newsletter

National Association of Boards of Pharmacy®

AWARE GET INFORMED. PRESCRIPTION DRUG SAFETY®

June-July 2012 / Volume 41 Number 6

aid to government
the profession
the public
1904 to 2012

Upcoming Events

July 24-25, 2012
NABP Program Review and Training
NABP Headquarters

August 2-4, 2012
NABP/AACP District 5 Meeting
Duluth, MN

August 11-13, 2012
NABP/AACP District 3 Meeting
Savannah, GA

September 19-20, 2012
NABP Interactive Member Forum
Northbrook, IL

October 14-16, 2012
NABP/AACP Districts 1 & 2 Meeting
Skytop, PA

October 31-November 2, 2012
NABP/AACP District 4 Meeting
Ann Arbor, MI

Pharmacist Prescribing: Is Collaborative Practice a Path of the Future?

As policymakers and other stakeholders continue debating how to best balance affordable health care and patient access, they are increasingly looking to expand the role pharmacists play in patient care. Numerous factors, including rising health care costs, a longer-living population, and increased reliance on pharmacotherapy, as well as advances in pharmaceutical and biomedical research, increased minimum educational standards for pharmacists entering the workforce, and the shortage of primary care practitioners are encouraging a re-examination of the role pharmacists play in the provision of health care. Increasingly, and not exclusively confined to institutional settings, pharmacists may work in a clinical role as an active part of a team, providing patient-centered drug therapy management as well as disease-prevention and health-improvement services. As part of their role in medication therapy management, pharmacists increasingly are gaining the authority, through collaborative practice agreements, to prescribe medications, as well.

©iStockphoto.com/STEEX

Regulatory Background

On the federal level, pharmacists have been expanding their roles for some time. Pharmacists in the ambulatory clinics of the Indian Health Service took an active role in medication therapy management as early as the 1960s. The Veterans Health Administration first established medication prescribing authority for "clinical pharmacy specialists" in 1995. Comparatively, change on the state level has progressed more slowly, but momentum has been increasing. In the last 20 years, for example, regulatory recognition of collaborative medication therapy management and other expanded services has increased dramatically, from a small handful of states in 1990 to the majority in 2012. In NABP's 2012 edition of its *Survey of Pharmacy Law*, all but 10 states or territories

(continued on page 134)

In This Issue. . .

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 63 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
Communications Manager

2012-2013 ACE Members Announced

Ten Reappointed to Oversee Development and Administration, and Safeguard Integrity and Validity of NABP Examinations

NABP is pleased to announce that 10 members have been reappointed to serve on the 2012-2013 Advisory Committee on Examinations (ACE). This standing committee, established by NABP in 1912, was created to safeguard the integrity and validity of NABP examinations.

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 convenes three to four times per year and consists of individuals who are affiliated members of NABP, including current active board of pharmacy members and administrative officers, individuals who have served within the last five years as a member or administrative officer of a board of pharmacy, and non-affiliated individuals who are practicing pharmacists or serving as pharmacy school faculty.

2012-2013 ACE Members

The following members renewed their term on June 1, 2012. As of press time, the position of Executive Committee liaison was pending.

Tom Houchens..... London, KY
(Chair)

Sara St Angelo..... Indianapolis, IN

Carl W. Aron..... Monroe, LA

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

Michael Duteau..... Baldwinsville, NY

Judy Gardner..... Atlanta, GA

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

John D. Taylor..... Tallahasse, FL
(Ex Officio Member, one-year term)

Neal F. Walker..... Hibbing, MN
(Ex Officio Member, one-year term)

Dale Eric Wurster..... Iowa City, IA
(Ex Officio Member, one-year term)

Members Convene to Evaluate and Develop Items for the MPJE

Terry Carr, RPh, president, and Mary K. Walker, RPh, executive director, both of the Wyoming State Board of Pharmacy, work to develop and review items for the Multistate Pharmacy Jurisprudence Examination® (MPJE®) during an item-writing workshop held at NABP Headquarters.

Task Force Makes Recommendations to Address Drug Diversion and Control in the Pharmacy

Drug diversion in licensed pharmacies, including diversion of controlled substances (CS), is a serious and growing concern, as stressed in the report of the Task Force on the Control and Accountability of Prescription Medications. The task force met October 26-27, 2011, and discussed numerous related concerns, such as the increased incidence of pharmacy personnel, especially unlicensed or unregistered staff, having access to and diverting prescription medications, including CS. The task force made 10 recommendations including recommended revisions to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act),* and future NABP actions related to pharmacy security, pharmacy and pharmacist responsibilities, and pharmacist continuing education, among other recommended actions.

The task force met at NABP Headquarters, and accepted the following charge:

1. Review existing state laws and regulations addressing the control and accountability of prescription drugs, the Report of the Task Force to Review and Recommend Revisions to the Controlled Substances Act, as well as relevant sections of the *Model Act.*
2. Recommend revisions, if necessary, to the *Model Act* addressing this issue.

In addition to discussing the diversion of prescription drugs by unlicensed or unregistered staff, members also discussed how security and inventory control provisions often lack specific safeguards to prevent diversion. To help boards of pharmacy address these concerns, the task force recommended revisions to the *Model Act* by adding language regarding additional oversight and specifics related to inventory functions by the pharmacist-in-charge (PIC), as well as accountability of the pharmacy owner and pharmacy permit holder. The task force also recommended several revisions related to security measures and requirements for criminal background checks for all pharmacy owners, pharmacy permit holders, pharmacy staff, and any other staff that has access to prescription medications.

The task force also discussed the concern that licensees, particularly pharmacy technicians, can easily obtain new employment after being terminated from a pharmacy due to a drug-related incident. The task force recommended that NABP encourage boards to incorporate existing *Model Act* language pertaining to the reporting of separation of employment of any licensee or registrant for drug-related reasons, such as abuse, theft, or diversion, and that the report should include the reason for the termination.

The task force also discussed the increased prevalence of newly graduated pharmacists accepting PIC positions and that many have been called before their board for reasons indicating a lack of knowledge and awareness about the duties and responsibilities of being a PIC. Thus, the third recommendation of the task force is that NABP recommend to colleges and schools of pharmacy to increase the emphasis on the ethical and legal responsibilities related to the PIC position as part of relevant courses, such as pharmacy law or pharmacy management.

The task force also recommended that, as PICs assume a legal responsibility to manage the pharmacy and practice in a safe and secure manner, NABP should encourage boards to require continuing education for PICs pertaining to the legal responsibilities of this position. Further, as many PICs face ethical dilemmas, it is recommended that NABP encourage pharmacy associations and employers to develop educational and training programs that focus on the ethical and legal responsibilities of the PIC. To help boards in educating pharmacists, and particularly PICs, about how to

(continued on page 132)

Executive Committee

Malcolm J. Broussard
Chairperson
One-year term

Michael A. Burleson
President
One-year term

Karen M. Ryle
President-elect
One-year term

Joseph L. Adams
Treasurer
One-year term

James T. DeVita
Member, District 1
Serving third year of a three-year term

Edward G. McGinley
Member, District 2
Serving third year of a three-year term

Mark T. Conradi
Member, District 3
Serving second year of a three-year term

William John Cover
Member, District 4
Serving second year of a three-year term

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

Jeanne D. Waggener
Member, District 6
Serving first year of a three-year term

Mark D. Johnston
Member, District 7
Serving first year of a three-year term

Hal Wand
Member, District 8
Serving second year of a three-year term

NABP Executive Committee elections are held each year at the Association's Annual Meeting.

108th Annual Meeting Report of Counsel: The First Amendment as Applied to the Regulatory Community

By Dale J. Atkinson, JD

The First Amendment to the United States Constitution provides that "Congress shall make no laws respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances." This free speech and right to exercise freedom of religion has been the subject of legal debate through countless judicial opinions and analyses for centuries.

Of late, several legal opinions have addressed speech and religious rights related to issues relevant to the regulatory communities, specifically matters that impact legislative, educational, and rulemaking settings. The purpose of the 2012 NABP Report of Counsel is to provide readers with an outline of three of these cases and provide the boards of pharmacy with related perspectives in this complex arena.

A First Amendment Right to Cast Legislative Votes?

Nevada Commission on Ethics v. Carrigan, 131 S. Ct. 2343, 180 L. Ed 2d 150 (2011)

Nevada's ethics laws require public officials to recuse themselves from voting on or advocating the passage or failure of "a matter with respect to which the independence of judgment of a reasonable person in his situation would be materially affected by . . . his commitment in a private capacity to the interests of others." The Ethics in Government Laws are administered and enforced by the Nevada Commission on Ethics, a legislative-executive commission composed of eight members, four of whom are appointed by the governor and four of whom are appointed by the Legislative Commission.

The mission of the Nevada Commission mandates that it "strives to enhance the public's faith and confidence in government by ensuring that public officers and public employees uphold the public trust by committing themselves to avoid conflicts between their private interests and their public duties." The breadth of the Nevada ethics laws covers pharmacy board members and staff and most NABP member jurisdictions have similar laws, which set forth parameters to which board members and staff must adhere or potentially face reprimand or other sanctions.

The Nevada Commission investigated an elected member of the City Council of Sparks, NV, in response to complaints that the council member had violated the ethics laws. In particular, the complaints alleged that the council member voted to approve an application for a casino/hotel development in spite of a disabling conflict of interest. A longtime friend and campaign manager for the council member worked as a paid consultant for the developer and benefited from the approval of the permits. Upon completion of the investigation, the Nevada Commission concluded that the council member had a disqualifying conflict and issued a censure for failing to abstain from the voting on the permit application. The

Nevada Commission did not impose any civil penalty because it found the actions of the council member were not willful. Buttressing this conclusion regarding non-willful acts was the fact that the council member consulted the Sparks city attorney and was advised that disclosure of the relationship before voting would satisfy his obligations under the ethics laws. The council member did, in fact, disclose his relationship prior to the vote.

Based upon the censure imposed, the council member filed litigation in Nevada State court against the Nevada Commission alleging that the provisions of the ethics laws he was found to have violated were unconstitutional in violation of the First Amendment of the US Constitution. The lower court denied his petition, but the Nevada Supreme Court reversed, finding that the council member's right to vote was protected by the First Amendment and, under a strict scrutiny analysis, the section of the ethics law found to have been violated was unconstitutionally overbroad. The Nevada Supreme Court's analysis concluded that a legislator's vote is protected speech as it is a "core legislative function." The matter was appealed to the US Supreme Court, which granted *certiorari*.

The US Supreme Court initially provided an overview of the First Amendment and emphasized that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content. But, it also noted that the amendment has no application when what is restricted is not protected speech. The court noted that the Nevada law not only addresses the prohibition regarding voting on matters where a conflict exists, but also prohibits conflicted persons from advocating the passage or failure of the proposal. The court and all parties agreed that if the prohibition on voting meets constitutional scrutiny then the prohibition on advocating will also be constitutionally permissible.

The US Supreme Court embarked on a historical analysis of the initial adoption of Congressional recusal rules dating back to 1789. Indeed, the original House of Representatives rules on recusal were adopted within one week of that chamber first achieving a quorum and such rules were in effect when the First Amendment was submitted for ratification. As noted by the court, no one objected to the recusal rules under the First Amendment debate and "their failure to note any inconsistency between the two suggests there was none." While the Senate did not as quickly adopt rules requiring recusal, Thomas Jefferson adopted such rules when he was president of the Senate in 1801.

Judges are also subject to conflict of interest principles, which require recusal, the parameters of which date back to 1792. The court noted the differences between the vote of a legislator and the vote of a judge and the differences between legislative and judicial recusal rules, but nonetheless referred to the fact that there appear to be no First Amendment challenges to either such required recusals and the failure of the council member to cite any cases supporting his position. Instead, the council member cited several lower court cases from recent years that were quickly distinguished by the Supreme Court.

The court furthered its analysis by asking itself how restrictions upon a legislator's voting are not restrictions upon such legislator's protected speech. In important language, the court emphasized that a legislator's vote is "the commitment of his apportioned share of the legislature's power to the passage or defeat of a particu-

(continued on page 126)

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

Legal Briefs

(continued from page 125)

lar proposal. The legislative power thus committed is not personal to the legislator but belongs to the people; the legislator has no personal right to it." It further opined that a legislator "casts his vote as a trustee for his constituents, not as a prerogative of personal power."

Dissenting justices of the Supreme Court argued that voting on legislative matters allows for legislators to express "deeply held and, at times, highly unpopular views often at great personal or political peril," thus qualifying as communications subject to protections. However, the majority court stressed that the act of voting "symbolizes nothing" and that even if the legislator has and would like to convey his deeply held personal belief, such does not transform action into First Amendment speech. Legislative voting is non-symbolic and is engaged in for an independent governmental purpose. Even if a legislative vote were deemed to be expressive, the court noted the argument would still "miss the mark" as the Supreme Court has rejected the notion that the First Amendment confers a right to use governmental mechanics to convey a message.

Based upon its analysis, the US Supreme Court reversed and remanded the judgment of the Nevada Supreme Court. This First Amendment opinion provides much fodder for regulatory board members and should act as an opportunity to emphasize the fiduciary responsibilities board members hold as public protectors. As referenced by the court, legislative acts are not personal to the "voter" but are cast on behalf of all constituents. Finally, the inability of board members to maintain this impartiality can, and should, subject them to recusal. Failure to declare and act will subject board members to sanctions.

An additional case to note that also emphasizes the important role board members play as fiduciary participants, albeit unrelated to free speech, is the matter of the FTC v. the North Carolina State Board of Dental Examiners. This case involves a Federal Trade Commission (FTC) administrative ruling finding that the North Carolina State Board of Dental Examiners violated the antitrust laws by interpreting its scope of practice to limit teeth whitening services to licensed dentists. The FTC case has been the subject of a previous *NABP Newsletter* article (*NABP Legal Briefs: FTC: Facinorous Teeth Case,* Volume 40, No. 7 (August 2011)) (available at *www.nabp.net/news/nabp-legal-briefs-ftc-facinorous-teeth-case).* Although the case continues to wind its way through the judicial system, one of the elements discussed by the FTC was the self-regulation of dentists. That is, the regulatory board was composed of licensed dentists who may derive an economic benefit from decreased competition from unlicensed teeth whiteners.

Boards of pharmacy and their individual members are encouraged to understand and comply with applicable ethics laws. Board members are placed in a position of trust and are required to act in the interest of the public. The Nevada ethics and FTC cases are illustrations of how individual board members must understand and adhere to the public protection mission of the boards. Pressing personal agendas or those of specified employers or constituents can be fatal to the regulatory process, potentially subject the board to liability, and, under certain circumstances, subject a board member to personal liability.

A First Amendment Right to Refuse to Provide Counseling in an Educational Practicum

Ward v. Polite, 667 F.3d 727 (6th Cir. 2012)

The First Amendment also has been the subject of litigation regarding student matriculation through the education process. In many professions, graduation from an accredited or recognized educational program is a prerequisite to licensure and failure to graduate from such a program will be a bar to licensure. Without debating the gatekeeper to licensure role educational programs play, removal from an academic program will stimulate litigation and, as illustrated below, may implicate the right to free speech.

In its graduate level counseling degree program, Eastern Michigan University prohibits students from discriminating against others based upon sexual orientation. The school also teaches students to affirm a client's values during counseling sessions. Students seeking a master's degree in counseling must participate in a practicum as a required course in experiential learning. During the practicum, graduate students put their training into practice by counseling actual clients.

A graduate student on numerous occasions expressed her conviction that her faith (Christianity) prevented her from affirming same-sex relationships as well as certain other conduct, such as extra-marital relationships. This stance was well known and was the subject of discussions and debate with professors during her successful academic coursework. Boasting a 3.91 grade point average, she enrolled in a student practicum as one of her final required courses.

During the practicum, the faculty supervisor asked her to counsel a gay client. In response, the student asked to either refer the client to another counselor or, alternatively, permit counseling to commence with an understanding that a referral would be made if the counseling sessions turned to relationship issues. The faculty advisor referred the client and later met with the student. During this meeting, the advisor stated that no practicum student had ever made such a request and that her actions created an "ethical dilemma" for the student and university. During an informal review

of the student initiated by the school, discussions occurred regarding the student's refusal to counsel the assigned client and her religious objection to affirming same-sex relationships. The school provided the student with the option of either withdrawing from the program or seeking a formal review. The student elected to seek a formal review.

The formal review process involves a hearing before a committee of several faculty members and one student to consider allegations of improper behavior or poor academic performance of a student. Prior to her hearing, the student was informed that she had violated two provisions of the American Counseling Association's (ACA) Code of Ethics. These two provisions involved imposing values that are inconsistent with counseling goals and engaging in discrimination based upon sexual orientation. In response to these allegations, the student testified that she did not discriminate against anyone and that she had no issues counseling gay and lesbian clients so long as the university did not require her to affirm their sexual orientation.

Shortly after the hearing, the university sent the student a letter informing her that the unanimous decision of the committee was to expel her from the program effective immediately based upon her unwillingness to change her behavior. The student appealed the decision to the dean of the college, which was denied. Thereafter, she filed litigation in federal court against the university and others (defendants) alleging violations of the First and Fourteenth Amendments of the US Constitution. In short, the First Amendment is applicable to the states through the Fourteenth Amendment. The federal district court granted the defendants motion for summary judgment and denied the student's cross motions for summary judgment. Summary judgment motions argue that there are no material issues of fact in dispute and the court can, as a matter of law and without a trial, determine the outcome of the case. In finding in favor of the defendants, the district court held that the university "permissibly enforced a neutral and generally applicable curricular requirement and did not target her because of her speech or religious beliefs." The student appealed the matter to the Sixth Circuit Court of Appeals.

On appeal, the court engaged in a thorough analysis of the role schools play in developing and administering curriculum choices, noting the considerable flexibility recognized. In particular, schools are free to design courses and policies for enforcement so long as they "amount to reasonable means of furthering legitimate educational ends." The court also noted that freedom of speech claims implicate two potentially competing "strands of law." First, governmental bodies (including public high schools and universities) have wide latitude to control their own speech citing numerous cases in support of restrictive activity. Next, the court pointed out that public schools are "not expression-free enclaves" citing numerous cases that have found restrictions to be violative of the First Amendment.

In reconciling these lines of cases, the court cited the need for an application of these principles in light of the special characteristics of the school environment. So long as its actions are reasonably related to legitimate pedagogical concerns, public schools may limit student speech. Restriction on speech related to legitimate pedagogical concerns allows teachers and administrators to account for student maturity and students do not have the First Amendment right to veto a program's curriculum or required classes. "A school need not tolerate student speech that is inconsistent with its basic educational mission." However, on the other hand, the First Amendment "does not permit educators to invoke curriculum as a pretext for punishing [a] student for her . . . religion."

The court of appeals reversed the lower court and found that the matter deserved to go to a jury to make material factual determinations. It held that questions existed as to whether the student indeed violated the ACA Code of Ethics. In point, the court found that the ACA Code of Ethics provides for values-based referrals, several textbooks permitted and encouraged values-based referrals, testimony supported widespread referral of gay and lesbian clients based upon relationship sessions, and, finally, separate ACA Code of Ethics provisions adopted by the school discourage conversion therapy. In short, the court asked "what exactly did [the student] do wrong in making a referral request?"

The court emphasized that the legal issues at stake did not involve the existing school policies, but rather the fact that the school did **not** have a no referral policy for practicum students while at the same time adhering to an ethics code that permitted and encouraged values-based referrals. Accordingly, the court of appeals reversed and remanded the case for further proceedings.

Again, under a free speech analysis, several scenarios are relevant to the regulatory boards, including not only the potential for a candidate to be ineligible for licensure based upon the acts of a third-party educational institution, but also how a board may address a complaint against a licensee for either refusing to treat or attempting to refer to another practitioner an identified population. Such questions provide a segue into the next case.

A First Amendment Right to Refuse to Fill

Stormans Inc v. Selecky, 2012 U.S. Dist. LEXIS 22370 (Western Dist. WA 2012)

The Washington State Board of Pharmacy promul-

(continued on page 128)

Legal Briefs

(continued from page 127)

gated regulations in 2007 that resulted in two new rules. The first rule was referred to as a **delivery rule** and imposes upon pharmacists a duty to deliver lawfully prescribed drugs or devices in a timely manner consistent with reasonable expectations for filling the prescription. Exceptions to this mandate include the following:

- prescriptions containing an obvious or known error,
- national or state emergencies or guidelines affecting availability,
- lack of specialized equipment or expertise on the part of the pharmacy,
- potentially fraudulent prescriptions, or
- unavailability of the drug or device despite good faith compliance with applicable stocking rules.

This delivery rule coincides with an existing **stocking rule,** which requires pharmacies to "stock a representative assortment of drugs in order to meet the pharmaceutical needs of its patients."

In addition to the delivery rule, the 2007 rulemaking process resulted in the **pharmacist responsibility rule,** which prohibits a pharmacist from:

- destroying or refusing to return unfilled a lawful prescription,
- violating a patient's privacy, and
- unlawfully discriminating against, intimidating, or harassing a patient.

Under rules in existence, a pharmacist may refuse to fill a prescription, but a pharmacy may not. The 2007 rules recognized this distinction and took such into consideration during the adoption process. Thus, under Washington law, a pharmacist with a sincere religious belief can refuse to fill a prescription and the pharmacy can comply with the delivery rule by having another on-duty pharmacist fill and dispense the product.

On July 25, 2007, the day the new rules became effective, two pharmacists and a corporate pharmacy (plaintiffs) filed suit in federal court against Washington State Department of Health officials (defendants). The litigation was premised upon religious beliefs and the impact such a rule would have on emergency contraceptives (Plan B and ella). The plaintiffs asserted three constitutional claims and sought to strike down the new rules as violative of certain constitutional rights, including their right to substantive due process; their right to free exercise of religion; and their right to equal protection under the law.

Multiple procedural gyrations occurred in the case, including the entry of a preliminary injunction by the District Court prohibiting the enforcement of the rules. The defendants appealed the matter to the 9th Circuit Court of Appeals, which reversed the preliminary injunction based upon the application of the wrong standard. The 9th Circuit remanded the matter to the District Court that entered a new order.

The District Court first addressed the plaintiffs' substantive due process claim. Substantive due process provides heightened protection against government interference with certain fundamental rights and liberty interests under the Fourteenth Amendment. Substantive due process requires scrutiny of the right or interest at stake. To be the beneficiary of this heightened scrutiny, a right or interest must be "deeply rooted in the Nation's history and tradition." Further, the fundamental liberty interest must be subject to a "careful description." Based upon these high standards, courts are cautioned against expanding the concept of substantive due process.

The plaintiffs argued that they have a fundamental right to refrain from actively participating in the termination of a human life and that the state cannot compel them to violate their right of conscience. The court engaged in a thorough analysis of past jurisprudence and distinguished the current matter from previous opinions. The previous cases addressed assisted suicides and Death with Dignity legislation and concluded that "states can **prohibit** medical providers from assisting in the taking of a life and can **permit** them to participate in the taking of a life. But can the state **compel** medical providers to participate in the taking of a life?"

Distinguishing the past cases from the current case is the disagreement on whether a life is at stake. Thus, the court engaged in an analysis of the definition of the beginning of life, including *Roe v. Wade*. Because the beginning of life has yet to be defined for purposes of constitutional law and because it is unclear as to whether previous US Supreme Court precedent would apply to emergency contraceptives, the District Court held that it would not expand the scope of existing substantive due process. Accordingly, the court refused to expand the fundamental right of conscience to the plaintiffs under these circumstances and held that substantive due process rights were not at stake.

Regarding the First Amendment, the plaintiffs argued that the new rules violate their right to the free exercise of religion and force them to choose between their religious beliefs and their livelihood. The court noted that if a law is neutral and generally applicable, it need only be rationally related to a legitimate governmental interest and incidental burdening of a religious belief may be tolerated. The court then assessed whether the rules were neutral and generally applicable. In its analysis, the court found that the rules were facially neutral as they do not contain any reference to religious practice, conduct, or motivation.

However, the court noted that the rules were "riddled with exemptions for secular conduct, but contain no such exemptions for identical religiously-motivated conduct." For example, a pharmacy can

refuse to stock a drug for a host of secular reasons such as a drug falls outside the pharmacy's niche; has a short shelf life; is expensive; attracts criminal activity; requires excessive paperwork; and the list goes on. Indeed, such refusal to stock can occur even if there is a demand for such drugs by patients. Further, the delivery rule is undermined by secular exceptions. For example, a pharmacy may decline to accept Medicare or Medicaid or a particular insurance coverage. As cited by the court, "a pharmacy is permitted to refuse to stock oxycodone because it fears robbery, but the same pharmacy cannot refuse to stock Plan B because it objects on religious grounds."

The court rejected the defendants' arguments in response to the above and emphasized the failure of the defendants to be able to articulate why a refuse and refer policy creates greater difficulties when a pharmacy declines to stock a drug for religious reasons, rather than for secular reasons. Also, the court noted that legislative history supports the fact that the rules were drafted "primarily for the purpose of forcing pharmacies (and, in turn, pharmacists) to dispense Plan B over sincerely held religious beliefs." This legislative history included an assessment of communications from the governor and interest groups.

Thus, the court found that the rules were not neutral in their operation and could not be upheld unless they were narrowly tailored to achieve a compelling state interest. Under this strict scrutiny analysis, the court noted that a law restrictive of religious practice must advance "interests of the highest order" and "must be tailored in pursuit of those interests" in order to survive First Amendment scrutiny. Due to the fact that the rules are riddled with secular exemptions that undermine the goal of increased patient access to medications, the court determined that they cannot withstand this legal challenge. After a quick analysis of the remaining equal protection and other discrimination claims, the court concluded that the board's rules discriminate intentionally and impinge the plaintiff's fundamental right to free exercise of religion. It entered an order permanently enjoining their enforcement against the plaintiffs.

The implications of the First Amendment on the regulatory community can be profound. While boards of pharmacy must diligently pursue the regulation of the profession in the interest of public protection, they must also be aware of the impact of the restrictive nature of government regulation, the need for neutral and generally applicable laws in both drafting and enforcement, as well as fundamental rights of the applicants, licensees, and consumers.

NABP Reappoints Michael Moné to Serve on ACPE Board

NABP is pleased to announce that Michael A. Moné, JD, RPh, a member of the Ohio State Board of Pharmacy, has been reappointed by the NABP Executive Committee to serve on the Accreditation Council for Pharmacy Education (ACPE) Board of Directors for another six-year term ending in 2018.

As an active member of NABP, Moné served for three years as an Executive Committee member representing District 3 from 2002 to 2005. Moné has also participated in many of the Association's committees, including serving as chair of the Committee on Constitution and Bylaws, as Executive Committee liaison to the Advisory Committee on Examinations, and as a member of the Committee on Law Enforcement/Legislation. In addition, Moné has served as a member of the Multistate Pharmacy Jurisprudence Examination® Review Committee since 1998.

Currently, Moné is the vice president, anti-diversion and senior regulatory counsel for Cardinal Health, Inc. Prior to this position, Moné served as the director of regulatory compliance for Medicine Shoppe International. From 1996 to 2004 he served as the executive director of the Kentucky Board of Pharmacy, and from 1993 to 1996 he served as an assistant attorney general for the state of Florida.

Moné has also contributed to the practice of pharmacy as a leader in several pharmacy organizations and law associations. He has been an active member of the American Pharmacists Association, the United States Pharmacopeial Convention, the Florida Pharmacy Association, and the Leon County Pharmacy Association. He has also served on the Kentucky Governor's Task Force on Controlled Substance Abuse in 2000, and was a member of the Attorney General's task force to develop the Kentucky All Schedule Prescription Electronic Reporting system, Kentucky's prescription monitoring program.

Moné received his bachelor of science degree in pharmacy from the University of Florida College of Pharmacy and a juris doctorate from the University of Florida College of Law.

Moné rejoins NABP's other representatives on the ACPE board: Dennis K. McAllister, RPh, FASHP, director, regulatory affairs, Express Scripts, whose term expires in 2016, and Donna S. Wall, PharmD, BCPS, FASHP, clinical pharmacist, Indiana University Health at Indiana University Hospital, whose term ends in 2014.

NABP, the American Association of Colleges of Pharmacy, and the American Pharmacists Association each appoint three members to the ACPE Board of Directors.

Annual Report of Counsel on Association Legal Affairs

Since the 2011 Annual Meeting, NABP marked several exciting milestones in its 108-year history. The Legal Affairs Department provided substantial support to the Association in realizing these achievements.

NABP filed its very first patent applications with the United States Patent and Trademark Office in February 2012. Competency Assessment Department staff developed Pallet Assembly℠ and the Outlier Detection Tool, two novel computerized processes that fortify the security of NABP examinations, from their development and delivery to identifying irregular or suspect scores. Legal Affairs staff assisted in the application filings, and will continue to monitor their progress.

Equally noteworthy is NABP's submission of a registry application to the Internet Corporation for Assigned Names and Numbers (ICANN). Legal Affairs negotiated contracts in support of NABP's application to become the registry for the .pharmacy generic Top-Level Domain. Similar to the .aero domain, which is dedicated to the aviation industry, .pharmacy would be available to professional entities and individuals in the pharmacy-related field. If ICANN approves the application, NABP would establish sound policies for its oversight of the registration process when entities seek to purchase .pharmacy domains for their bona fide pharmacy-related activities.

In late 2011, NABP filed, and won, its first domain dispute against an individual who improperly registered domains using the VIPPS® trademark from the NABP Verified Internet Pharmacy Practice Sites℠ program. The Web site addresses were awarded to NABP, and the Legal Affairs Department assisted in the arbitration action and domain transfer process.

Moreover, NABP officially partnered with the Accreditation Council for Pharmacy Education to jointly operate the CPE Monitor™ service. The service collects and reports continuing pharmacy education, and is a key resource for individual licensees and regulatory boards. The Legal Affairs Department negotiated the contract and assisted in filing trademark applications for this important initiative.

The Legal Affairs Department continues to work closely with its legal counterparts who represent the boards of pharmacy. In the past year, Legal Affairs negotiated many contracts with board counsel for the provision of valuable educational and public health protection services such as licensure examinations, newsletters, inspections, and NABP PMP InterConnect℠ access. In the coming year, the department plans to implement additional efforts to foster stronger relationships with board counsel.

Litigation Matters

In March 2009, an examination candidate filed a lawsuit against NABP and Carmen Catizone [NABP executive director/secretary] following the invalidation of his North American Pharmacist Licensure Examination® (NAPLEX®) score. He alleged breach of contract, defamation, negligence, and intentional infliction of emotional distress.

Two years later, on April 13, 2011, the US District Court for the Eastern District of Michigan dismissed all claims against NABP and Catizone by granting the summary judgment motion that NABP filed. The candidate appealed the decision to the US Court of Appeals for the Sixth Circuit. On April 5, 2012, the Court of Appeals affirmed the District Court's decision. Accordingly, all claims have been dismissed. The candidate did not file a motion for rehearing with the Appellate Court, but may elect to file a petition for a writ of certiorari with the US Supreme Court.

This lawsuit involves key examination services that NABP provides on behalf of the boards of pharmacy. Because the integrity and security of the NAPLEX and Multistate Pharmacy Jurisprudence Examination® are of vital importance to the Association and its members, NABP continues to invest substantial resources to protect the licensure examinations, including litigation efforts aimed at thwarting testing misconduct.

Conclusion

The landmark initiatives of the Association in the past year are a testament to the growth of NABP and its significant endeavors in support of its member boards of pharmacy. The Legal Affairs Department continues to assist NABP in these efforts to alleviate government burden and educate and safeguard consumers. Fostering the NABP-member board partnership is critical to the success of both organizations, and essential in overcoming challenges to the integrity of our public health protection efforts.

Newly Approved e-Advertiser

The following entity was accredited through the NABP e-Advertiser Approval℠ Program:

ScriptRelief, LLC
www.rxreliefcard.com

A full listing of NABP-approved e-Advertisers is available on the NABP Web site at *www.nabp.net*.

Task Force Recommends Broad Regulations, *Model Act* Revisions, and Future NABP Actions to Help Ensure Safety of Technology Systems

Acknowledging that pharmacy practice technology systems rapidly evolve, and many times outpace regulations, the Task Force on Pharmacy Practice Technology Systems agreed that focusing on broadly written regulations that can encompass future technologies would be an effective approach for boards of pharmacy. Implementing advanced technologies in the pharmacy benefits patients by creating more time for direct patient care and thus, improving patient outcomes, as recognized by NABP members. Thus, with patient safety goals in mind, the NABP membership agreed that uniformity of the terms found in the laws and regulations for such technology systems is needed and would assist boards of pharmacy in assessing and authorizing new technologies, and called for the establishment of the task force.

The Task Force on Pharmacy Practice Technology Systems met November 1-2, 2011, at NABP Headquarters, and undertook the following charge:

1. Review existing current state laws and regulations addressing the use of technology systems and relevant *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* language.
2. Recommend revisions, if necessary, to the *Model Act* addressing this issue.
3. Propose a mechanism for researching, advising state boards of pharmacy, and updating the *Model Act* on future innovations and changes in technology.

The first recommendation of the task force is that the Association should work with the boards to recognize that technology can be utilized to improve patient outcomes, but without specific proscriptive laws or rules, and rather by utilizing laws and rules that are broadly written and place responsibility on the pharmacist on duty and the pharmacy permit holder. The task force agreed that specifying who holds responsibility for overseeing the technology is important to ensure accountability and public safety in the event of system failures.

Task force members also agreed that a pre-determined rubric would assist boards of pharmacy in the development and implementation of non-specific regulations for technology systems, and would provide for quality assurance and accountability. Members recommended that NABP should encourage boards to adopt specific requirements to assist in technology systems assessment. Specifically, pharmacies should be required to implement policies and procedures that address the following categories:

- training;
- security and confidentiality;
- record keeping and accountability;
- quality assurance;
- quality improvement;
- workflow processes; and
- emergency procedures.

Members recommended that each category in the rubric would have a broad set of rules that are not specific to a particular technology.

The third recommendation of the task force was that NABP staff should review the *Model Act* to determine where amendments are needed to replace technology-specific provisions with "shared services" concept language that is used by several states. Shared services language addresses technological advances in pharmacy practice, as well as the trend for involvement of more than one pharmacist in the dispensing process. Members discussed how the shared services concept language is more general and allows for broad categories of systems, and should replace language such as "central fill" and "remote dispensing." They also discussed how shared services language can account for both operational technology-supported functions, such as counting, packaging, and labeling, as well as cognitive technology-supported functions, such as order entry verification and drug utilization review.

In addition, members acknowledged that technology systems evolve rapidly, often at a pace surpassing the ability of many boards of pharmacy to keep up by helping to enact new laws or by implementing new regulations. Thus, the task force recommended that NABP should assist by assessing emerging technologies to determine if they can improve patient care, while ensuring public safety.

Finally, due to the rapid pace of technological advancement, the task force recommended that NABP should consider establishing an ongoing task force that meets regularly to discuss this issue and determine if further action is necessary to assist the boards of pharmacy with the assessment and approval of pharmacy practice technology systems.

The establishment of the Task Force on Pharmacy Practice Technology Systems was called for in NABP Resolution No. 107-1-11 that was approved at the Association's 107th Annual Meeting in May 2011. Task force members included Patricia "Trish" D'Antonio, MS, MBA, RPh, CGP, chair; Lee Ann Bundrick, RPh; Danna Droz, JD, RPh; Amy Mattila, PharmD; Dennis McAllister, RPh, FASHP; Michael Podgurski, RPh; and Kenneth Saunders, PharmD, RP, TTS. James T. DeVita, RPh, served as the Executive Committee liaison.

The recommendations of the task force were approved by the NABP Executive Committee during its February 2012 meeting. The full report of the task force is available in the Members section of the NABP Web site at *www.nabp.net/members.*

April 2012 FPGEE Score Results Now Available

The score reports from the April 19, 2012 Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) administration are now available. Candidates who sat for the April 19 administration may now enter their equivalency examination number and date of birth to access an electronic download of their score reports through the NABP secure network login page. The login page may be accessed through a link available at *www.nabp.net/programs/examination/fpgee*.

A total of 881 candidates sat for the April 19, 2012 administration. The next FPGEE is scheduled for November 9, 2012. More information about the FPGEE is available in the Programs section of the NABP Web site at *www.nabp.net/programs*.

Accountability Task Force

(continued from page 123)

properly execute their legal responsibilities in order to maintain pharmacy security and prevent employee theft, the task force also recommended that NABP develop relevant resources and programs.

The task force also agreed that initial and random drug screenings play an important role in the deterrence of employee theft and diversion, and recommended that NABP strongly encourage pharmacy employers to conduct such screenings on all employees who have access to prescription drugs. Further, the task force recommended that pharmacy employers verify that common carriers have in place security provisions, such as conducting criminal background checks and random drug screens on its employees who have access to prescription drugs.

Regarding required background checks for licensees and registrants, the task force noted the ongoing problem of individuals being admitted to pharmacy schools and pharmacy technician education programs without a background check or other inquiries that would identify reasons that would prohibit licensure or registration. Thus, the task force recommended that NABP work with the American Association of Colleges of Pharmacy (AACP), the Accreditation Council for Pharmacy Education, and other stakeholders to harmonize entry qualifications for such programs so as to prohibit admission of individuals who would never qualify for licensure or registration.

Members also agreed on the importance of a multi-faceted educational approach that includes coordinated efforts by boards and schools of pharmacy. Thus, the task force recommended that NABP should encourage NABP/AACP district meeting chairs to include the topics of drug diversion and prescription drug abuse in joint session programming.

Finally, the task force recommended that NABP should issue a public statement of concern regarding drug diversion and prescription drug abuse that incorporates the AWAR$_X$E® consumer protection program.

The Task Force on the Control and Accountability of Prescription Medications was established as a result of Resolution 107-3-11, which was passed at the Association's 107th Annual Meeting in May 2011, calling for the review of issues related to the control and accountability of prescription medications. Task force members included John Kirtley, PharmD, chair; Herb Bobo, RPh; William Fitzpatrick, RPh; Virginia Herold, MS; Gary Karel, RPh; Douglas R. Lang, RPh; Alice Mendoza, RPh; Leo Richardson, PhD; and Joanne Trifone, RPh. Edward G. McGinley, MBA, RPh, served as the Executive Committee liaison.

The recommendations of the task force were reviewed and amended by the Committee on Law Enforcement/Legislation in February 2012 and subsequently approved by the NABP Executive Committee during its May 2012 meeting. The full report of the task force is available in the Members section of the NABP Web site at *www.nabp.net/members*.

Newly Accredited Vet-VIPPS Facility

The following veterinary Internet pharmacy was accredited through the NABP Veterinary-Verified Internet Pharmacy Practice Sites℠ (Vet-VIPPS®) program:

Revival Animal Health, Inc
www.revivalanimal.com

A full listing of the accredited Vet-VIPPS sites is available on the NABP Web site at *www.nabp.net*.

NABP Holds First Ever PCOA Forum, Offers Communicative and Informative Atmosphere for Attendees to Hear from Colleagues

On April 19, 2012, nearly 30 representatives from schools and colleges of pharmacy, the American Association of Colleges of Pharmacy, and the Accreditation Council for Pharmacy Education, gathered at NABP Headquarters for the first ever Pharmacy Curriculum Outcomes Assessment® (PCOA®) Forum. The forum was held to cultivate a communicative, educational, and collegial environment for PCOA users, prospective users, stakeholders, and developers to convene and share their own perspectives and experiences regarding the assessment.

Sharing Experiences

The forum began with an explanation of the developmental history and background of the PCOA, after which NABP staff provided a technical summary of the assessment including an overview of past years' administration results. The remainder of the meeting was driven by the attendees, consisting of five brief presentations, followed by an afternoon of open discussion, allowing for attendees to dialogue among each other and tailor the forum to their specific interests and needs.

During the presentations, representatives from five different schools and colleges of pharmacy shared how they utilize the data received from the PCOA administration. In addition, the panelists explained in detail how they have applied the assessment within their universities.

In his presentation, Sam Augustine, PharmD, FAPhA, professor, pharmacy practice, Creighton University School of Pharmacy and Health Professions, explained his university's purpose for administering the PCOA as threefold: to benchmark longitudinal assessment of student learning, increase reliability of outcomes assessment through triangulation of measurements to assure comparability between a campus and distance pathway, and evaluate the efficacy of the PCOA as a capstone assessment. Lorraine Cicero, MS, PharmD, assistant dean, Academic and Student Affairs, and associate professor of pharmacy practice, shared her experiences with the PCOA at Long Island University, where the PCOA was implemented three years ago, and described how the university developed an evaluation process based on students' scores. At the University of Mississippi, David McCaffrey, MS, PhD, professor of pharmacy administration and research professor in the Research Institute of Pharmaceutical Sciences, explained that the PCOA, though not employed as a high-stakes assessment, has been utilized by some students as supporting evidence of their fitness to matriculate despite marginal standing with regard to the university's academic policies. The university also tracks longitudinal assessment for each student as well as each class cohort in each of the four main content areas of the PCOA.

In another presentation, Jamie Fairclough, MPH, MS Pharm, PhD, assistant professor and director of community health programs, Palm Beach Atlantic University, uses the PCOA to benchmark student performance and curricular effectiveness with other colleges using a standardized validated instrument. Furthermore, the data suggested a positive correlation between grade point average and the PCOA scores across program years and over time.

At Wilkes University, the PCOA is used to evaluate student performance in pharmacy curriculum. Rhonda Waskiewicz, EdD, assistant dean at Wilkes, has conducted studies addressing student motivation in low-stakes assessment and the effects of incentivizing in assessment outcomes.

With the intent of providing a well-rounded and valuable experience for all attendees, the forum cultivated an atmosphere where current users of the PCOA were able to discuss, share, and evaluate new ways in which to interpret assessment data, while potential new users had the chance to see the full picture from the incumbent users of the program.

Overall, the forum received enthusiastic feedback from attendees, many of whom expressed the importance of having the chance to participate in an open and informative event where they were able to also network with their colleagues.

The PCOA is an independent, objective, and external tool to assist the colleges and schools of pharmacy in assessing student performance in United States pharmacy curricula. Since its operational launch in 2008, the assessment has been administered to more than 14,000 students from 46 different schools and colleges of pharmacy. The 2013 PCOA administration is scheduled to be available to the schools and colleges of pharmacy from January 28, 2013 to February 16, 2013. Informational packets will be sent to the schools in late summer 2012. More information about the PCOA can be found at *www.nabp.net/programs*.

Pharmacist Prescribing

(continued from page 121)

answered "yes" to the question, "May pharmacists initiate, modify, and/or discontinue drug therapy pursuant to a collaborative practice agreement or protocol?" In some states this authority may be quite limited. In Maine, for example, it applies only to oral contraception and requires a collaborative practice agreement and training, and in New York, it applies only in teaching hospitals. However, the fact that the majority of states have collaborative practice agreement regulations is notable.

Steps Forward: Pharmacist Prescribing Authority

While pharmacists may not initiate drug therapy as often as they are permitted to modify or discontinue treatment, prescribing is becoming more common. In most states that allow the practice, prescribing takes place within the bounds of a collaborative practice agreement with a specific practitioner and within a defined protocol. Washington State, for example, is a trailblazer and has allowed pharmacist prescribing since 1979, initially only in hospitals and since expanding to include even retail pharmacies. Pharmacists intending to prescribe must file their protocol agreement with the Washington State Board of Pharmacy. The written protocol is good for up to two years, and must include such information as the type of prescriptive authority decisions the pharmacist is authorized to make; the types of diseases, drugs, or drug categories involved; the general decision criteria or plan the pharmacist will follow when making therapeutic decisions; and the pharmacist's plans for such activities as documentation and communication with the authorizing practitioner. A number of other states feature broadly similar requirements for collaborative practice.

Much less common are instances in which pharmacists have independent limited prescribing authority. In Idaho, pharmacists last year received limited prescriptive authority to provide patients with fluoride supplements and most immunizations for patients over the age of 12. (See "Idaho Grants Pharmacists Limited Prescriptive Authority, Amends Definition of 'Drug Outlet' to Expand Regulatory Authority" in the October 2011 *NABP Newsletter*.) In Florida, pharmacists may prescribe independently from a limited formulary; restrictions include no prescribing to pregnant or nursing women, limiting the medication supply to 34 days, no refills, and advising the patient to see an appropriate health care provider if the prescription does not alleviate the presenting condition. One factor that has limited the ability of pharmacists in Florida to prescribe using this formulary is that many of the products listed are now available over-the-counter or have been discontinued. Other factors that may limit use of the formulary include liability concerns and requirements for record keeping not being supported by the pharmacy systems in place.

Some states require additional education for pharmacists to participate in collaborative drug therapy management or to hold prescriptive authority, ranging from completing a training course on smoking cessation before offering that service to patients, to obtaining a credential in a particular area of disease-state management. Other states have begun to create a new designation entirely for those pharmacists who plan to prescribe. North Carolina authorizes "clinical pharmacist practitioners" to "implement predetermined drug therapy, which includes diagnosis and product selection by the patient's physician, modify prescription drug dosages, dosage forms, and dosage schedules, and to order laboratory tests"; clinical pharmacist practitioners in certain hospitals and other health facilities may also order medications. New Mexico recognizes "pharmacist clinicians," defined as pharmacists "with additional training, at least equivalent to the training received by a physician assistant . . . who exercises prescriptive authority in accordance with guidelines or protocol." In 2010, Montana enacted legislation modeled after the New Mexico and North Carolina examples, and created the designation of "clinical pharmacist practitioner . . . a licensed pharmacist in good standing who . . . is certified by the board . . . to provide drug therapy management, including initiating, modifying, or discontinuing therapies, identifying and managing drug-related problems, or ordering tests under the direction or supervision of a prescriber."

In a few states, including California, Massachusetts, Minnesota, Montana, New Mexico, North Carolina, North Dakota, and Washington, pharmacists in certain circumstances may obtain a Drug Enforcement Administration number. The ability to write prescriptions for controlled substances opens the door for pharmacists to take an increased collaborative role in such areas as pain management, cancer treatment, end-of-life and hospice care, substance abuse programs, and other conditions that might require scheduled drugs.

Potential Speed Bumps

While collaborative medication therapy management and pharmacist prescribing seem to hold a great deal of promise to positively affect patient outcomes, increase health care access, and help control health care costs, there are difficulties. The American College of Clinical Pharmacy, in a 2003 position statement, noted some of the elements that needed to exist "for pharmacists to participate effectively" in collaborative drug therapy management: "a collaborative practice environment; access to patients; access to medical records; a defined level of education, training,

knowledge, skills, and abilities; documentation of clinical activities; and payment for pharmacists' activities." Each of these elements poses its own challenges. Pharmacists must find a physician willing to enter into a collaborative relationship, and that physician generally must refer patients to the participating pharmacist. Pharmacists may find it difficult to gain access to a patient's medical records. Documentation must be shared in a timely yet secure manner in a collaborative arrangement. And pharmacists face a large challenge in being reimbursed for their non-dispensing services.

Indeed, in a survey of advanced-practice pharmacists in North Carolina and New Mexico respondents identified reimbursement as one of the largest barriers to program success. "We found that [the advanced-practice pharmacists] were well regarded, in high demand, and providing important services," reported the researchers in the *American Journal of Health-System Pharmacy*. The researchers also noted that "Unless some form of reimbursement through governmental channels is enacted, the model of advanced-practice pharmacy is not likely to succeed." On the federal level, Congress has considered bills to recognize pharmacists as mid-level providers and allow them to bill Medicare Part B for clinical pharmacy services three times in the last eight years; thus far, all bills have died in committee.

In the absence of federal recognition of pharmacists as Medicare Part B providers, pharmacist organizations such as the American Society of Health-System Pharmacists (ASHP) hope to make progress on the state level. "[I]t is not necessary to wait for this federal legislative breakthrough in order to make progress with other payers, such as state Medicaid programs," ASHP noted in a 2008 policy analysis. "Pharmacists already have provider status in a growing number of programs, which eventually may lead to universal provider recognition."

Other, perhaps more philosophical, challenges also remain. These include addressing conflict of interest concerns, both in terms of patient safety and economic incentives, particularly in a retail pharmacy setting in which the pharmacist could theoretically act as both prescriber and dispenser. And perhaps hovering over all considerations remains the delicate task of establishing a pharmacy practice-wide vision of how pharmacists as prescribers fit into the overall future of health care, and how to reconcile that vision with the visions of other health care providers, particularly other prescribers. In an essay in the December 2011 *American Journal of Health-System Pharmacy* Lisa Nissen, BPharm, PhD, FSHP, FHKPA, associate professor, University of Queensland School of Pharmacy, spelled out some of these issues: "It is more a question of critically examining where pharmacist prescribers would be best placed within the health care system, and where they can provide the greatest value, while managing issues related to their scope of practice and conflicts of interest," she wrote. "The challenge will be to determine our own futures, recognize the value that we can add to the health system, and achieve this by working more collaboratively with medical practitioners and policymakers."

> And perhaps hovering over all considerations remains the delicate task of establishing a pharmacy practice-wide vision of how pharmacists as prescribers fit into the overall future of health care, and how to reconcile that vision with the visions of other health care providers, particularly other prescibers.

The Path Ahead

At NABP's 107th Annual Meeting in May 2011, delegates passed Resolution 107-4-11, "Pharmacists and Pharmacy Care," tasking the Association with encouraging and supporting "efforts by the profession to study the primary care health activities in which pharmacists can be engaged and methods by which pharmacists could be incorporated into the medical home model . . ." and also with working with various stakeholders "to facilitate a broader understanding of the potential for pharmacists, as providers, to engage in primary health care activities and ensure appropriate availability of primary health care services for all citizens." As this resolution reflects, the interest in increasing the pharmacist scope of practice continues to intensify, and the pharmacy profession appears poised for further change.

California has captured the changing landscape of pharmacy practice in its laws: "Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes," the state's Business and Professions Code states. "Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities." This dynamism may require legislators and regulators to continue to revisit state laws and regulations – but should yield the ultimate goal: increased access to needed health care and improved patient outcomes.

Nine States Now Sharing PMP Data Through NABP InterConnect

With the deployment of the NABP PMP InterConnect℠ in the states of Arizona and Kansas, nine state prescription monitoring programs (PMPs) are now able to share controlled substance prescription data. Since the launch of NABP InterConnect, the system that facilitates the secure sharing of data between state PMPs, over 350,000 requests have been processed through the system. In April, the Arizona Controlled Substances Prescription Monitoring Program and the Kansas Tracking and Reporting of Controlled Substances program, known as K-TRACS, joined PMPs in Connecticut, Indiana, Michigan, North Dakota, Ohio, South Carolina, and Virginia, which have implemented use of the NABP InterConnect, giving authorized PMP users the ability to request and share program data across state lines. It is anticipated that more than 20 states will be sharing data or in a memorandum of understanding to share data using the NABP InterConnect by the end of 2012.

NABP InterConnect/ Health Information Exchange Connection Pilot Moves Forward

NABP and NABP InterConnect participant Indiana Scheduled Prescription Electronic Collection and Tracking (INSPECT) developed a pilot program, to be initiated in July and scheduled for completion in summer 2012, as part of a national initiative aimed to increase utilization of PMPs. The pilot, part of the national Enhancing Access to Prescription Drug Monitoring Programs Project, uses the established NABP InterConnect connection with the INSPECT program, to connect to the Indiana Health Information Exchange as a means of integrating PMP data directly into electronic medical records in an emergency room department. Results of the pilot will be reported as part of the Enhancing Access to Prescription Drug Monitoring Programs Project.

NABP InterConnect Participation Continues to Grow

As of press time,

- NABP InterConnect has been deployed to authorized PMP users by PMPs in the states of Arizona, Connecticut, Kansas, Indiana, Michigan, North Dakota, Ohio, South Carolina, and Virginia. PMPs in Kentucky and New Mexico are on track to go live by the end of summer 2012.
- PMPs in the following states have executed a memorandum of understanding (MOU) with NABP to participate in the NABP InterConnect: Mississippi, Utah, and West Virginia.
- The following PMPs intend to sign on to use the NABP InterConnect and have MOUs under review: Delaware, Illinois, Louisiana, Montana, Nevada, North Carolina, Rhode Island, and South Dakota.

The most up-to-date information about state PMP participation is presented in the NABP PMP InterConnect map, available in the NABP InterConnect section of the NABP Web site at *www.nabp.net/programs*. Additional information about NABP InterConnect development, governance, and funding is also available on the NABP Web site.

NABP InterConnect Steering Committee Convenes

The NABP InterConnect steering committee met at NABP Headquarters March 27-29, 2012, to discuss various issues and actions related to governance structure and functionality enhancements, as well as administrative and other matters.

Boards of Pharmacy Now Able to Report Disciplinary Actions Taken Against Individuals Directly to HIPDB through Web-Based Interface

In May, NABP launched a Web-based interface that enables the state boards of pharmacy to report disciplinary actions taken against individuals through a convenient and secure online portal. This reporting tool will assist the boards in meeting requirements set forth by the United States Department of Health and Human Services, Health Resources and Services Administration, Division of Practitioner Data Banks. Implemented in 2010, these rules require state health care entity licensing and certification authorities, along with health care practitioner licensing and certification authorities, peer review organizations, and private accreditation organizations, to report adverse licensing actions taken since January 1, 1992, to the Healthcare Integrity and Protection Data Bank (HIPDB) and National Practitioner Data Bank.

This new electronic reporting tool allows boards of pharmacy that have designated the Association as their reporting agent to submit disciplinary actions taken against pharmacists, pharmacy technicians, and pharmacy interns directly to HIPDB. In addition, all boards of pharmacy are able to report individual disciplinary action data simultaneously to the NABP Clearinghouse through this tool. The individual reporting capability is housed in the same secure, Web-based interface the boards of pharmacy use to report facility disciplinary actions and manage candidate eligibility for the North American Pharmacist Licensure Examination® and Multistate Pharmacy Jurisprudence Examination®. In addition, the boards of pharmacy have the option to search, query, store, and export available disciplinary data.

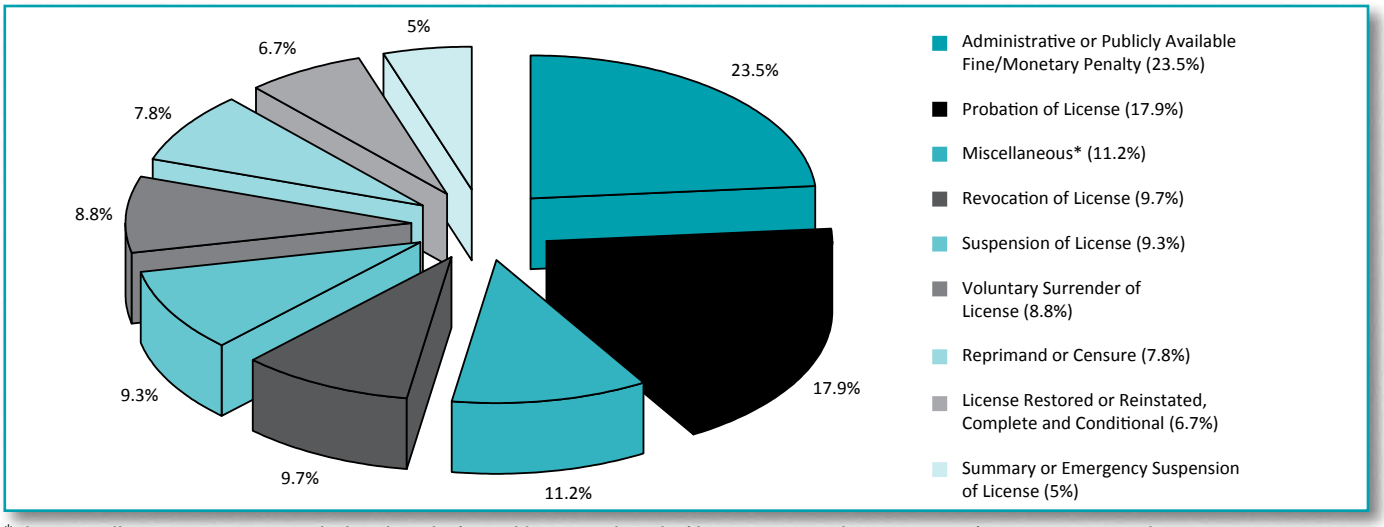
The user-friendly interface cuts down on the time boards must spend inputting disciplinary action data by providing an organized electronic form to input data specifically required by HIPDB. As an added benefit, the system automatically responds in real time to the boards with a document control number to confirm receipt of complete data or an alert if an error or missing information is detected. To ensure that the boards obtain maximum benefit from the individual reporting tool, NABP plans to hold informational Webinars in July, providing a demonstration and detailed instruction on using the system.

First Quarter Reporting

As an essential component to maintaining the integrity of the licensure transfer program among the states, reporting to the NABP Clearinghouse is required by the NABP Constitution and Bylaws. Findings from the first quarter 2012 reporting totals demonstrate continued reporting efforts by the state boards of pharmacy. A total of 816 records were reported to the database during the first quarter, 63% of which were actions taken on pharmacists and 37% of which were actions taken on pharmacy technicians. This is a decrease of 48% from the total number of records reported during the first quarter 2011; however, with the significant

(continued on page 138)

Figure A: Disciplinary Actions Reported First Quarter 2012



*The miscellaneous category includes denial of initial license; denial of license renewal; extension of previous action; license restoration or reinstatement denied; limitation or restriction on license; other licensure action – not classified; and reduction of previous action.

Clearinghouse Update

(continued from page 137)

increase of submissions in 2010, it is likely that the number of records reported during the first few months of 2011 may have remained unusually high as some states may still have been working to catch up on any backlogs in disciplinary reporting.

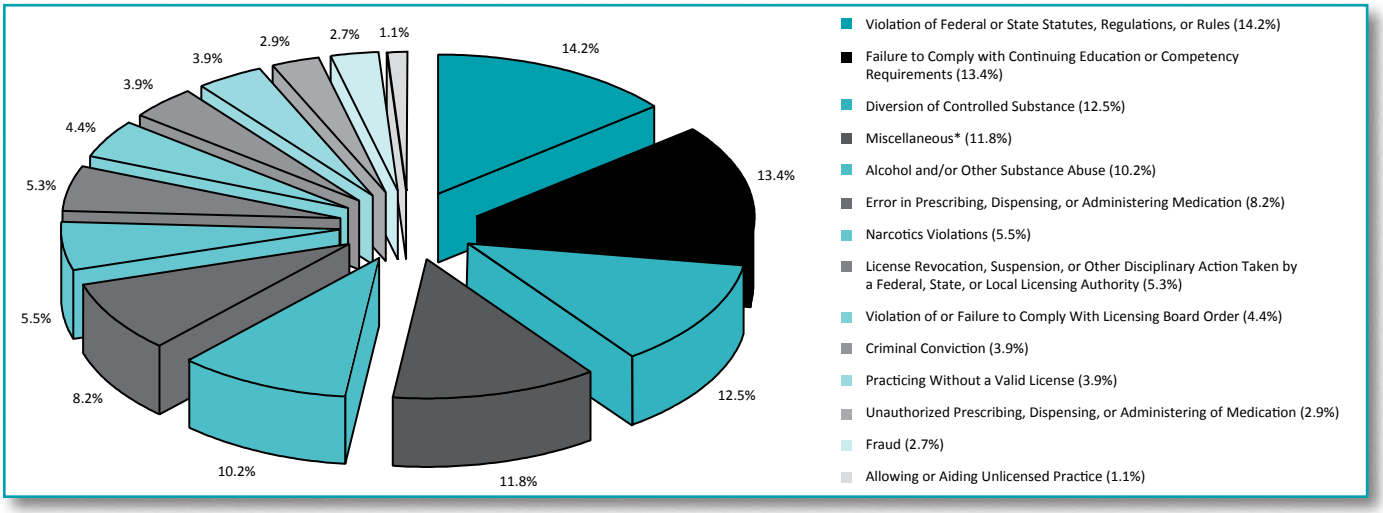
The administrative or publicly available fine/monetary penalty category accounted for the most actions reported with 192, or 23.5%, of the total 816 actions. Probation of license was the second most reported action during the first quarter with 146, or 17.9%, of the actions reported. Consisting of several smaller categories, the third most common action reported was the miscellaneous category with 91, or 11.2%, of the total actions. (See Figure A.)

Data indicates that of all the actions taken during the first quarter, 14.2% were taken due to violation of federal or state statutes, regulations, or rules. Failure to comply with continuing education or competency requirements held the second highest percentage overall with 13.4%. Another 12.5% of the actions reported during the first quarter were taken due to diversion of controlled substance. (See Figure B.)

Currently 31 boards of pharmacy have designated NABP as their HIPDB reporting agent; however, all boards of pharmacy are encouraged to utilize the online tool to report pharmacy disciplinary actions to the NABP Clearinghouse regardless of whether NABP is their reporting agent.

More information on reporting to the NABP Clearinghouse and how to designate NABP as a HIPDB reporting agent can be obtained by visiting the Member Services section of the NABP Web site located at *www.nabp.net/programs.*

Figure B: Basis for Disciplinary Actions Reported First Quarter 2012



*The miscellaneous category includes immediate threat to health or safety; improper or inadequate supervision or delegation; misrepresentation of credentials; negligence; other – not classified; and unable to practice safely.

Around the Association

Board Member Appointments

- **William Francis, MBA, RPh,** has been appointed a member of the Arizona State Board of Pharmacy. Francis's appointment will expire on January 16, 2017.
- **Armand Potestio, RPh,** has been appointed a member of the Colorado State Board of Pharmacy. Potestio's appointment will expire on July 1, 2015.
- **Heather Hawker, JD,** has been appointed a public member of the Colorado State Board of Pharmacy. Hawker's appointment will expire on July 1, 2015.
- **Ginny Orndorff, MA, MBA,** has been appointed a public member of the Colorado State Board of Pharmacy. Orndorff's appointment will expire on July 1, 2015.
- **Richard Carbray, RPh,** has been appointed a member of the Connecticut Commission of Pharmacy. Carbray is serving at the discretion of the governing body.
- **Angelo DeFazio, RPh,** has been appointed a member of the Connecticut Commission of Pharmacy. DeFazio is serving at the discretion of the governing body.
- **Ed Sperry** has been appointed a public member of the Idaho State Board of Pharmacy. Sperry's appointment will expire on June 30, 2013.

(continued on page 140)

Indiana Board Now Requiring CPE Monitor Registration and NABP e-Profile ID for License and Certification Renewals

Pharmacists and pharmacy technicians who are renewing their license or certification in Indiana will now need to be registered for CPE Monitor™ and obtain their NABP e-Profile ID prior to completing their renewal applications. Implemented administratively through the Indiana Board of Pharmacy's rules, this new requirement will enable the Board and NABP to sync their systems and ensure the accuracy of licensee data within the two systems. Additionally, by utilizing the e-profile ID to pre-sync its system to NABP's, the Board will have full access to an online registry of its licensees' completed continuing pharmacy education (CPE) credits once the capability is live in 2013. This will give the Board the ability to conduct audits electronically when monitoring compliance with CPE requirements.

"NABP's forward looking investment in technology and security has allowed the Board to vastly improve the level, speed, and efficiency in which it provides administrative services (without raising fees) to Indiana licensees in areas such as license transfer, CE audits, and reporting," states Phil Wickizer, JD, then director, Indiana Board of Pharmacy. "We look forward to being able to utilize CPE Monitor next year and in working with the Association to develop additional services to assist pharmacists and pharmacy technicians in our state and others."

The official Indiana Board license renewal period began on May 1, 2012, with all licenses and certifications expiring on June 30, 2012. With the conclusion of this renewal period, NABP will begin utilizing the e-Profile IDs provided by Indiana licensees to match data stored in the Association's system with the Board's data. The syncing of these systems will allow NABP to provide real-time feedback to the Board and will provide enhanced data exchange capabilities, which will further expedite license verification processes and other board regulatory tasks that require validation of licensee compliance. In the future, it is expected that the synced systems will be able to regularly exchange data in agreed upon intervals and will be able to provide real-time data sharing.

Additionally, the Indiana Board's utilization of the e-Profile ID as the unique identifier will eliminate the need for the Board to use sensitive data to link to the NABP database, further protecting individuals' personal information. NABP will also be able to improve its services to the Board by expediting verification processes for other programs and applications such as license transfer, NABP pre-examinations and examinations, and the many accreditation programs.

NABP anticipates Indiana to be the first of many states to implement data exchange capabilities with the Association through e-Profile ID matching. The boards of pharmacy will be able to use the verified data available through the linked systems as a resource to assist in daily regulatory tasks relating to their licensees. Ultimately, it is NABP's hope that these processes will assist the boards in expediting verification procedures and further tightening security measures.

Register for CPE Monitor; Obtain e-Profile ID

Licensees not only in Indiana, but in all states, are encouraged to obtain their e-Profile ID by creating their NABP e-Profile and registering for CPE Monitor, if they have not done so already. Even if a licensee already created an e-Profile, completion of CPE Monitor registration is necessary to fully activate his or her e-Profile ID. In order for the CPE Monitor service to electronically track and record Accreditation Council for Pharmacy Education (ACPE)-accredited CPE credit in the NABP e-Profile, the e-Profile ID along with the licensee's date of birth (MMDD) must be submitted to providers when participating in an ACPE-accredited CPE activity. It is important that the correct information is provided to ensure that CPE credit is accurately recorded in the e-Profile through the CPE Monitor service.

As part of the NABP e-Profile, the CPE Monitor service will store a comprehensive list of individuals' CPE activities and provides a convenient tool for boards of pharmacy, pharmacists, and pharmacy technicians to electronically track their CPE credit. At press time, more than 80 providers had implemented their systems with CPE Monitor. As additional providers come on board, pharmacists and pharmacy technicians will be able to view their CPE credit through their NABP e-Profiles.

Currently, more than 160,000 pharmacists and 81,000 pharmacy technicians have set up their e-Profiles. To obtain an e-Profile ID, licensees may visit *www.MyCPEmonitor.net,* create an e-Profile, and register for CPE Monitor.

Expos and Presentations Widen AWARXE Audience

Reaching pharmacists, regulators, employers, seniors, and others, AWARXE® continues to have a presence at various health-related expos, conventions, and meetings across the country.

- **American Pharmacists Association, Annual Meeting and Exposition, New Orleans, LA, March 9-12, 2012**
  NABP staff hosted a booth, providing information on AWARXE and CPE Monitor™ to over 1,750 attendees who visited the booth. Attendees received AWARXE bookmarks and flyers, and an AWARXE/NABP airline plastic travel pouch.
- **Active Senior Expo, Bloomingdale, IL, March 28, 2012**
  The "Does a Drug Dealer Lurk in Your Medicine Cabinet?" theme was used to engage seniors and encourage participation in the April 28 Drug Enforcement Administration Take-Back Day. AWARXE flyers listed local collection site locations and included facts on the dangers of purchasing medications online. AWARXE bookmarks were provided, along with Know Your Dose information, as part of a partnership with the Acetaminophen Awareness Coalition.
- **National Rx Drug Abuse Summit, Orlando, FL, April 10-12, 2012**
  NABP staff hosted a booth in the Exposition Hall, providing information on AWARXE and PMP InterConnect℠ to over 750 summit attendees including federal and state regulators and legislators, as well as health care providers, law enforcement, and addiction treatment professionals, among others.
- **North Dakota Pharmacists Association Convention, Jamestown, ND, April 12-15, 2012**
  Laurel Haroldson, RPh, member, North Dakota State Board of Pharmacy hosted an AWARXE table, showed AWARXE public service announcements, and provided information to over 150 North Dakota pharmacists and pharmacy technicians.
- **Hamden Chamber of Commerce Business & Community Expo, Hamden, CT, April 17, 2012**
  Edith G. Goodmaster, board member, Connecticut Commission of Pharmacy hosted an AWARXE educational display at this expo that brought in over 1,000 attendees.
- **Cannon Falls Area Chamber of Commerce Breakfast, Canon Falls, MN, April 26, 2012**
  Stacy Larson, community prevention director/IT manager, Chemical Health Initiative of Goodhue County presented AWARXE employer information and resources to over 40 chamber members and encouraged participation in the Goodhue County S.A.F.E. Medication Disposal program.
- **2012 School Resource Officer & D.A.R.E. Officer Combined Conference, Oregon, OH, June 24-26, 2012**
  As part of an educational session on prescription drug awareness and abuse in the school setting, Jesse Wimberly, compliance agent, Ohio State Board of Pharmacy, shared AWARXE facts and resources with attendees. In addition to D.A.R.E. officers and school resource officers, attendees of the conference included school administrators, teachers, principals, school counselors, school-based police officers, juvenile probation officers, and detectives.

Around the Association

(continued from page 138)

- **William Mixon, MS, RPh,** has been appointed a member of the North Carolina Board of Pharmacy. Mixon's appointment will expire on April 30, 2017.
- **Carol Yates Day, RPh,** has been appointed a member of the North Carolina Board of Pharmacy. Day's appointment will expire on April 30, 2017.
- **Claudia Alexander, MS,** has been appointed a public member of the New York State Board of Pharmacy. Alexander's appointment will expire on March 31, 2017.
- **Kimberly Zammit, PharmD, BCPS, FASHP,** has been appointed a member of the New York State Board of Pharmacy. Zammit's appointment will expire on September 30, 2016.
- **Mark Zilner, RPh,** has been appointed a member of the Pennsylvania State Board of Pharmacy. Zilner's appointment will expire on March 5, 2018.
- **Katie True** has been appointed a public member of the Pennsylvania State Board of Pharmacy. True is serving at the discretion of the governor.
- **Emma Zavala-Suarez, JD,** has been appointed a public member of the Washington State Board of Pharmacy. Zavala-Suarez's appointment will expire on January 19, 2014.
- **Sepideh Soleimanpour, MBA-HA, RPh,** has been appointed a member of the Washington State Board of Pharmacy. Soleimanpour's appointment will expire on January 19, 2016.
- **Daniel Rubin, MPP,** has been appointed a public member of the Washington State Board of Pharmacy. Rubin's appointment will expire on January 19, 2016.

AWARXE Reaches Out to Over 65 Million Consumers Via Internet Social Media, TV and Radio PSAs, and Magazine Ad

Program Educates on Preventing Prescription Drug Abuse by Safe Medication Disposal

AWARXE® has reached over 65 million consumers through Internet, radio, and TV public service announcements (PSAs); online social media channels; and national magazine advertising.

AWARXE messages reached 10 million consumers through a social media campaign that resulted in detailed posts by popular bloggers, articles on news sites by social media writers, and placement of AWARXE Web banners on popular Web sites.

Health care, parenting, caregiving, and pet health bloggers engaged their readers with AWARXE information about the dangers of prescription drug abuse, the importance of proper disposal of unneeded medications, and the Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day on April 28, 2012. For example, several bloggers created blog post features that highlighted interview questions answered by NABP staff, along with AWARXE facts, and provided their readers with links to AWARXE PSAs and the AWARXE Web site. Several social media writers also promoted their AWARXE blog posts and articles with tweets to their followers, further expanding the reach of the AWARXE message.

In addition, several Web sites placed an animated AWARXE banner, highlighting DEA Drug Take-Back Day information, with clicks bringing users to the AWARXE Web site.

Interactive Press Release Reaches 11 Million More

Blogger participation and AWARXE banner placements led up to an AWARXE social media press release that highlighted the DEA Take-Back Day, and had an audience reach of over 11 million readers during the last week of April. This interactive press release gave viewers over 300 options for sharing the release, video links, and the AWARXE Web site through social media outlets.

Building on the momentum of blogger and Web site engagement with the AWARXE message, the second portion of the social media campaign, which was launched in mid-June, provided these Internet writers and sites with facts on counterfeit drug dangers, the risks of buying from Internet drug outlets, and information on buying medicine online using VIPPS® (Verified Internet Pharmacy Practice Sites℠)-accredited Internet pharmacies.

'Like' AWARXE on Facebook

Along with the social media campaign, the AWARXE Facebook page has been successfully relaunched, and continues to collect new "likes" as posts are made about medication disposal events, prescription drug abuse, counterfeit drug dangers, and medication safety issues.

Print Ads, TV, and Radio Expand Reach

With one in four grandparents indicating that they leave medications out and easily accessible, as reported in a recent study, there is a continued need to raise awareness among this group about protecting children and teens by securely storing and safely disposing of medications. An April *AARP Bulletin* ad helped bring the AWARXE message to this group, with the ad reaching 29 million adults aged 55 and older. Demographic data shows that over 50% of consumers aged 55 to 59 are grandparents, at least 68% of consumers aged 60 to 64 are grandparents, and 75% of consumers age 65 to 74 are grandparents. So, while a good portion of the blog posts and online articles reached the sandwich generation due to several placements on sites for moms and caregivers, the *AARP Bulletin* ad helped inform millions of grandparents and other adults over age 55.

Reaching a broad audience, AWARXE also provided television and radio stations in 16 geographic markets with broadcast PSAs for TV and recorded radio PSAs, as well as live-read scripts for radio announcers. All PSAs raised awareness about the importance of proper medication disposal in preventing abuse. From October 19, 2011 to May 2, 2012, TV PSAs received a total of 856 airings on 19 stations, with 14,147,597 total impressions. And, from March 5, 2012 to April 28, 2012, there were 791 airings on 15 radio stations, resulting in 871,000 impressions.

MT Board's PMP Now Accepts Data from Pharmacies

Beginning on March 12, 2012, Montana's Prescription Drug Registry, operated by the Montana Board of Pharmacy, began accepting data from pharmacies. As of April 12, 2012, pharmacies are required to report controlled substances dispensing on a weekly basis, and are also required to provide historical data going back to July 1, 2011.

The Board expects the registry to be fully available for query (searching) by fall 2012. More information about the Montana Prescription Drug Registry is available on the Board's Web site at *http://bsd.dli.mt.gov/license/bsd_boards/pha_board/board_page.asp.*

NJ Board Encourages Use of NJPMP

The New Jersey State Board of Pharmacy is encouraging licensed pharmacists to register to access the New Jersey Prescription Monitoring Program (NJPMP) and to use NJPMP data to help prevent prescription drug abuse.

Since September 1, 2011, New Jersey-licensed pharmacies have populated the NJPMP database with information on more than 6 million prescriptions for controlled dangerous substances (CDS) and human growth hormone. This highly detailed data has helped identify users who allegedly took advantage of doctors, pharmacists, and insurance companies, by purchasing astronomical quantities of narcotic CDS.

Several of these cases came to light thanks to individual pharmacists, who registered to access the NJPMP and learned about the CDS histories of clients. The Board notes that the NJPMP empowers registered users to identify warning signs of abuse and diversion, by learning whether a client has purchased CDS from an excessive number of pharmacies, or has obtained prescriptions from an excessive number of prescribers.

Pharmacists who are licensed by the state of New Jersey, and in good standing with the Board, may register for their own NJPMP access account. More information about the NJPMP can be found at *www.NJConsumerAffairs.gov/pmp.*

SD Implements PDMP to Track Controlled Drugs

The South Dakota State Board of Pharmacy has implemented a prescription drug monitoring program (PDMP) designed to track the dispensing of controlled drugs. Prescribers and pharmacists are able to use the patient information in the system in a variety of ways including detecting substance abuse problems, supplementing the patient's evaluation, confirming the patient's drug history, and documenting the patient's adherence to medication therapy. The South Dakota PDMP database includes all retail and outpatient dispensing records, except emergency room-dispensed quantities for 48 hours or less. In addition to drugs dispensed by South Dakota pharmacies, it also includes drugs dispensed to South Dakota residents by nonresident pharmacies. If a prescriber or pharmacist has a concern about a patient, he or she can look up the patient's history in the South Dakota PDMP. The database will show the controlled drugs the patient has received within the specified time period, the prescriber's name, and where the drugs were dispensed. Information will be available in seconds. Prescribers and pharmacists must register with the South Dakota PDMP and request access in order to utilize the online service.

MN Board Adopts Definition of Limited Service Pharmacy

The Minnesota Board of Pharmacy adopted a definition of limited service pharmacy, which reads "A pharmacy to which the board may assign a restricted license to perform a narrow range of the activities that constitute the practice of pharmacy." Currently, there are several different scenarios for which a limited service pharmacy license might be appropriate. For example, the Board has received inquiries from pharmacists who want to open an office at which they will perform vaccinations and conduct medication therapy management. These pharmacists do not intend to fill prescriptions at these offices and therefore do not need to purchase or store drugs. The Board notes that issuing a limited service pharmacy license to such an office may help the pharmacists obtain reimbursement from third-party payers that require such services to be performed in a licensed pharmacy.

NC Board No Longer Approves CE Courses Not Accredited by ACPE or NCAP

Beginning March 1, 2012, the North Carolina Board of Pharmacy ceased approving requests for continuing education (CE) courses that are not accredited by the Accreditation Council for Pharmacy Education (ACPE) or the North Carolina Association of Pharmacists (NCAP). The reasons for the policy are two-fold: (1) the volume of such requests has increased substantially in the past two years, hindering Board staff's ability to focus on the Board's core functions; and (2) relatedly, Board staff was concerned about its ability to assess these requests for substantive acceptability as CE courses.

CE programs approved by Board staff on or before February 29, 2012, will remain available on the Board CE page and may be used for 2013 license renewal.

Going forward, the Board will continue to provide credit for certain categories of non-ACPE and non-NCAP CE (eg, Board meeting attendance, CPR training, precepting, residency, Spanish or other foreign language class, continuing medical education, continuing nursing education, continuing dental education).

FDA Warns Medical Practices About Counterfeits in US and Risks to Patients

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

The warning letters were sent following two incidences of counterfeit cancer drugs found in US medical practices. In February 2012, FDA alerted health care providers and patients that a counterfeit version of Avastin® 400 mg/16 mL, an injectable cancer medication, may have been purchased and used by some US medical practices. The counterfeit version of Avastin does not contain the medicine's active ingredient, bevacizumab, which may have resulted in patients not receiving needed therapy.

In April 2012, FDA issued letters to medical practices regarding a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab), also an injectable cancer medication, that originated from a foreign source. FDA lab tests confirmed that the counterfeit contains no active ingredient. Further, FDA indicates that even if the identified drugs were not counterfeit, Altuzan is not approved by FDA for use in the US; it is an approved drug in Turkey. Medical practices obtained the counterfeit Altuzan and other unapproved products through foreign sources, in particular from Richards Pharma, also known as Richards Services, Warwick Healthcare Solutions, or Ban Dune Marketing Inc. Many, if not all, of the products sold and distributed through this distributor have not been approved by FDA.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business. Also, suspected criminal activity can be reported to the FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web Site at *www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.* More information and a list of the medical practices that were sent warning letters is available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.*

Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at *www.abbott.com/vicodin-consumer-alert.htm.* In addition, Abbott explains that labeling for Fenak® Plus was found underneath the counterfeit Vicodin ES label. Fenak Plus contains a different active ingredient (diclofenac) than Vicodin ES and is used to treat pain and fever. Vicodin ES is a controlled substance pain relief medication and therefore should only be sold in the US through secure drug supply channels to reach consumers.

Abbott advises that anyone who has the counterfeit version should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA OCI by calling 800/551-3989 or by completing the online form on the OCI Web Site at *www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.*

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site, *www.safemedicines.org/resources-for-healthcare-professionals.html.* Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

nabp newsletter

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

CPE Monitor Service Receives Enthusiastic Response, APhA Drawing Winners Announced

On March 9-12, 2012, nearly 1,750 attendees stopped by the NABP booth at the American Pharmacists Association (APhA) Annual Meeting and Exposition in New Orleans, LA. Many visitors shared their enthusiasm for the CPE Monitor™ service, a collaborative effort between NABP, the Accreditation Council for Pharmacy Education (ACPE), and ACPE providers. They also mentioned that they were eager for the opportunity to track their ACPE-accredited continuing pharmacy education (CPE) credits electronically through their NABP e-Profile.

NABP congratulates those who won the drawing at the NABP booth. Kristin Smith, PharmD, received the Apple iPad®, valued at $499, and the following six individuals won a $50 American Express gift card: Mario Ferreira; Carl Franklin, RPh; Anne Haines, RPh; Kim Le; Lisa Patel; and Philip Slater.