newsletter

National Association of Boards of Pharmacy®

AWARE GET INFORMED. PRESCRIPTION DRUG SAFETY®

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aid to government
the profession
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1904 to 2012

Upcoming Events

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

September 29, 2012
DEA National Drug Take-Back Day

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

October 21-24, 2012
NABP/AACP Districts 6, 7, & 8 Meeting
Little Rock, AR

FDA Considers New Drug Paradigm: Nonprescription With Safe-Use Conditions

In an effort to address some of the causes behind widespread undertreatment of many common diseases and medical conditions, Food and Drug Administration (FDA) is considering a new paradigm under which it would approve certain drugs that would normally require a prescription for nonprescription use – under "safe use" conditions. "[S]ome consumers do not seek necessary medical care, which may include prescription drug therapy, because of the cost and time required to visit a health care practitioner for an initial diagnosis and an initial prescription," noted FDA in announcing a public hearing to discuss the issue. "Some patients who obtain an initial prescription do not continue on necessary medication because they would need to make additional visits to a health care practitioner for a . . . refill . . . FDA believes that some of these visits could be eliminated by making certain prescription medications available without a prescription but with certain other conditions of safe use that would ensure they could be used safely and effectively without the initial involvement of a health care practitioner."

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FDA has noted that expanding the definition of nonprescription drugs could potentially provide a number of benefits to consumers, along with easier access to and an increased appropriate use of needed medications, including decreased health care costs and greater access to health screening. Critics, on the other hand, worry that such a system would make it easier for patients to take a wrong medication or dose, and could fragment patient care, decrease necessary visits to health care providers, and fail to reduce costs, among other concerns.

Having determined that it has the authority to make this paradigm shift through rulemaking, FDA has been soliciting input from stakeholders ranging from physicians and pharmacists to consumer advocates and technology providers as it gathers information regarding the practicalities and possible impacts of such a change. FDA held a public hearing

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In This Issue. . .

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New Drug Paradigm

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to hear presentations and comments from interested parties March 22-23, 2012, and accepted written comments until May 7, 2012. As of press time, no timetable had been set for FDA to complete its review of the information submitted and make a decision as to whether or how to proceed.

How Would It Work?

FDA has noted that drugs would need to be considered for inclusion in a nonprescription-with-safe-use-conditions paradigm on a case-by-case basis, but has mentioned several categories of medications or medical conditions that might be appropriate candidates. In its public hearing notice, for example, the agency singled out some undertreated chronic medical conditions – including hyperlipidemia, hypertension, and migraine headaches – that might lend themselves to the new paradigm. "Rescue" medications that might require an initial prescription but could subsequently be purchased without – such as asthma inhalers or epinephrine for allergic reactions – might be another promising category.

The safe-use conditions FDA has thus far envisioned take advantage of two changes in health care over recent years. The first is increasingly sophisticated information technologies. "We are crafting changes for the future and want to incorporate innovations and new technologies into CDER's regulatory practices," stated Janet Woodcock, MD, director, Center for Drug Evaluation and Research (CDER), FDA. "The rules for nonprescription status were established in an age when widespread access to information technology did not exist. The world is evolving."

Technology, for example, could allow consumers to use a kiosk in the pharmacy, an online connection to access an Internet questionnaire, or a smart phone in a variety of locations to follow an algorithm that would help them diagnose a health condition and determine an appropriate medication. The interactive capabilities of such algorithms also allow for a strong educational aspect, educating consumers about potential contraindications, the need for additional tests, or other medications or foods with which a particular drug should not be combined. Technology such as electronic medical records could also allow communication with a patient's health care practitioner(s), to help prevent fragmentation of care.

The second change that would enable FDA's vision of safe-use conditions taps into the expanding role of pharmacists in providing patient care. (For more on pharmacists' expanding roles, see, "Pharmacist Prescribing: Path of the Future?" in the June/July 2012 *NABP Newsletter*.) "Pharmacists could help the consumer verify the diagnosis, perhaps by going through an algorithm with them or, say . . . helping them interpret tests, or they could help in deciding whether the medication was right for the consumer, and they could reinforce the directions for appropriate use of the medication," Woodcock told attendees at the public hearing. ". . . Greater pharmacist involvement could provide an avenue to bring non-adherent individuals back to health care and get them involved back in their health care." Pharmacists would likewise be important in supplying routine monitoring for patients diagnosed with a chronic condition, performing such actions as testing for cholesterol levels or liver function.

Many details, however, remain to be clearly delineated. For instance, FDA has noted that its proposed paradigm would raise a unique (and as yet, unresolved) issue: some of the medications would have conditions of prescription use and conditions of nonprescription use at the same time. "We would have to figure out how to deal with that because . . . in some of these scenarios, we are proposing the difference would be the condition of access, not the actual physical state of the drug," explained Woodcock at the March hearing.

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NABP Interactive Forum Series Returns this Fall

This fall board of pharmacy members and executive officers will once again have the opportunity to unite with their colleagues during the NABP Interactive Forum series. Held as two separate forums, the first will be tailored specifically to board of pharmacy members and will be held in September. The second will be tailored to the board of pharmacy executive officers and will be held in November. The NABP Interactive Member Forum and the NABP Interactive Executive Officer Forum will each take place over two days. A forum for board compliance officers is scheduled to return in fall 2013.

Both forums will include presentations on timely and relevant topics developed directly from suggestions submitted by attendees in advance of the meeting, in addition to networking opportunities.

The forums were first announced in 2010 at the NABP 106th Annual Meeting, as part of an initiative to provide additional support and resources to the member boards of pharmacy. With the success of the first three forums and the eagerness of the boards to reconvene with their peers, the series returns this year to continue a partnership to protect public health through awareness.

Members

The NABP Interactive Member Forum invites each executive officer to designate one member from his or her board to attend the Member Forum at no charge. As with the previous forums, airfare, hotel accommodations, and meals will be paid by NABP. In addition, there is no registration fee for the meeting. During the forum, which will be held September 19-20, 2012, attendees will have the chance to meet with their peers to discuss regulatory trends and challenges faced by their boards.

Executive Officers

The NABP Interactive Executive Officer Forum is set to take place November 13-14, 2012. Each state board of pharmacy executive officer is invited to attend the forum at no charge. Like the Member Forum, airfare, hotel accommodations, and meals will be paid by NABP and there is no registration fee for the meeting.

Information on registering for the Member Forum was sent to the board of pharmacy executive directors in July. Invitations to the Executive Officer Forum will be sent closer to the event. Both meetings will be held at the Hilton Northbrook, in Northbrook, IL.

Comments Sought on Draft Standards for Community Pharmacy Practice Accreditation

The Center for Pharmacy Practice Accreditation is seeking review and comment on the newly released draft standards for community pharmacy practice accreditation. The draft standards will serve as the basis for community pharmacy accreditation and are designed to facilitate the delivery of quality pharmacy services to patients, as well as recognize and stimulate innovative community pharmacy practices.

Input is being sought from pharmacists, health care system stakeholders, consumer groups, and patients. The deadline for submission is August 15, 2012. The draft standards can be reviewed, and comments submitted, at *http://cppa.pharmacist.com*.

The Center for Pharmacy Practice Accreditation is a partnership between NABP and the American Pharmacists Association. The community pharmacy accreditation program is voluntary and seeks to recognize quality, enhance patient safety, and provide a mechanism for community pharmacy practices to distinguish themselves. More information on the program is available at *http://cppa.pharmacist.com*.

Executive Committee

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One-year term

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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.

IOWA: Information on What's Available

By Dale J. Atkinson, JD

Increased media attention to licensure issues and the performance of regulatory boards provide the public with a perspective of why boards exist and their duties and responsibilities. Of course, most media attention is critical of the regulatory boards and the political fallout can be devastating, including deregulation of a profession. Numerous recent political proposals illustrate suggested consolidation of boards and, in some cases, deregulation of numerous professions.

Government, including regulatory agencies, operates under open meetings and open records laws to provide transparency of government actions and allow for public oversight. Such laws exist in all jurisdictions and apply to the boards of pharmacy. The vehicle for media access to information about boards of pharmacy of each respective jurisdiction can be found in the open records laws, sometimes referred to as freedom of information laws. Open records laws are subject to exceptions to protect the integrity of administrative investigations, matters of confidence protected under other laws, personnel, and under certain specifically delineated circumstances. However, the rule is disclosure unless specifically excepted from the applicability of the law. Matters disclosed to a board of pharmacy may subject an otherwise confidential document to public disclosure. Consider the following.

In September 2008, police arrested a pharmacist employed by a publicly funded acute care community hospital for suspicion of operating a vehicle while intoxicated. During an interview with law enforcement officials, the pharmacist stated that she diverted prescription medications, including controlled substances, from the hospital. Based upon this information, the Iowa Board of Pharmacy summarily suspended the pharmacist's license indefinitely and commenced an investigation.

As part of its investigation, the Board contacted the pharmacist-in-charge (PIC) of the hospital pharmacy. The PIC was employed by an outside vendor and worked under a contract with the hospital. Based upon the circumstances, the PIC voluntarily undertook an internal audit of the pharmacy in order to obtain immediate answers to the situation, take action if necessary, and because it was the "responsible thing to do." The internal audit was completed in December 2008 and the results were provided to the hospital's chief medical officer, to the operations manager at the outside vendor, as well as to the Board. The PIC stated that he provided the results of the audit to the Board because it was relevant to and would assist the Board in its investigation.

Approximately one year after the results of the internal audit were submitted, the Board filed administrative charges against the hospital pharmacy and the PIC. Specific to the PIC, the Board alleged a lack of competency and inadequate controls for allegedly failing to maintain an adequate record of controlled substance transactions. The statement of charges included reference to the internal audit, which confirmed shortages of controlled substances. Under Iowa law, the statement of charges is a public record.

Upon reviewing the statement of charges, the local newspaper (*Register*) sought to obtain a copy of the internal audit from the hospital under the Iowa Open Records Law. The hospital refused to release the audit claiming it was confidential and exempt from disclosure. Based upon a declaratory action filed by the PIC against the hospital, a district court entered a temporary injunction prohibiting disclosure of the audit and, after an evidentiary hearing, entered a permanent injunction prohibiting disclosure. The district court noted that "the statutory objective of assuring a free flow of information is better met by extending confidentiality" contained in the Iowa law. The *Register* appealed the matter to the Iowa Supreme Court.

On appeal, the *Register* argued that the internal audit was not part of a complaint or the investigative work product of the Board and was, thus, not within the scope of the exceptions in the law. In short, applicable Iowa law provides that:

> complaint files, investigation files, other investigation reports, and other investigative information in the possession of a licensing board or peer review committee acting under the authority of a licensing board or its employees or agents which relates to licensee discipline are privileged and confidential, and are not subject to discovery, subpoena, or other means of legal compulsion. . .

As noted by the Iowa Supreme Court, the simplicity of the statute may be read to apply to information *within the possession of the licensing board* and not to information within the possession of third parties. However, such an interpretation may not provide a common sense result. For instance, an expert opinion in the hands of the Board may be deemed confidential, while the same opinion in the hands of the expert is not confidential. Thus, the court noted that a plausible argument may be made that the statutory privilege for information possessed by the Board may be propounded by third-party possessors of that same information. In other words, the confidentiality of information is based upon the information provided to the Board to allow it to perform its statutory functions, not on the possessor of such information.

Citing that no controlling case law on this topic exists in Iowa, the Iowa Supreme Court outlined several cases addressing licensee access to information once an administrative action is filed, ancillary access in medical malpractice actions, and conflicting cases regarding third-party possession of investigative materials. The court concluded the need for:

> a nuanced position regarding what information is protected by privilege statutes related to licensee discipline or peer review. On the one hand, the mere fact that a copy of the document is possessed by a third party should not be determinative of the privilege issue if the privilege is to have any substance. On the other hand, the providing of information to a licensing body or peer review committee should not transform otherwise discoverable information into privileged material.

The court consulted multiple treatises that divide disclosure issues into three categories. The first category relates to documents generated by an organization that reflect internal deliberations and functions of the licensing board and are considered privileged under Iowa law. The second category consists of preexisting documents submitted to the licensing board and are not subject to the privilege because they were generated before the

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

Fall FPGEE Administration Approaching; Registration Ends October 26

The next Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) administration is scheduled to be held November 9, 2012. Candidates may sit for the examination at any Pearson VUE test center located within the continental United States.

For candidates who have been accepted to sit for the FPGEE, the deadline to register with NABP for the November 9 administration is October 26, 2012. Candidates will have the opportunity to choose from more than 200 Pearson VUE testing locations for the examination. Candidates must schedule their appointment to test with Pearson VUE by November 2, 2012. Scheduling is completed through the Pearson VUE Web site or by contacting Pearson VUE's customer service at 888/709-2679.

NABP provides the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification Program as a means of documenting the educational equivalency of a candidate's foreign pharmacy education, as well as a foreign license and/or registration, which assists state boards of pharmacy in qualifying candidates for US licensure. The FPGEE is one component of this program.

In addition, candidates must also pass the Test of English as a Foreign Language Internet-based Test. The FPGEC Certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the 50 United States, the District of Columbia, Guam, and Puerto Rico where the certification is recognized.

To prepare for the FPGEE, NABP recommends that applicants take the Pre-FPGEE®, the official FPGEE practice examination written and developed by NABP. This practice examination is designed to help prepare candidates for the FPGEE by providing the types of questions and format typically seen on the FPGEE. The Pre-FPGEE is assembled from actual test questions that have previously appeared on the FPGEE.

Additional information on the FPGEE as well as the Pre-FPGEE is available in the Programs section of the NABP Web site at *www.nabp.net/programs.*

Legal Briefs

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investigation or charges commenced and do not rely upon the need for candor and protection. The third category involves those documents created for the purpose of submission to the licensing board and require the need for protection to ensure candor and frankness in discussions and deliberations.

Under the current facts, the court emphasized that the basis for the internal audit was to obtain immediate answers to the situation, take action if necessary, and it was characterized as the "responsible thing to do." Such reasons do not in any way implicate or relate to the Board's deliberative functions. Indeed, such stated goals relate to the functioning of the hospital pharmacy, not the Board. Further, while the PIC did provide the internal audit to the Board to ensure access to complete information, his reason for undertaking the audit in the first place was not related to the Board's investigation. Because the internal audit was prepared for reasons independent of the Board's investigation, the Iowa Supreme Court held that the report would be treated as a preexisting document and was not subject to the privilege.

The PIC and hospital also argued that the audit was protected from disclosure under another section of the law addressing closed session of the Board. Iowa law allows for withholding from disclosure documents and matters discussed in closed session. In particular, they argued that litigation strategy and matters related to a pharmacist's competence are eligible for discussion in closed session and provide a mechanism for non-disclosure. Based upon the potential for litigation and the fact that competence was at stake, the PIC and hospital argued against disclosure. Citing the presumption in favor of disclosure and narrow construction of any exemptions, the court rejected these arguments and held that the audit was not related to a legal strategy of the Board nor was the audit an evaluation of the competence of the PIC.

Finally, the court rejected attempts by the PIC and hospital to secure an injunction preventing the disclosure of the internal audit. Accordingly, the internal audit was subject to disclosure to the *Register* and not subject to one of the exceptions regarding public documents.

The applicability of open records laws presents many interesting challenges to boards of pharmacy and other public entities. As referenced, the media influence on the regulatory community through investigative reporting can be profound. Boards of pharmacy are encouraged to continue to emphasize their mission of public protection and ensure documentation of such activities.

Hall v. Broadlawns Medical Center, 2012 Iowa Sup. LEXIS 22 (IA 2012)

Continued NABP Actions Vital to Protecting Public from Rogue Internet Drug Outlet Dangers, Task Force Advises

Applying for the .pharmacy generic Top-Level Domain (gTLD), supporting relevant legislation, and educating consumers, health care providers, and law enforcement, are among the many actions NABP should continue to undertake in order to protect the public health from Internet drug outlets, as agreed by the 2011-2012 NABP Task Force on Internet Pharmacy Practice. Task force members discussed the complex network of operations behind rogue Internet drug outlets to determine how such entities can be shut down, and made several recommendations in this regard. Further, members discussed the importance of continuing to share NABP's research findings on rogue Internet drug outlets with both United States and international regulators, law enforcement, and other stakeholders. Members also agreed that the Association should take additional actions to support boards of pharmacy efforts to help shut down rogue Web sites illegally selling drug products.

The Task Force on Internet Pharmacy Practice met March 6-7, 2012, at NABP Headquarters and accepted their charge as follows:

1. Review existing Internet pharmacy practices;
2. Review current state laws and regulations, Verified Internet Pharmacy Practice Sites℠ (VIPPS®) program standards, and NABP *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* language; and
3. Examine future opportunities and challenges in an emerging global environment.

Support for .pharmacy Application

Task force members were presented with information on the NABP application to the Internet Corporation for Assigned Names and Numbers (ICANN) to obtain and operate the .pharmacy gTLD. Members agreed that if granted, the .pharmacy gTLD has the potential to greatly enhance patient safety for those who purchase medication online. (See page 157 for additional information on the NABP .pharmacy gTLD application.) Therefore, the task force recommended that NABP continue efforts to acquire the .pharmacy domain, and also encourage boards of pharmacy to submit letters indicating their support of the application to ICANN. The task force also recommended that the Association continue to establish relationships with global regulatory authorities as NABP moves forward with the application process.

The task force also agreed on the importance of educating consumers, health care providers, and law enforcement of the risks of purchasing medications online from rogue sites, and recommended that NABP continue to use AWAR$_X$E® public service announcements to communicate this message.

Supporting Board Efforts

Task force members also discussed what additional efforts can be taken by boards of pharmacy to help shut down operators of rogue sites selling drug products in their states. They agreed that as such Internet outlets are not licensed as pharmacies, nor are those sending the products licensed as pharmacists, strictly enforcing the laws and regulations in place that prohibit unlicensed practice is vital to curtailing these practices. Further, the task force recommends that NABP support the boards in such efforts, as well as their efforts to protect against the unauthorized use of patient information.

As sharing information about rogue Internet drug outlets is paramount in the process of protecting the public, the task force also recommended that NABP encourage boards or other regulatory agencies to share information on rogue outlets with the appropriate federal agencies. The task force agreed that boards could submit information such as case studies and unresolved complaints to NABP for inclusion in the NABP Clearinghouse or the quarterly progress report of the Internet Drug Outlet Identification program, as appropriate.

To further support boards of pharmacy, the task force recommended amendments to the NABP *Model Act* so as to provide the boards with language to incorporate into state laws and regulations in order to further enhance public protection against rogue Internet drug outlets. Specifically, the task force recommended that NABP staff review and recommend the following changes to the *Model Act:*

- amend the definition of "practice of pharmacy" so that the act of accepting a prescription constitutes the practice of pharmacy and, thus, Web sites that "accept" or "process" prescriptions require licensure;
- prohibit licensees from affiliating with Web sites that may deceive or defraud patients or that violate state or federal pharmacy practice laws and regulations;
- strengthen penalties for unlicensed practice/ stronger enforcement language;

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Task Force on Internet Pharmacy Practice

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- establish regulations requiring the posting of specific information about Internet pharmacy ownership and services, and detailed information to patients about how their personal information will be used and disclosed (ensuring that such notice is at least equivalent to that required of "brick and mortar" pharmacies);
- require nonresident pharmacies to comply with the laws of patients' domicile; and
- establish security requirements such as the encryption of protected health information (PHI) on Internet pharmacy Web sites that mirrors VIPPS criterion No. 7 requiring the transmission of PHI to be in accord with Health Insurance Portability and Accountability Act requirements.

Members also discussed that while it may be difficult to curtail rogue sites from operating, requiring VIPPS accreditation provides for increased enforcement and public protection. States that require VIPPS accreditation have a means to ensure that domestically licensed pharmacies operating online are doing so legally. Thus, the task force recommends that NABP continue to encourage boards of pharmacy to require VIPPS accreditation for all Internet pharmacies providing pharmacy services to residents of their states.

Continuing Collaborative Efforts to Curtail Rogue Outlets

Members also recommended that NABP should support actions that help to protect the public health by addressing rogue Internet drug outlets at critical points of operation such as dealings with search engines, domain name registrars (DNRs), and payment service providers.

The task force viewed a presentation by the Alliance for Safe Online Pharmacies containing detailed information on the critical points of the Internet ecosystem as they relate to rogue Internet drug outlets. The presentation highlighted how such critical points can be utilized to curtail the rogue sites from conducting business over the Internet. For example, DNRs, who lease domain names to Web site operators are required by their Uniform Domain-Name Dispute Resolution Policy (UDRP) to prohibit the use of their domain name registration services in the furtherance of illegal behavior. As another example, Web hosting services, which provide space on a server owned or leased for use by Web site operators, can also take down illegally operating sites using the UDRP. Requirements for search engine companies, payment service providers, shippers, and shipping ports were also reviewed.

Members discussed that such entities can be "put on notice" by enumerating the laws or regulations they are violating by allowing rogue Internet drug outlets to operate. So, for example, DNRs should refuse to do business with rogue Internet drug outlets and such notice to search engines should include a request that they remove the rogue Internet drug outlet from their search results.

Supporting Federal Legislation and Global-Reaching Efforts

The task force also reviewed the Online Pharmacy Safety Act of 2011, which had been introduced to US Congress prior to their meeting, and agreed that the bill, as written at the time of the meeting, would assist boards of pharmacy in combating rogue Internet drug outlets. The House and Senate versions of the bill, which had been referred to committee at the time of the task force meeting, were not considered further in the 2012 legislative year.

With the increased risk of counterfeit drugs entering the US supply chain via Internet purchases, the task force also recommended that NABP continue to support efforts, both domestically and internationally, to keep the domestic prescription drug supply chain free of counterfeit drugs. For example, members agreed that the Association should continue to support efforts such as the Verified-Accredited Wholesale Distributors® accreditation program that NABP launched in 2005. The task force also agreed that NABP should collaborate with global entities such as the International Pharmaceutical Federation, the European Commission, and INTERPOL regarding efforts to prevent the trafficking of counterfeit drugs.

Task force members included Jeanne Waggener, RPh, chair; Ronald Guse; Steven Haiber, RPh; Lenna Israbian-Jamgochian, PharmD; Luis Rivera-Lleras, RPh; and Charles Wetherbee, JD. Libby Baney, JD, served as an ex officio member and William John Cover, RPh, served as Executive Committee liaison.

The recommendations of the task force were reviewed and 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 Approved e-Advertiser

The following entity was accredited through the NABP e-Advertiser Approval[CM] Program:

Associates Consulting Corp dba Suboxone Services
www.suboxoneservices.com

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

NABP InterConnect Committed to PMIX Architecture Compliance; BJA Immediately Releases Funding for InterConnect Participants

NABP, in partnership with the Bureau of Justice Assistance (BJA), announced in May 2012 its commitment to comply with the Prescription Monitoring Information Exchange (PMIX) architecture to facilitate interstate data sharing. Specifically, NABP immediately began to implement the "hub-to-hub" specification of the architecture, thereby enabling the sharing of information with any state without regard to their local technology and expanding the number of information sharing partners for current and future NABP PMP InterConnect℠ users. Once completed, this will ensure that all states using NABP InterConnect are fully compliant with the PMIX architecture, thereby satisfying federal grant conditions as well as positioning states to share data more broadly in the future.

In addition, NABP pledges to continue its work with the Alliance of States with Prescription Monitoring Programs (ASPMP) and other partners to maintain the PMIX architecture and support development of a certification process to assist states in meeting their interoperability and data sharing goals. In recognition of NABP's commitment to move forward aggressively, the BJA agreed to immediately clarify its existing guidance on allowable uses of Harold Rogers Prescription Drug Monitoring Program grant funds. State prescription monitoring programs (PMPs) that adopt NABP InterConnect as their interstate data sharing solution will now be considered compliant with the PMIX architecture and therefore able to utilize Harold Rogers Prescription Drug Monitoring Program funds to support information sharing, to include NABP InterConnect implementation, or to repurpose such funding in a manner consistent with the goals of their grant application. Interested states may immediately make requests for a Grant Adjustment Notice through their BJA grant managers.

In operation since August 2011, NABP InterConnect has already processed over 400,000 interstate requests for PMP data. Building on the success of the nine states that are already connected to and using NABP InterConnect and the more than 10 others that intend to sign on, compliance with the PMIX architecture will give additional PMPs the option to utilize NABP InterConnect as their preferred data sharing solution. In addition, this will allow existing NABP InterConnect states to reallocate funds to other important PMP-related initiatives. The BJA, working in partnership with NABP and ASPMP, has worked diligently to develop an encompassing architecture that will support interoperability of PMP systems, hubs, and other exchange partners. NABP is pleased to have been a part of the process and a key contributor to the success of the PMIX architecture. NABP will continue to work with BJA and other governmental partners to continue its advocacy and support for the needs of the NABP InterConnect member states.

Additional information about the NABP PMP InterConnect is available in the Programs section of the NABP Web site, *www.nabp.net.*

Newly Accredited VAWD Facilities

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

Baxter Healthcare SA dba Baxter Healthcare of Puerto Rico
Cataño, PR

Fagron, Inc
St Paul, MN

McKesson Corporation dba McKesson Drug Company
Ruther Glen, VA

Owens & Minor Distribution, Inc
Hanover, MD
Waunakee, WI
West Valley City, UT

Rising Pharmaceuticals, Inc
Allendale, NJ

SourceOne Healthcare Technologies, Inc
Hazelwood, MO

Stericycle, Inc
Indianapolis, IN

Teleflex Medical Incorporated
Durham, NC
Fort Worth, TX

Value Drug Company
Altoona, PA

VWR International, LLC
Bridgeport, NJ

WBC Group, LLC dba Meyer Distributing Company; Milliken Medical
Hudson, OH

A full listing of more than 520 accredited VAWD facilities is available on the NABP Web site at *www.nabp.net.*

NABP Task Force Advises Introducing Recommended CSA and CFR Revisions to Appropriate US Lawmakers and Federal Agencies

Having made several recommendations for revisions to the Controlled Substances Act (CSA), the NABP task force charged with reviewing the law recommended that the Association take the necessary steps to introduce the proposed CSA revisions to the appropriate members of the United States Congress. Additionally, the task force recommended that a letter be sent to Drug Enforcement Administration (DEA) requesting that the agency review certain portions of the Code of Federal Regulations (CFR) and consider revisions reflecting the task force's recommended revisions to the CSA. These actions were among the five recommendations presented in the report of the 2011-2012 Task Force to Review and Recommend Revisions to the Controlled Substances Act.

A task force first convened on this topic in 2011 but the enormity of the assignment required that a second task force be formed. During that initial task force meeting, members reviewed and identified potential revisions to the CSA and accompanying regulations. The final report of the 2010-2011 task force included 41 recommendations, with 21 of these calling for amendments to the CSA or the CFR, and was approved by the Executive Committee in May 2011.

At their meeting on January 24-25, 2012, at NABP Headquarters, the 2011-2012 CSA task force accepted the following charge:

1. Review the recommendations made by the 2010-2011 Task Force to Review and Recommend Revisions to the CSA.
2. Recommend additional revisions, if necessary, to the CSA or accompanying CFR.
3. Present recommendations to Congress.

During their meeting, the task force members reviewed the 2010-2011 Report of the Task Force to Review and Recommend Revisions to the CSA and determined they would focus on recommending revisions only to the CSA so as to follow federal procedure. Members determined that once the CSA is revised, the relevant CFR can then be addressed.

The task force agreed with definitions recommended by the 2010-2011 task force, including definitions of "addict," "administer," "practitioner," and "prescribe" suggested for Section 802, Definitions. The task force also recommended that several additional definitions in Section 802 be revised. Specifically, it was recommended that "agent" include the terms "prescribing practitioner" and "ultimate user" to expand the definition, and that "ultimate user" be revised to reflect revisions to "agent." Regarding the definition of "dispense," the task force agreed with the 2010-2011 task force recommendation but determined that "ultimate user's agent" needed to be included in the definition and also determined that wherever "dispense" appeared in the CSA, revision may be necessary to add "prescribing" as a separate function. Also, the task force recommended that, for clarity, the term "prescription" be defined in the CSA

as "a written, electronic, or oral order for a controlled substance issued by a practitioner for an ultimate user."

In sections of the code relating to registration, the task force recommends adding "prescribing" as a separate practitioner function, where necessary, throughout the entire section. Also, in Section 829, Prescriptions, the task force recommends adding "ultimate user's agent," for consistency throughout the CSA, to the provisions regarding how and to whom prescriptions may be dispensed. Further, the task force agreed that the time in which a Schedule II controlled substances (CS) can be filled should be limited to six months, and that the act should clarify that a CS may be dispensed directly to a practitioner for administration to an ultimate user.

The task force also recommended adding a provision mandating that the CSA and related rules, regulations, and procedures must be reviewed every 10 years with public comments solicited as part of the review process.

Next Steps

As legislation must be introduced in Congress in order to have the task force's recommended revisions to the CSA considered by DEA, it was also recommend that NABP engage in the process to the extent possible. The task force determined that the most appropriate sponsor who could accomplish this would be a member of the Senate Committee on the Judiciary.

CFR Revisions to Address Now

Although the task force agreed to first address the CSA, members decided that several CFR provisions, which the 2010-2011 task force recommended revising pertaining to prescription transfers and electronic storage of records, could possibly be addressed sooner. The task force opined that DEA has the ability to revise the CFR without a congressional directive and recommended that NABP issue a letter to DEA, not providing specific language, but rather requesting that DEA strongly consider the following:

- allowing for all records to be stored electronically at a central location, including executed order forms and inventories;
- removing the requirement that prescription transfers must be communicated directly between two licensed pharmacists where the pharmacies share an electronic, real-time, online database; and
- allowing for an electronic record for the dispensing of nonprescription CS.

Members concurred that the letter should encourage that revisions such as these, which reflect technological advances, be implemented in a timely manner.

In addition, the task force recommends that NABP send a letter to the Secretary of the Department of Health and Human Services (HHS) requesting that 21 CFR 290.5, which contains the warning statement that is required on the prescription label for Schedule II through IV CS prescriptions, be reviewed and revised according to the 2010-2011 task force's recommendation. Specifically, members agreed with the previous task force's recommendation that the warning statement should be removed; however, if HHS determines that the current statement should remain, NABP should urge that it be reworded for increased understandability to "It is unlawful to share this medication." The 2010-2011 task force "realized that the spirit of the warning label is to decrease rampant drug abuse and addiction, but believed that the label should only contain important patient information."

The task force also recommended that NABP staff review and suggest appropriate amendments to the *Model State Pharmacy Act*

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New Drug Paradigm

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Supporters and Critics

In addition to its work on the mechanics of the proposal, at its public hearing in March, FDA heard from a wide range of organizations with views on the proposed paradigm ranging from unreservedly enthusiastic to openly critical and many in between.

Pharmacist groups generally voiced their enthusiasm for the proposal and noted that pharmacists' education and training had prepared them to take on such a role as that envisioned by FDA. "Under the proposed paradigm, pharmacists could select or recommend additional medication therapy, review patients' current therapies and recommend any medication changes to the patients' physicians," Cynthia Reilly, BS Pharm, director, Practice Development Division, American Society of Health-System Pharmacists, told FDA. "Pharmacists would counsel patients on their new medication regimens, implement strategies to improve adherence and be available to answer patients' questions. Pharmacists already provide these and additional services via established collaborative practice agreements in 43 states, through which they manage complex therapies, including anticoagulants."

Pharmacists also emphasized their status as the most accessible health care provider and their participation on health care teams working to optimize patient health. "This is a significant opportunity for pharmacists to improve public health and increase access," Tom Menighan, BS Pharm, ScD, MBA, executive vice president and chief executive officer, American Pharmacists Association, told panelists. "The new paradigm being considered should not segment or silo patient care activity in the pharmacy but rather provide for redirecting undertreated patients back into care to reduce morbidity and decrease costs."

Pharmacist-related areas of concern include such issues as a payment mechanism so pharmacists could be reimbursed for services provided, availability of appropriate communication technology, and workflow management for already overtaxed pharmacists. Liability ramifications also remain unclear.

Representatives of technology providers were likewise enthusiastic about the proposed paradigm. Presenters demonstrated systems already capable of walking patients through interactive algorithms to determine health conditions and recommended medications, while other speakers noted that educational materials for pharmacy personnel already existed. Sophisticated electronic health record technology could allow patients to seamlessly move through accessing medications in FDA's paradigm.

Consumer advocates were more divided in their reactions. While some groups felt that over-the-counter (OTC) access to some medications would be lifesaving, others felt that other medical conditions, such as asthma, were too complex to deal with on an OTC basis, even with pharmacist involvement. Many presenters raised the concern of medication cost, as OTC drugs are not typically covered by insurance.

Physician groups largely opposed the proposed paradigm. They expressed concern with lack of physician involvement in a patient's regular care, particularly in the case of chronic diseases. "A different or more intensive therapy might be required," noted Sandra Adamson Fryhofer, MD, MACP, FRCP, on behalf of the American Medical Association. "Sometimes patients develop new diseases, new co-morbidity. This may call for a change in treatment plan. Not having a physician involved can delay that change in treatment and could harm the patient."

NABP's Position

NABP has consistently supported utilizing pharmacists in allowing consumers increased access to certain nonprescription medications and welcomed FDA rulemaking to this effect, always with the understanding that primary pharmacy regulatory authority resides with the states. In 2007, NABP testified in support of a proposed creation of a third class of "behind-the-counter" drugs that would have been available without a prescription but only after consultation with a pharmacist. Indeed, as NABP pointed out to FDA's 2012 panel during the March public hearing, NABP's member boards have passed three related resolutions since 1993. NABP believes that the pharmacist has traditionally been and continues to be an accessible and underutilized health care provider. Requiring pharmacists' counseling and monitoring is a logical condition of safe use for safe and effective nonprescription dispensing of certain drug products.

Pharmacists are uniquely qualified by extensive training and experience to provide quality care under FDA's new paradigm. Moreover, further additional specialized training would be unnecessary. NABP told the panel that specific conditions of safe use for a particular product could be managed through existing continuing education and professional development programs.

Pharmacist involvement would provide further benefits because they are uniquely positioned and readily accessible for ongoing, post-marketing data collection that could assist in monitoring and assuring safe and effective use of any product addressed by FDA's proposed paradigm.

With an increasing shortage of primary health care providers and other barriers to optimum

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NABP Submits Application to Obtain and Operate New .Pharmacy gTLD; Anticipates Next Steps in ICANN Review Process

NABP, with the support of a global coalition of stakeholders, has successfully submitted an application to the Internet Corporation for Assigned Names and Numbers (ICANN) to obtain and operate the new .pharmacy generic Top-Level Domain (gTLD). The Association is the only organization to apply for this gTLD and is now anticipating the next steps of the ICANN review process.

ICANN received nearly 1,930 gTLD applications before the window to submit closed on May 30, 2012. Key dates and next steps in the ICANN review process, and a summary of the relevant status or news for the NABP .pharmacy application follows.

- **May 30, 2012:** ICANN new gTLD application window closed. The NABP .pharmacy application was successfully submitted by the deadline.
- **June 13, 2012:** Known as "Reveal Day," ICANN published on its Web site the list of all applied for gTLDs and applicants.
- **June 13, 2012:** With the publication of all new gTLD applicants, ICANN opened the public comment period, which remains open until August 12, 2012.
- **June 13, 2012:** ICANN also opened the formal objection period, which remains open for approximately seven months. After the filing period closes, ICANN will move objections received through a dispute resolution process estimated to take five months. Applicants have 30 days from the closing of the filing window to respond to any objections filed against their application.
- **June 27, 2012:** ICANN released a statement terminating its proposed Digital Archery process for prioritizing applications into batches, which would have determined the order by which these applications would be processed. The ICANN Board has indicated that all applications will be processed through the initial evaluation together.
- **July 12, 2012:** Initial evaluations were scheduled to begin.

As part of the process, ICANN also scheduled two public meetings during this time frame, the first in Prague, Czech Republic, on June 24-29, 2012, and the second in Toronto, Canada, on October 14-19, 2012.

Under the proposed NABP plan, use of the .pharmacy domain will be restricted to legitimate Web site operators the world over that adhere to the pharmacy laws specific to the jurisdictions in which the pharmacy is domiciled and to which it sells prescription drugs. As such, the .pharmacy gTLD will provide a powerful tool to educate consumers, distinguish legitimate Internet pharmacies from the thousands of rogue Internet drug outlets, and reinforce the value of purchasing medications only from trustworthy online sources. Additional information about the NABP .pharmacy application is available in the May 2012 *NABP Newsletter,* which can be accessed in the Publications section of the NABP Web site, *www.nabp.net.*

New Drug Paradigm

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medication compliance, NABP remains concerned about underserved and undertreated consumers and the resulting negative public health outcomes. The new paradigm would indeed increase consumer access to necessary medical care by making certain products available to patients under well-defined and controlled conditions.

FDA has received a number of widely varying – and sometimes contradictory – comments on the agency's ambitious proposed paradigm, and many questions remain unanswered. NABP will continue to monitor developments involving the issue, and will report on FDA's actions regarding the proposal.

CSA Task Force

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and Model Rules of the National Association of Boards of Pharmacy that incorporate the recommended revisions to the CSA and CFR.

Members of the Task Force to Review and Recommend Revisions to the CSA included William T. Winsley, MS, RPh, chair and Executive Committee liaison; Susan DelMonico, JD, RPh; Rebecca Deschamps, RPh; W. Benjamin Fry, RPh, FIACP, FACA; Caroline Juran, RPh; Suzan Kedron, JD; Susan Martin, PharmD, RPh; Jerry Moore, JD; and Suzanne Neuber, RPh.

The recommendations of the task force were reviewed and 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.*

Transition to CPE Monitor Continues as Additional ACPE-Accredited Providers Begin Electronically Transmitting CPE Data

With more than 550,000 continuing pharmacy education (CPE) activity records now stored in the CPE Monitor™ system and over 90 Accreditation Council for Pharmacy Education (ACPE)-accredited providers actively transmitting CPE data through the service, many pharmacists and pharmacy technicians will be able to begin viewing and tracking their CPE credit online through their NABP e-Profile.

To do so, licensees must first obtain their e-Profile ID by setting up their e-Profile and then registering for CPE Monitor. As ACPE-accredited providers transition their systems to CPE Monitor, they will begin requiring licensees to submit their e-Profile ID along with their date of birth (MMDD) in order to obtain CPE credit for an activity. Providing the e-Profile ID and date of birth when taking an ACPE-accredited CPE activity allows CPE Monitor to accurately match and record licensees' CPE credits once in the system.

Upon receipt of each participating licensee's information, the provider transmits the data to ACPE for verification. ACPE then submits the verified data to NABP for uploading into the CPE Monitor section of the licensee's e-Profile. Beginning in 2013, providers will be allotted 60 days from the date of participation in the CPE activity to transmit CPE data to ACPE; however, during the transition period in 2012 providers will not be held to the 60-day reporting period. With this grace period for reporting CPE data, licensees may see a slight delay in viewing their data online.

To further ensure that CPE Monitor records remain as up to date as possible, NABP recently worked with ACPE to increase the rate at which e-Profile data is exchanged. By increasing this frequency from every six hours to every three hours, NABP will be able to confirm that the data matches ACPE's data and remains up to speed with new e-Profile IDs as licensees create their e-Profiles.

NABP continues to encourage licensees to obtain their e-Profile IDs by creating their NABP e-Profiles and registering for CPE Monitor, if they have not done so already. Beginning in 2013, all licensees will need to have an e-Profile ID in order to obtain CPE credit from ACPE-accredited providers.

Currently, more than 164,000 pharmacists and 87,000 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.

Around the Association

Executive Director Change

Tanja Battle is now serving as the executive director of the Georgia State Board of Pharmacy.

Board Member Appointments

- **Edward McKenna, RPh,** has been appointed a member of the Iowa Board of Pharmacy. McKenna's appointment will expire on April 30, 2015.
- **John Worden, PharmD,** has been appointed a member of the Kansas State Board of Pharmacy. Worden's appointment will expire on April 30, 2016.
- **Michael Lonergan, RPh,** has been appointed a member of the Kansas State Board of Pharmacy. Lonergan's appointment will expire on April 30, 2016.
- **Shane Wendel, RPh,** has been appointed a member of the North Dakota State Board of Pharmacy. Wendel's appointment will expire on May 9, 2017.

Board Member Reappointments

- **Lori DeVito, RPh,** has been reappointed a member of the Alaska Board of Pharmacy. DeVito's reappointment will expire on March 1, 2016.
- **Christopher Kim, RPh,** has been reappointed a member of the Alaska Board of Pharmacy. Kim's reappointment will expire on March 1, 2016.
- **Susan Frey, RPh,** has been reappointed a member of the Iowa Board of Pharmacy. Frey's reappointment will expire on April 30, 2015.
- **Ned Milenkovich, PharmD, JD,** has been reappointed a member of the Illinois State Board of Pharmacy. Milenkovich's reappointment will expire on April 1, 2017.
- **Fernando Gonzalez, RPh,** has been reappointed a member of the New York State Board of Pharmacy. Gonzalez's reappointment will expire on January 31, 2017.
- **John Croce, RPh,** has been reappointed a member of the New York State Board of Pharmacy. Croce's reappointment will expire on January 31, 2017.
- **Richard Kolezynski, RPh,** has been reappointed a member

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NABP Seeks Item Writers to Develop New Test Questions for the NAPLEX, MPJE, FPGEE, PCOA, and PARE

NABP is currently seeking individuals to serve as item writers for the North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), the Pharmacy Curriculum Outcomes Assessment® (PCOA®), and the Pharmacist Assessment for Remediation Evaluation℠ (PARE℠).

Pharmacists in all areas of practice, and faculty from schools and colleges of pharmacy are encouraged to apply.

Item writers will be evaluated based on the specific needs of the programs. Those who are selected will be invited to attend a workshop at NABP Headquarters with travel, lodging, and ancillary expenses paid by NABP.

Attendees will receive detailed instructions and training materials describing the item-writing process and content-related requirements for their designated examination. Item writers will then be asked to develop new test items that will be considered for inclusion in NABP examinations and assessments.

NAPLEX

The NAPLEX is an examination that assesses the knowledge, judgment, and skills expected for entry-level pharmacists. The three content areas of the examination are:

- Assess pharmacotherapy to ensure safe and effective therapeutic outcomes
- Assess safe and accurate preparation and dispensing of medications
- Assess, recommend, and provide health care information that promotes public health

MPJE

The MPJE is an examination that combines federal and state-specific questions that test an individual's knowledge in pharmacy jurisprudence in the following content areas:

- Legal aspects of pharmacy practice
- Licensure, registration, certification, and operational requirements
- Regulatory structure

FPGEE

The FPGEE is a comprehensive examination that measures an individual's knowledge of United States-accredited pharmacy curricula and is administered to those who have been educated in pharmacy outside of the US. The content areas are:

- Basic biomedical sciences
- Pharmaceutical sciences
- Social/behavioral/administrative pharmacy sciences
- Clinical sciences

PCOA

The PCOA is an assessment that is administered to pharmacy students in all four professional years. The assessment follows a blueprint that is representative of US-accredited pharmacy curricula, including:

- Basic biomedical sciences
- Pharmaceutical sciences
- Social/behavioral/administrative pharmacy sciences
- Clinical sciences

PARE

The PARE is a multidimensional assessment that the boards of pharmacy may use as an auxiliary tool when making decisions regarding pharmacist practice. The content areas are:

- Medication safety and the practice of pharmacy
- Professional ethics/pharmacist judgment
- Clinical pharmacy

How to Apply

Interested individuals should e-mail, fax, or mail a letter of interest indicating their current practice/educational setting, specialties/certifications, and years of experience, along with a résumé or curriculum vitae:

- via e-mail at exec-office@nabp.net;
- via fax at 847/391-4502; or
- via mail to NABP Executive Director/Secretary Carmen A. Catizone at 1600 Feehanville Drive, Mount Prospect, IL 60056.

Please note, applications are accepted on a continuous basis and kept on file for a period of five years.

For more information about item writing, contact NABP at custserv@nabp.net.

As Threat of Counterfeit Drugs Grows and Online Peddlers Proliferate, AWARxE Informs Consumers, Legislators About Dangers

Incidents of global counterfeit drug discoveries documented by pharmaceutical security experts more than doubled from 2005, when over 1,000 incidents were recorded, to 2010 when over 2,000 incidents were recorded. Through a second Internet public service announcement (PSA) campaign launched in mid-June 2012, the AWARxE® Consumer Protection Program is reaching out to millions of consumers, warning them about counterfeit drug dangers, and the risks of using Internet drug outlets that often market and distribute to Americans counterfeit, sub-standard, and unapproved drug products. The Internet PSA campaign also reaches out to United States legislators, with the aim of raising awareness about the urgency of the issue, and informing them about NABP actions to help protect Americans from Internet drug outlets.

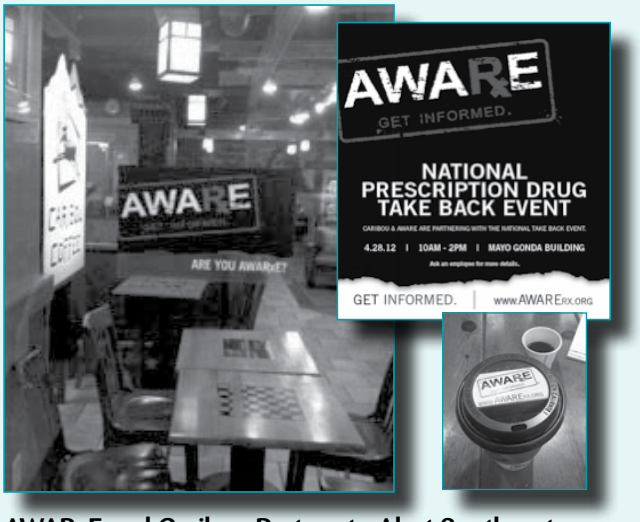
The Internet PSA campaign began by distributing animated AWARxE Web site banners to popular Web sites and by reaching out to bloggers, encouraging them to share this important health safety information with their readers. Following the same plan used for the first segment of the AWARxE Internet campaign that reached 21 million consumers from March to April 2012, the current campaign focuses on Internet sites and bloggers publishing in the areas of health, senior living, caregiving, parenting, and veterinary health, with the added area of legislative issues.

Web site banners display shocking facts about counterfeit drug dangers, and a click brings the reader to AWARxE videos and links to *www.AWARERx.org* for additional information. As with the first segment of the campaign, an Internet social media press release was also distributed via Web site channels during the week of July 9, 2012, and gave viewers over 300 options for sharing the release, video links, and the AWARxE Web site through social media outlets.

Numerous NABP actions over the past two decades have helped protect the public health from counterfeits and Internet drug outlets and through the quarterly *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators* the Association informs regulators, legislators, and industry stakeholders about NABP's research and related actions. The AWARxE Internet PSA campaign brings relevant information from NABP research and actions into content and formats that are easily accessible to millions of online consumers.

AWARxE Electronic News Launched

Also initiated in June 2012, the *AWARxE Prescription Drug Safety News* electronic newsletter now keeps consumers, stakeholders, NABP members, and others informed on the latest program and related news. The monthly complimentary publication includes news on counterfeit drugs, Internet drug outlets, and efforts to combat these problems, as well as information on preventing prescription drug abuse and using medications safely. Interested individuals can subscribe to *AWARxE Prescription Drug Safety News* by completing the online sign-up form on the AWARxE Web site, *www.AWARERx.org/newsletterSignup.php.*



AWARxE and Caribou Partner to Alert Southeast Minnesota About Prescription Drug Abuse

Caribou Coffee stores in southeastern Minnesota teamed with AWARxE® to alert consumers about the dangers of prescription drug abuse and to encourage participation in local Drug Enforcement Administration drug take-back opportunities as a means of preventing abuse. Caribou stores displayed posters and table cards with AWARxE facts and also used AWARxE coffee lid stickers for customer beverages. Caribou developed a coupon offer as well, with information about AWARxE printed on the coupon. All AWARxE messaging distributed by Caribou alerted readers to visit *www.AWARERx.org* for additional information.

AR Summit Focused on Rx Drug Abuse

On April 26, 2012, the Arkansas Department of Human Services hosted the first ever Arkansas Prescription Drug Summit, which was organized to explore the current problems of prescription drug abuse in the state and across the nation.

This free summit was organized and sponsored by the Arkansas Drug Director's Office; Conner Eldridge, United States attorney, Western District of Arkansas; Chris Thyer, US attorney, Eastern District of Arkansas; the Arkansas Attorney General's Office; the Arkansas State Board of Pharmacy; and a host of other stakeholders. The conference was supported by the Arkansas State Board of Pharmacy as an educational opportunity for Board licensees and permit holders, and provided up to 6.25 hours of live continuing education. The summit also provided attendees with many featured speakers and panelists, including a keynote address from Arkansas Attorney General Dustin McDaniel.

The Board's hope is that this conference will become an annual event for the state where the Board can continue to have interprofessional discussions and interactions on issues of drug abuse.

More information on the event is available in the Board's May 2012 *Newsletter* at *www.nabp.net/publications/assets/AR052012.pdf.*

OH Board Clarifies OARRS Requirements for Reportable Drugs

The Ohio State Board of Pharmacy reminded all pharmacists who are filling prescriptions for Ohio Automated Rx Reporting System (OARRS) reportable drugs, which includes all controlled substances (CS) and products containing tramadol, to run an OARRS report if certain conditions occur for that prescription. Pharmacists must run an OARRS report if the patient is being treated with an OARRS reportable drug for greater than 12 weeks or if certain red flag issues occur during the fill process, such as:

- Patient is being treated with an OARRS reportable drug by multiple prescribers
- Abuse/overuse (ie, early refills)
- Patient coming from outside your normal fill area
- Prescriber from outside your normal fill area
- Patient appears impaired upon delivery of script
- Patient asks for certain drug by color/trade name/markings

Additional information about OARRS and about the new requirements is available on the Board's Web site at *https://www.ohiopmp.gov/portal/default.aspx.*

CT Legislature Passes Medical Marijuana Bill

A bill (HB 5389) legalizing the use of medical marijuana by certain patients in Connecticut under strict requirements passed in the Connecticut Legislature on May 4, 2012. Under the act, doctors will need to certify patients' medical needs for the drug before it will be dispensed, and patients and their caregivers must register with the Connecticut Department of Consumer Protection. Patients with debilitating medical conditions such as cancer, glaucoma, HIV, and multiple sclerosis, among other disease states, may qualify for treatment with medical marijuana. Also, the law will only allow patients to obtain medical marijuana from licensed dispensaries, which under the law means a pharmacist "who the Department of Consumer Protection determines to be qualified to acquire, possess, distribute and dispense marijuana" and "who is licensed as a dispensary." Dispensaries will be required to obtain the drug from licensed producers.

Connecticut Governor Dannel Malloy is expected to sign the bill, and stated, "We don't want Connecticut to follow the path pursued by some other states, which essentially would legalize marijuana for anyone willing to find the right doctor and get the right prescription. In my opinion, such efforts run counter to federal law. Under this proposal, however, the Department of Consumer Protection will be able to carefully regulate and monitor the medicinal use of this drug in order to avoid the problems encountered in some other states."

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Around the Association

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of the Ohio State Board of Pharmacy. Kolezynski's reappointment will expire on June 30, 2015.

Board Officer Changes

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

- **Del Fanning, RPh,** President
- **Sara St Angelo, PharmD, RPh,** Vice President

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

- **Susan Frey, RPh,** Chairperson
- **Deeann Wedemeyer-Oleson, PharmD, RPh,** Vice Chairperson

The North Carolina Board of Pharmacy has elected the following officers to the Board:

- **Gene Minton, RPh,** President
- **Ellis Marks, RPh,** Vice President

The Washington State Board of Pharmacy has elected the following officers to the Board:

- **Christopher Barry, RPh,** Chairperson
- **Donna Feild, MBA, RPh,** Vice Chairperson

Help Prevent Children's Exposure to Fentanyl Patches

Food and Drug Administration (FDA) urges health care providers to educate patients and their caregivers about the appropriate storage, use, and disposal of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening.

FDA evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises proper disposal of used or unneeded patches. FDA recommends that the adhesive sides of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home." FDA's consumer Web page provides detailed information for patients and caregivers. Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions.

The FDA safety alert about fentanyl patch safety is available at *www.fda.gov/Drugs/DrugSafety/ucm300747.htm*. Additional information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWAR$_X$E® Web site, *www.AWARERX.ORG*.

Acetaminophen Coalition Asks Providers to Educate Patients

The Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition's Know Your Dose campaign reminds patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time.

Additional medication safety tips and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWAR$_X$E Web site. Also, an interactive educational game was developed as part of the campaign and is available on the Know Your Dose Web site, *www.knowyourdose.org/game*. The interactive game engages consumers by inviting them to help three characters learn how to take medicine that contains acetaminophen safely. The game answers some of the most common questions surrounding the safe use of acetaminophen. The AWAR$_X$E Consumer Protection Program and NABP are part of the Acetaminophen Awareness Coalition.

Avoid Improper Use of Single-Dose, Single-Use Vials

Centers for Disease Control and Prevention (CDC) issued a statement reminding health care providers that medications labeled as "single dose" or "single use" are to be used for only one patient, and that this practice protects patients from life-threatening infections that occur when medications become contaminated from unsafe use. In restating these guidelines, CDC seeks to dispel inaccuracies being disseminated to health care providers. CDC notes that while concerns have been raised about whether these guidelines contribute to drug shortages, and the agency recognizes the problem of drug shortages, such shortages are a result of

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State Board News

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WA Pharmacies May Now Fill Out-of-State ARNP Prescriptions

A new law in Washington State allows pharmacies to fill prescriptions for CS written by Advanced Registered Nurse Practitioners (ARNPs) licensed outside of Washington working within their scope of practice. This law amended the state's Controlled Substances Act by adding ARNPs to the list of practitioners with prescriptive authority for CS in any state. ARNPs with prescriptive authority for CS from Idaho and Oregon write prescriptions for their patients who may reside in Washington or may wish to have their prescriptions filled in Washington. The new law allows Washington pharmacies to fill these prescriptions for CS. The law, signed by Governor Christine Gregoire on March 7, 2012, became effective on June 7, 2012.

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 certain services to be performed in a licensed pharmacy.

Professional Affairs Update

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manufacturing, shipping, and other issues unrelated to the guidelines.

CDC's priority is protecting patients from harm, and the agency indicates in a position statement that "CDC routinely investigates and is apprised of infectious disease outbreaks involving single-dose/single-use vials being used for multiple patients. These outbreaks cause extensive harm to patients, and they are associated with significant health care and legal expenses. Therefore, CDC continues to strongly support its current policies regarding single-dose/single-use vials."

CDC adds further that "It is imperative that drug shortages and drug waste concerns are dealt with appropriately and do not lead to unsafe medical practices that impose increased disease risk on patients. Shortages of some essential medications may warrant implementation of meticulously applied practice and quality standards to subdivide contents of single-dose/single-use vials, as stated in United States Pharmacopeia General Chapter ‹797› Pharmaceutical Compounding – Sterile Preparations."

The CDC statement, available at *www.cdc.gov/injectionsafety/CDC position-SingleUseVial.html*, also includes a list of basic safe injection practices, a chart summarizing related misperceptions versus facts, and agency responses to frequently asked questions.

Members Convene for MPJE Review Committee Meeting

Members of the Multistate Pharmacy Jurisprudence Examination® (MPJE®) Review Committee discuss and evaluate items for the examination. **Pictured at left:** Steve Morse, RPh, of Ohio. **Pictured at right:** Alan M. Shepley, RPh, of Iowa, and Denise M. Frank, RPh, of Minnesota.

nabp newsletter

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