmaceutical sciences, social/behavioral/administrative pharmacy sciences, and clinical sciences.

Pharmacists in all areas of practice, and faculty from schools and colleges of pharmacy are encouraged to apply. Pharmacists chosen to serve as item writers must hold an active unrestricted license in any state or territory of the United States and will have their license(s) verified through the NABP Clearinghouse.

Interested individuals should mail or fax a letter of interest indicating their current practice/educational setting, specialties/ certifications, and years of experience, along with a resume or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone, at 1600 Feehanville Drive, Mount Prospect, IL 60056; fax 847/391-4502. Applications are accepted on a continuous basis and kept on file for five years.

Item writers will be selected based on the specific needs of the programs. Those who are chosen will be asked to attend a workshop at NABP Headquarters with travel and lodging expenses paid by NABP. These workshops occur several times per year. Attendees will receive detailed instructions and training materials describing the item-writing process and content-related requirements for their designated examination. Item writers will then be asked to develop new test items that will be considered for inclusion in NABP licensure and certification examination programs.

For more information about item writing, contact NABP at custserv@nabp.net.
FDA Takes Next Step to Establish Permanent Offices in China

Food and Drug Administration (FDA) has received approval from the US State Department to establish eight full-time permanent FDA positions at US diplomatic posts in the People’s Republic of China, pending authorization from the Chinese government. FDA plans to hire and place FDA staff in China over the next 18 months. In addition, FDA plans to hire five local Chinese nationals to work with the new FDA staff at the US Embassy in Beijing and the US Consulates General in Shanghai and Guangzhou.


FDA Names Products Requiring Risk Evaluation, Mitigation Strategy

FDA has identified 25 drugs and biologic products for which it will require the manufacturers to submit a safety plan, called a Risk Evaluation and Mitigation Strategy (REMS). These products have been identified as beneficial to patients but especially dangerous if not used properly. Under the Food and Drug Administration Amendments Act of 2007, FDA can require manufacturers to submit a REMS when a drug first comes on the market, or later if FDA becomes aware of new safety data about the drug, to help ensure that health care professionals prescribe the drug correctly and that patients use it safely.

The manufacturers of the 25 drugs and biologic products identified must submit to FDA a proposed REMS by September 21, 2008. More information, including the 25 drugs and biologic products identified, is available on the FDA Web site at www.fda.gov/OHRMS/DOCKETS/98fr/E8-6201.htm.

Senate Passes Bill to Restrict Distribution of Controlled Substances Online

On April 1, 2008, the United States Senate passed the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 to impose registration and reporting requirements on Internet pharmacies that dispense controlled substances. Under the proposed legislation, an Internet pharmacy must:
1. post on its home page a statement of its compliance with this act;
2. comply with licensure requirements in each state in which it operates and with all applicable federal and state laws;
3. post on its home page certain information about the business owner, a list of the states in which it operates and is licensed, and certain information about the location of the pharmacy; the qualifications of its pharmacist-in-charge and practitioners who provide medical consultations, and a certification of its registration; and
4. notify the Attorney General and applicable state boards of pharmacy prior to offering to dispense controlled substances. The bill also prohibits an Internet pharmacy from selling a controlled substance without a valid prescription, and establishes criminal penalties for violating this act. The House version of this bill (HR 6353) was introduced on June 24, 2008, and is posted on the Library of Congress Web site at http://thomas.loc.gov.

Google Launches Online Medical Records Service

Google launched a medical records service on May 19, 2008, allowing users to store and manage their health care information online. United States residents can register for the service, called Google Health, and then authorize dozens of partners to upload their medical records to Google’s servers. Users can then add their own data and decide who can access it.

The service is free and enables people to maintain electronic copies of information such as prescriptions, lab test results, hospital stays, and medical conditions stored on Google computers. In response to privacy concerns, Google says it has built a secure computer platform separate from its search system to host medical records as part of an emphasis on protecting sensitive health information.

Microsoft began offering a similar HealthVault service in October 2007.

AMA Issues Policy on Unapproved Compounded Medications

American Medical Association (AMA) has issued a policy regarding compounded medications that are not approved by FDA. The policy states that AMA:

- recognizes that compounding pharmacies must comply with current United States Pharmacopeia and National Formulary (USP-NF) compounding monographs, when available, and

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Hawaii Adopts Law Allowing Importation of Foreign Drugs

The Hawaii legislature recently adopted a law allowing residents to buy foreign prescription drugs over the Internet. The law enrolls Hawaii in the I-SaveRx program, which will ship unapproved drugs from overseas to state residents, in conflict with federal law.

Hawaii Governor Linda Lingle vetoed the bill on May 1, 2008, whereupon the members of the Senate and House overrode the veto by a two-thirds vote. Since Illinois implemented the I-SaveRx prescription drug program in 2004, Wisconsin, Missouri, Kansas, and Vermont have joined the program as participating states. The program is set to begin in Hawaii by July 1, 2009.

It is the position of NABP that allowing and encouraging the illegal purchase and importation of medications from other countries without the appropriate regulatory safeguards is a serious threat to the US regulatory foundation and to patient safety.

The law is posted on the Hawaii legislature Web site at www.capitol.hawaii.gov/session2008/Bills/HB7-SD1_.pdf.

Minnesota Adopts Law to Thwart Illicit Internet Drug Outlets

Minnesota Governor Tim Pawlenty signed a law on May 19, 2008, which, among other things, cracks down on pharmacies that work with illegitimate Web sites. In addition, the legislation modifies a 2007 law pertaining to a controlled substances electronic prescription monitoring program. The legislation is intended to curb the operation of illicit Internet drug outlets in Minnesota. The bill was created in response to the 2006 prescription drug overdose of St Cloud, MN resident Justin Pearson, who obtained a prescription for a controlled substance from an Internet drug outlet by filling out an online questionnaire without a medical evaluation. Dubbed “Justin’s Bill,” the legislation requires a face-to-face visit between the patient and the practitioner who prescribes a commonly abused prescription drug. The law is effective as of May 20 and is posted on the Minnesota Senate Web site at www.revisor.leg.state.mn.us/bin/bldbill.php?bill=S2941.3.html&session=ls85.

Florida Passes Bill Requiring Registration of Technicians

Under a bill signed recently by Florida Governor Charlie Crist, pharmacy technicians must register with the Florida Board of Pharmacy by 2010. Starting in 2011, the new law requires them to complete one of the following: a board-approved training program, 1,500 hours of work as a technician under a Florida licensed pharmacist, or certification by a program accredited by the National Commission for Certifying Agencies.


LA Board Approves Collaborative Drug Therapy Management Rule

The Louisiana Board of Pharmacy and the Louisiana State Board of Medical Examiners have completed the rulemaking process to allow pharmacists and physicians to enter into collaborative practice agreements for the purpose of managing drug therapy for certain conditions in their mutual patients. The pharmacist and the physician are both required to submit applications and be approved prior to participating in collaborative drug therapy management (CDTM). A Notice of Intent to Collaborate must then be submitted to the CDTM Advisory Committee at the Board of Medical Examiners.

There is no fee for the issuance or renewal for this registration. Pharmacists may collaborate with more than one physician, providing that separate collaborative practice agreements are entered into with each collaborating physician in addition to submitting separate Notices of Intent to Collaborate.

WA Methamphetamine Work Group Says Logs Successful

Many states, including Washington, have seen a drop in methamphetamine drug labs and dump sites. State and federal regulations restricting the availability of products used to manufacture methamphetamine have contributed to this drop.

In 2006, the legislature required the Washington State Board of Pharmacy to conduct a statewide pilot project. The pilot required retailers to document all sales transactions of products containing ephedrine, pseudoephedrine, and phenylpropanolamine. The Board convened the Methamphetamine Work Group to evaluate the results of the pilot and report its findings and recommendations to the legislature.

The work group concluded that retail transaction logs are effective in restricting access to over-the-counter drugs for the illegal manufacturing of methamphetamine. As a law enforcement tool, the work group recommended an electronic point-of-sale data collection system.
MD Passes Legislation for Comprehensive PBM Oversight

The Maryland General Assembly passed a comprehensive legislative package on April 17, 2008, providing regulatory oversight of pharmacy beneficiary managers (PBMs). The bills require all PBMs to register with the state, disclose certain information before switching a prescription, provide fee schedule information to pharmacies, and ensure that any person responsible for making prescription decisions is authorized to do so.

Approximately 95% of all patients with prescription drug coverage receive benefits through a PBM. PBMs manage an estimated 70% of prescription drugs dispensed through retail pharmacies that are covered by private third-party payers.

WV Law Allows Pharmacists to Give Immunizations

On March 31, 2008, West Virginia Governor Joe Manchin III signed into law a bill allowing pharmacists to immunize adult patients against influenza, pneumonia, hepatitis A and B, tetanus, and herpes zoster.

The legislation requires pharmacists to complete a course approved by the West Virginia Board of Pharmacy based on standards established by the Centers for Disease Control and Prevention, and maintain basic life-support certification approved by the American Red Cross or American Health Association. With the adoption of this law, effective as of June 2008, West Virginia becomes the 48th state to allow pharmacists to immunize patients.

NAPLEX Review Committee Members, Item Writers Convene

On April 18-19, 2008, members of the North American Pharmacist Licensure Examination™ (NAPLEX®) Review Committee and item writers assembled to create new pretest items for the examination. Pictured above from left to right are: Cynthia P. Koh-Knox, PharmD, RPh, clinical associate professor of pharmacy practice and associate director, pharmacy continuing education, Purdue University College of Pharmacy, Nursing, and Health Sciences; Neal F. Walker, RPh, pharmacy manager, Fairview University Medical Center-Mesabi; and Cynthia Sieck, PharmD, pharmacist, Medication Management Program, Kaiser Permanente – Northwest.
Members Prepare New Items During MPJE Item-Writing Workshop

The Multistate Pharmacy Jurisprudence Examination® (MPJE®) Review Committee convened on June 5-6, 2008, at NABP Headquarters to discuss and prepare new items. Pictured above are Steve Morse, RPh, director, Supply Chain Integrity and Regulatory Operations, Cardinal Health, and Ronald J. Klein, RPh, executive director, Montana Board of Pharmacy.

Legal Affairs
(continued from page 95)
Regents, and will ask for the court’s permission to amend the original complaint to include new information that NABP has gathered relating to the allegations of copyright infringement against the Board of Regents. Most recently, NABP filed a complaint with a state board of pharmacy because NABP could not verify the validity of a candidate’s examination score, resulting in the state board’s immediate suspension of the candidate’s license. NABP has offered to provide testimony and information in support of the board’s licensure prosecution.

NABP strongly encourages boards of pharmacy to collaborate with the Association in addressing future examination irregularity issues. From gathering and sharing information to gaining a better understanding of examination administration and psychometrics, boards of pharmacy that work with NABP will be better prepared to handle these matters and respond to questions that may be raised by candidates.

Conclusion
Over the last 12 months, NABP has taken a multifaceted approach to address actions that threaten the integrity of our educational and public health protection programs. NABP is confident that continued success will be achieved through its strong partnership with the member boards of pharmacy.

Drug Outlets Operating in Conflict
(continued from page 110)
These lists, along with program criteria and related patient information, are accessible in the Internet Pharmacies section of the NABP Web site at www.nabp.net.

The new Internet Drug Outlet Identification program is an outgrowth of a 2007 NABP resolution, “Internet Pharmacy Public Safety Awareness,” in which the Association pledges to continue collaborating with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources. As part of this initiative, NABP will provide information to assist state and federal regulators in their efforts to shut down rogue Internet drug outlets.
### NEWLY ACCREDITED VAWD FACILITIES

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

<table>
<thead>
<tr>
<th>Facility Name</th>
<th>Location</th>
<th>Accredited Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>AmerisourceBergen Drug Corporation</td>
<td>Eden Prairie, MN</td>
<td>April 14, 2008</td>
</tr>
<tr>
<td>Aurobindo Pharma USA, Inc</td>
<td>Cranbury, NJ</td>
<td>March 13, 2008</td>
</tr>
<tr>
<td>Cardinal Health 200, Inc dba Cardinal Health</td>
<td>Buford, GA</td>
<td>May 7, 2008</td>
</tr>
<tr>
<td>McKesson Corporation dba McKesson Drug Company</td>
<td>Aurora, CO</td>
<td>March 22, 2008</td>
</tr>
<tr>
<td>MWI Veterinary Supply Co</td>
<td>Nampa, ID</td>
<td>April 1, 2008</td>
</tr>
<tr>
<td>MWI Veterinary Supply Co</td>
<td>Edwardsville, KS</td>
<td>April 22, 2008</td>
</tr>
<tr>
<td>Nationwide Medical/Surgical, Inc</td>
<td>Van Nuys, CA</td>
<td>May 1, 2008</td>
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<tr>
<td>McKesson Drug Company</td>
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<tr>
<td>Phoenix Pharmaceutical, Inc</td>
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<td>Priority Solutions</td>
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<tr>
<td>Schnucks Pharmacy Service Center</td>
<td>Bridgeton, MO</td>
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<tr>
<td>Stericycle, Inc</td>
<td>Indianapolis, IN</td>
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A full listing of accredited VAWD facilities is available on the NABP Web site at [www.nabp.net](http://www.nabp.net).