newsletter

National Association of Boards of Pharmacy®

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Upcoming Events

September 1-2, 2015
Task Force on Pharmacist Prescriptive Authority
NABP Headquarters

September 9-10, 2015
Task Force on the Regulation of Pharmacist Care Services
Rosemont, IL

September 14-17, 2015
NABP/AACP Districts 6, 7, & 8 Meeting
Incline Village, NV

September 24-26, 2015
NABP/AACP Districts 1 & 2 Meeting
Portsmouth, NH

October 6-7, 2015
Tri-Regulator Symposium
Arlington, VA

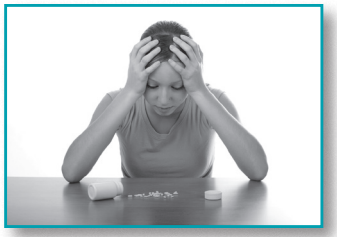
October 13-14, 2015
NABP Interactive Executive Officer Forum
Northbrook, IL

Task Force Recommends Further Educational Initiatives to Fight Prescription Drug Abuse

As the prescription drug abuse epidemic in the United States continues to claim an estimated 15,000 lives each year, the NABP Task Force on Prescription Drug Abuse issued recommendations to improve educational initiatives aimed at pharmacists, pharmacy students, prescribers, and patients. The task force made 14 recommendations in all, among which were recommendations addressing electronic prescribing of controlled substances (CS), "take-back" programs, a certification program for pain management, technician education, and concerns over the impact of physician-customer satisfaction evaluations.

The task force first recommended that NABP continue to support the education of pharmacists on topics related to CS dispensing and carrying out their corresponding responsibility to ensure that prescriptions are issued for a legitimate medical purpose. The members agreed that NABP should consider establishing a traveling speaker's bureau composed of expert practitioners and law enforcement representatives to provide information to pharmacists at various professional meetings. As part of these efforts, the task force members stressed the importance of teaching good communication skills to pharmacists so they can effectively communicate with patients and prescribers about "sensitive" issues related to CS dispensing.

After discussing the importance of ensuring that pharmacy students graduate with a clear understanding of their corresponding responsibility related to dispensing CS, the task force also recommended that NABP encourage pharmacy schools to further educate students on such topics. Members stressed that new pharmacists should be empowered to identify questionable CS prescriptions and have the communication skills necessary to address patients and the prescribers accordingly. Members agreed that many new pharmacists do not fully understand their responsibility before they begin working as pharmacists, especially if taking on pharmacist-in-charge (PIC) responsibilities. The task force suggested that NABP could keep pharmacy school deans abreast with information about challenges faced by new



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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 66 member boards of pharmacy to the profession and the public. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABP or any board unless expressly so stated. The subscription rate is $35 per year.

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Prescription Drug Abuse Task Force

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graduates, and that state boards of pharmacy should consider inviting students to board meetings in order to expose them to current pharmacy practice issues.

The task force additionally recommended that NABP encourage the education of prescribers and patients regarding the ease of access to CS. Overprescribing of CS can often leave patients with a large surplus that may be vulnerable to diversion, noted the task force. Members agreed that NABP should collaborate with other stakeholders to create prescribing guidelines and continuing education (CE) to curb the risks of overdose or diversion. The task force members also determined that it would be helpful for NABP to continue educating the public through its AWAR$_X$E® Prescription Drug Safety Program.

In addition, the task force recommended that NABP continue to encourage the use of CS "take-back" programs and locations in order to remove excess CS from the public domain. With the new Drug Enforcement Administration rule allowing for pharmacies to modify their registrations to become collectors for drug return and disposal, the task force agreed that NABP should inform the pharmacy community about how best to comply with this new rule and means of proper drug return, as well as continuing to inform the public about proper disposal of medication.

Since electronic prescribing is far more secure than paper or phoned-in prescriptions, the task force recommended that NABP continue to encourage electronic prescribing of CS to enhance security.

The task force also discussed the issue of how pain management patients are often shuffled between pain management specialists and primary care providers, and how pain management pharmacists could serve as a bridge for the patient between two or more treatment settings. Therefore, the task force recommended that NABP work with appropriate organizations to develop a pharmacist certification program on pain management that includes the pharmacist working collaboratively with prescribers to offer the best care for patients seeking pain management.

Members thought that a pain management pharmacist could routinely monitor prescription monitoring program data and verify legitimacy using services like NAR$_X$CHECK. The specialty pharmacist could also help ensure that the patient is adhering to any contract guidelines established between the patient and the prescriber.

Increasing the caliber of the pharmacy technicians working alongside pharmacists who are trying to make determinations about appropriate dispensing of CS was also a focus during the task force meeting. The task force recommended that NABP continue to work toward addressing the standards for pharmacy technician education by supporting the following:

- accrediting pharmacy technician training programs and pharmacy technician certification,

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Task Force Charges

The Task Force on Prescription Drug Abuse met at NABP Headquarters and accepted the following charges:

1. Review the Stakeholders' on the prescribing and dispensing of CS challenges and identified warning flags for practitioners consensus documents.
2. Identify actions pharmacists might take in their efforts to determine whether a questionable prescription has been written for a legitimate medical purpose.
3. Review Stakeholders' actions document intended to improve interprofessional dialogue in addressing warning flags and delivering the most appropriate patient care.
4. Recommend further actions to combat prescription drug abuse.

National .Pharmacy TLD Campaign Raises Consumer Awareness; General Availability Now Open

With the .Pharmacy Top-Level Domain (TLD) Program now accepting applications from all eligible pharmacies and related entities, NABP is continuing its efforts to increase consumer awareness of the program through an ongoing national campaign. Launched in late 2014, the .Pharmacy TLD Program aims to increase safety for patients shopping for prescription medications and obtaining pharmacy-related information online by making the ".pharmacy" at the end of a website address an indicator of safety. Efforts to reach consumers have included public service announcements (PSAs), blog articles, press releases, and a satellite media and Internet tour.

Since they were distributed in mid-January through the end of May 2015, .pharmacy PSAs have aired on television and radio stations nearly 17,000 times, reaching millions of viewers and listeners. At press time, the PSAs continue to air on national networks and local affiliates, including Escape, Grit, Fox Business, and Fox News.

In addition, Carmen A. Catizone, MS, RPh, DPh, executive director/secretary of NABP and Libby Baney, JD, executive director of the Alliance for Safe Online Pharmacies participated in a series of live and recorded interviews for television and radio stations as well as for bloggers. The interviews aired on networks across the country, including stations in Alabama, Connecticut, Texas, Washington State, and Nevada. A digital multimedia release was also sent out the following week. At press time, the total number of estimated viewers is over 3 million.

NABP began accepting applications for .pharmacy domain names from all eligible pharmacy-related entities at the start of general availability on June 3, 2015. Those eligible to apply include pharmacies, pharmacy benefit management companies, prescription drug information and pharmacy referral sites, prescription drug-related patient advocacy and consumer education sites, medical professionals' offices, schools and colleges of pharmacy, continuing pharmacy education providers, wholesale drug distributors, and pharmaceutical manufacturers.

As part of the application process, the content of the proposed website must be available for review by NABP either on an existing website or a staging site. NABP is establishing a network of international regulatory groups to facilitate evaluation of domain name applications from countries worldwide. Once approved, applicants may register the domain names through one of NABP's participating registrars. Those entities that hold a .pharmacy domain must reapply for the domain and re-register annually.

NABP member boards continue to be eligible to obtain a board-specific domain name at no cost and to register the name for a period of five years. Boards of pharmacy that have not yet requested a .pharmacy domain name may send a request by email to info@safe.pharmacy. NABP expects to continue making these domain names available at no cost to the boards.

At press time, NABP had received a total of 446 .pharmacy domain name requests and registered 212 domains for 32 boards of pharmacy, and 42 companies including 25 pharmacies, 12 veterinary pharmacies, three manufacturers, and two informational sites.

Additional details about the .Pharmacy TLD Program are available at *www.safe.pharmacy*, including a list of all registered .pharmacy domain names.

Executive Committee

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One-year term

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One-year term

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Serving third year of a second three-year term

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

Richard B. Mazzoni
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.

Preemption: The Maine Reason Canadian Importations Put on Ice

The legal issues surrounding the introduction of foreign prescription drugs into the United States market are complex and subject to the application of at least the federal and state laws. Further, these issues challenge the concept of federalism whereby state and federal governments share in the regulation of the industry and, under certain circumstances, federal law preempts state law. While states generally have the right to regulate the professions and, potentially, the flow of commerce, such states' rights are not unfettered and are subject to federal control in the interest of the collective rights of the states. Consider the following.

In 2013, the Maine Legislature passed legislation entitled "An Act to Facilitate the Personal Importation of Prescription Drugs From International Mail Order Prescription Pharmacies," also known as the Maine Pharmacy Act Amendments (MPA Amendments). The legislation was neither signed nor vetoed by the governor, thus it became effective 10 days after submission by the legislature. The MPA Amendments modified the Maine Pharmacy Practice Act and created an exception to the general requirement that those who engage in the practice of pharmacy be licensed by the Maine Board of Pharmacy (Board). In short, the MPA Amendments exempt from the Maine licensure requirements licensed retail pharmacies located in Canada, Great Britain, Northern Ireland, the Commonwealth of Australia, and New Zealand. Such exempted pharmacies must be duly licensed in their country and, as a result of the MPA Amendments, may "export prescription drugs by mail or carrier to a resident of [Maine] for that resident's personal use." Further, the MPA Amendments exempt from licensure an entity that "contracts to provide or facilitate the exportation of prescription drugs from a licensed retail pharmacy" from the countries listed above.

The MPA Amendments also include a "Consumer Choice Preserved" provision that allows residents of Maine to order from licensed retail pharmacies located outside the US (described above) and receive by mail or carrier prescription drugs for personal use. Finally, the MPA Amendments also affirmatively allow licensed retail pharmacies described above to dispense, provide, or facilitate prescription drugs for personal use from outside the US by mail or carrier to a resident of Maine. The justification for the MPA Amendments was based in part on Canadian drugs being "less expensive than those from the United States." In fact, the purpose of the MPA Amendments was to "expand the definition of a 'mail order prescription pharmacy' under the Maine Pharmacy Act to include an entity located outside of the United States that dispenses prescription medications by mail or carrier from a facility not located in [Maine] to a pharmacy or to a patient who resides in [Maine]."

Two Maine licensed pharmacists and three trade associations (Plaintiffs) filed suit under the Supremacy Clause of the US Constitution against the Maine Attorney General and the Commissioner of the Maine Department of Administrative and Financial Services in their official capacities (Defendants). The Plaintiffs argued that the Federal Food, Drug, and Cosmetic Act (FD&C Act) preempts certain amendments to the Maine Pharmacy Practice Act.

After some procedural wrangling, the parties filed competing cross motions for summary judgment, whereby the court is asked to rule on the legal issues without the need for a trial as there are no material issues of fact in dispute. Because the Plaintiffs argued that the MPA Amendments are invalid on their face, the court addressed the constitutionality of the law without any information about the effects of the amendments and/or how such were being enforced. A facial challenge is the most difficult to sustain as the Plaintiff must establish that no set of circumstances exists under which the Act would be valid.

The Plaintiffs argued that the FD&C Act creates a "closed" regulatory scheme that strictly limits the introduction of prescription drugs into interstate commerce. The FD&C Act prohibits the importation or introduction into interstate commerce of any new drug that has not received Food and Drug Administration (FDA) approval and also restricts the reimportation of drugs manufactured in the US but sent abroad to the original manufacturer. Further, in 2003, Congress enacted the Medicaid Prescription Drug, Improvement, and Modernization Act (MMA) which contemplates permitting pharmacists and wholesalers through the promulgation of regulations to import prescription drugs from Canada into the US. Upon certification by the Secretary of Health and Human Services that importation will be safe and cost effective, such regulations will be promulgated; however, no such certification nor regulations have occurred. The Plaintiffs argue that this Congressional contemplation through the MMA further supports the fact that state law regarding the importation of prescription drugs is preempted by federal law through the Supremacy Clause.

The Defendants argued that the MPA Amendments are within the sovereign authority of the state as they merely reduce the reach of the practice act and allow the state to choose not to regulate certain conduct. The Defendants assert the states' rights under the 10th Amendment of the US Constitution and argue that Maine cannot be compelled to administer federal regulatory programs.

In addressing preemption, the court noted that there are multiple ways federal law may preempt state law. First, Congress can expressly state that it is preempting state law. If not expressly stated, the judiciary may infer preemption through either "field" or "conflict" preemption. Field preemption occurs when the intent to displace state law can be inferred "from a framework that is so pervasive . . . that Congress left no room for the States to supplement it or where there is a federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."

Although not rigidly applied, conflict preemption can be categorized as impossibility or obstacle preemption. Impossibility preemption occurs where compliance with both state and federal law is a physical impossibility. Obstacle preemption occurs where the challenged state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Turning its attention to the arguments of the parties, the court first noted that there are competing issues around the various presumptions that can be made. First, there is a presumption that a statute is valid. On the other hand, and as argued by the Plaintiffs, there is a presumption of preemption as the MPA Amendments infringe on an area traditionally reserved to the states. In this case, the Plaintiffs argued that the MPA Amendments violate the Supremacy Clause under the theory of field preemption. The Defendants countered that the relevant field is limited to the regulation and licensure of pharmacists and pharmacies, a subject matter traditionally left to the states.

While recognizing the local sphere of public health and safety and the states rights to regulate the licensure of pharmacies and pharmacists, the court noted that the

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

Prescription Drug Abuse Task Force

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- requiring CE focused on drug diversion for technicians, and
- ensuring that educational programs do not admit students with backgrounds that would disqualify them from registration or licensure.

Although the task force agreed that pharmacy technicians are invaluable to pharmacists, they also discussed how pharmacy technicians can be a major source of CS diversion. Therefore, the task force members suggested that NABP support background checks prior to employment.

In another recommendation, the task force suggested that NABP communicate with the Joint Commission and Centers for Medicare and Medicaid Services to express concerns with customer satisfaction evaluation reviews (Press Ganey scores) and their possible influence on physician prescribing. The task force members questioned the value of Press Ganey scores, since a recently published study concluded that higher patient satisfaction was associated with greater health care cost (including costs for prescription drugs) and increased mortality. The task force members expressed concern as to how these patient evaluation/scores influence prescribing practices, since they may impact physician salaries, bonuses, and job retention.

Three recommendations addressed how the Association can continue to raise awareness among pharmacists. First, they recommended that NABP consider the dissemination of the "red flags" information in the *National Pharmacy Compliance News* of the NABP state newsletters as well as develop model policies and procedures addressing diversion prevention measures.

Second, the task force recommended that NABP continue to support the recommendations of the Task Force on the Control and Accountability of Prescription Medications, which met in 2011, particularly those that focused on PIC issues, and also work towards disseminating this information at national pharmacy association meetings.

Third, the task force recommended that NABP work with national groups to hold breakout sessions for board of pharmacy members and executive directors attending national meetings in order to encourage dialogue amongst various state members and the sharing of information.

The Task Force on Prescription Drug Abuse was established in response to the NABP Executive Committee's recommendation to explore the prescription drug abuse epidemic and actions that pharmacists can take to curtail the problem. The Task Force on Prescription Drug Abuse met September 9-10, 2014, at NABP Headquarters.

Task force members included John Foust, PharmD, DPh, chair; Thomas F.X. Bender, RPh; Christopher Dembny, RPh; Patty Gollner, PharmD, RPh; Edith Goodmaster; Diane Halvorson, RPhTech, CPhT; Janet Hart, RPh; Richard Indovina, Jr, MBA, RPh; Brandon Robinson, JD; Phyllis Stine, BS; and William T. "Bill" Winsley, MS. The NABP Executive Committee liaison was Jeanne D. Waggener, RPh.

The task force report was approved by the Executive Committee, with amendments related to three recommendations, during its February 2015 meeting and is available in the Members section of the NABP website at *www.nabp.net.*

Register Now for the September 28, 2015 FPGEE Administration

Registration is now available for the next Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) that will be administered on **September 28, 2015**. Foreign Pharmacy Graduate Examination Committee™ candidates who have been accepted to take the FPGEE may register using the link in the FPGEE section of the NABP website.

Within one week of registering with NABP, candidates will receive an Authorization to Test, and they may then schedule their test location with the NABP test vendor, Pearson VUE. Registration for scheduling an appointment with Pearson VUE opened on July 14, 2015, and candidates have until September 21, 2015, to schedule an appointment to test. NABP encourages early registration for optimal scheduling options as certain test centers fill up quickly.

To prepare for the FPGEE, NABP recommends that candidates take the Pre-FPGEE®, the practice examination for the FPGEE designed to help familiarize candidates with the types of questions on the actual examination.

Additional information about the FPGEE is available in the Programs section of the NABP website at *www.nabp.net.*

NABP Interactive Forum Series Returns This Fall

The NABP Interactive Forum series, to be held this fall, will once again offer an opportunity for dialogue on shared challenges board of pharmacy executive officers, compliance officers, and board legal counsel face. Held as two separate forums, the first will be tailored to the board of pharmacy executive officers and will be held in October. The second will be tailored specifically to board of pharmacy compliance officers and legal counsel and will be held in December. The annual NABP surveyor workshop will be held at the same time and surveyors will also participate in some of the forum sessions. The NABP Interactive Executive Officer Forum and the NABP Interactive Compliance Officer and Legal Counsel Forum will each take place over two days.

Both 2015 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.

Executive Officers

The NABP Interactive Executive Officer Forum is set to take place October 13-14, 2015. Each state board of pharmacy executive officer is invited to attend the forum at no charge. As with the previous forums, travel, hotel accommodations, and meals will be paid by NABP. There is no registration fee for the meeting. Information on registering for the Executive Officer Forum will be sent to the board of pharmacy executive directors by early August.

Compliance Officers and Legal Counsel

The NABP Interactive Compliance Officer and Legal Counsel Forum, which will be held December 1-2, 2015, invites each executive officer to select one compliance officer from his or her board to attend the forum at no charge. In addition, each executive officer may invite one attorney who serves as the board's legal counsel to participate in the forum. Like the Executive Officer Forum, travel, hotel accommodations, and meals will be paid by NABP and there is no registration fee for the meeting. During the forum, attendees will have the chance to meet with their peers to discuss regulatory trends and challenges faced by their boards. Programming will also include breakout sessions specific to each of the three groups – legal counsel, compliance officers, and surveyors. By combining the surveyor workshop with the forum, NABP surveyors will have the chance to learn directly from board of pharmacy compliance officers, inspectors, and investigators what their typical duties and challenges entail. Invitations to the Compliance Officer and Legal Counsel Forum will be sent by late October.

The forums were first announced at the NABP 106th Annual Meeting in 2010 as part of an initiative to provide additional support and resources to the member boards of pharmacy. A forum for board members is scheduled to return in fall 2016.

Both meetings will be held at the Hilton Northbrook, in Northbrook, IL.

2015 Tri-Regulator Meeting Brings NABP, FSMB, and NCSBN Together to Discuss Regulatory Issues, Facilitate Interprofessional Cooperation

Members from NABP, the Federation of State Medical Boards (FSMB), and the National Council of State Boards of Nursing (NCSBN) will have the opportunity to meet at the 2015 Tri-Regulator Symposium, to be held October 6-7, 2015, in Arlington, VA.

Events at the meeting will focus on the theme "Team-Based Care – Collaborative Regulation." Attendees will discuss current and future opportunities for interprofessional cooperation and collective challenges faced by these three groups.

Attendance is limited among the three organizations. NABP will be represented by the NABP Executive Committee as well as additional representatives from member boards of pharmacy. Attendance will be on a first-come, first-served basis. More information about the opportunity to attend the symposium was provided in the July 30, 2015 NABP Electronic Mailbag.

The Tri-Regulator Symposium is being sponsored by the Tri-Regulator Collaborative, which is composed of NABP, FSMB, and NCSBN. While each organization is autonomous with its own constituent membership, common values about public protections through state-based licensure unite the organizations for dialogue and consensus building.

The members recognize the potential benefits of collaborating to better protect the health, safety, and welfare of the public. Tri-Regulator Collaborative members also recognize the value of involving a broader constituency as issues emerge and, therefore, encourage other health care regulatory representatives to participate in relevant and pertinent issues.

Volunteer Item Writers Sought to Develop Questions for NABP Examinations and Assessments

NABP is seeking volunteers to serve as item writers for the North American Pharmacist Licensure Examination® (NAPLEX®), the 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®) programs.

The opportunity to participate as an item writer is currently available to pharmacists in all areas of practice, and faculty from schools and colleges of pharmacy.

Item writers will be selected based on the specific needs of the programs. Those who are selected will be asked 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 development process and content-related requirements for their designated examination program. Item writers will then engage in the development of new test items that will be considered for inclusion in NABP licensure, certification, and assessment examination programs.

The NAPLEX focuses on content domains relating to the knowledge, judgment, and skills an entry-level pharmacist is expected to demonstrate. The three competency areas of the examination are:

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

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

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

Writers for the MPJE are typically assigned by the participating jurisdiction; however, individuals may be selected to participate independent of board of pharmacy affiliation.

The FPGEE content domains cover curricula of accredited United States pharmacy schools including:

- Basic biomedical sciences,
- Pharmaceutical sciences,
- Social, behavioral, and administrative pharmacy sciences, and
- Clinical sciences.

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

- Basic biomedical sciences,
- Pharmaceutical sciences,
- Social, behavioral, and administrative pharmacy sciences, and
- Clinical sciences.

The PARE is a multidimensional assessment that the boards of pharmacy may use as an auxiliary tool when making decisions regarding pharmacist remediations or brief departures from practice.

The content areas are:

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

How to Apply

Interested individuals should complete the online NABP Item Writer Volunteer Interest Form available in the Meetings section of the NABP website under Examination Meetings, and upload a current résumé or curriculum vitae.

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

The blueprint for each examination and assessment program may be found in the Programs section of the NABP website at *www.nabp.net*. For more information about item writing, contact NABP at NABP_Comp_Assess@nabp.net.

Task Force Examines Strategies to Prevent Pharmacy Robberies and Thefts, Recommends *Model Act* Changes

With prescription drug abuse rates at epidemic proportions, pharmacies in many parts of the country have experienced an increase in the diversion of controlled substances (CS) through theft and armed robberies. Recognizing that robberies threaten the safety of pharmacy personnel and customers, NABP convened the Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts to determine how pharmacists and other stakeholders could help to limit these incidents. In pursuit of that goal, the task force recommended revising language in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*, including the addition of a new section focused on security. The task force also recommended that NABP continue to provide pharmacy robbery prevention resources through its communication vehicles, provide a related continuing pharmacy education (CPE) session at an Annual Meeting, and include additional warning signs in the *Stakeholders' Challenges and Red Flag Warning Signs Related to the Prescribing and Dispensing Controlled Substances* (consensus document).

The task force members discussed the need for enhanced pharmacy security and reflected on the threat to pharmacy personnel, since recent robberies have resulted in death and injury to pharmacy staff. They agreed that the protection of pharmacy employees from harm is paramount followed by the need to secure drugs from abuse and diversion. They determined that these goals should be the focus of actions and recommendations going forward.

Since the task force members concluded that pharmacy security requirements should be stressed in state regulations, the members agreed that separate attention to security in the *Model Act* was warranted. Therefore, a new security section was created in the *Model Act*, which incorporated some existing information, and added a new focus on technological features to emphasize the need for video surveillance and monitored alarm systems to help deter criminal activity. The new *Model Act* security section encompasses information about facility security measures to ward against robberies/burglaries and also internal security measures that protect drug inventory from employee theft and diversion.

Further, the task force stressed that the pharmacist-in-charge (PIC) and owner/licensee (facility permit holder) should share joint responsibility for protecting drug inventory and implementing measures to detect drug pilferage as soon as possible. The task force also recommended that, as part of his or her responsibility to "develop or adopt, implement or maintain" policies and procedures, the PIC, in conjunction with the owner/facility permit holder, should also be responsible for developing and reviewing actions to be taken to prevent and react to pharmacy robberies and thefts. Therefore, this new policy requirement was added to the *Model Act* policies and procedures responsibility section for the PIC.

In addition to focusing on facility security measures, the task force members agreed that it is important for pharmacists and pharmacy technicians to stay abreast with current information on best practices to deter pharmacy robberies and thefts. In addition, the task force members determined that it was imperative for members of the pharmacy community to know the actions they should take and those to avoid during such an incident. The goal of such guidance would be foremost to protect employees from harm and additionally to preserve the crime scene, which assists law enforcement in their subsequent investigation. As such, members agreed that NABP should continually provide information on this issue as it becomes available in its various communication vehicles, including *NABP e-News*, the *NABP Newsletter*, and the AWAR$_X$E® Prescription Drug Safety website.

The task force members also determined that it would be helpful for NABP to support CPE focused on pharmacy robbery and theft prevention and the actions pharmacists should take when such events occur. Therefore, the task force recommended that NABP

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Task Force Charges

The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met at NABP Headquarters and accepted their charge as follows:

1. Review actions taken by member boards to prevent the diversion of controlled substances by armed robberies and internal and external thefts as well as actions taken to mitigate potential harm to pharmacy personnel and the public.
2. Review and, if necessary, recommend amending the minimum security standards for pharmacies found in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act).*

Legal Briefs

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MPA Amendments extend beyond the regulation and licensure of such pharmacies or pharmacists. "The MPA Amendments do not, as the State asserts, simply repeal state licensure regulations; the MPA amendments select five countries whose licensed retail pharmacies 'may export' prescription drugs to Maine residents." In fact, the MPA Amendments attempt to enable the importation of cheaper foreign pharmaceuticals. Further referencing the FD&C Act, the court noted the federal regulatory scheme and the prohibition of importation or introduction into interstate commerce of any new drug not approved by FDA. Additionally, Congress specifically legislated the issue of Canadian importation through the enactment of the MMA, buttressing the intent of the federal regulation of products in interstate commerce.

Regarding the 10th Amendment, the court cited the fact that although the states cannot be compelled to enact or administer a federal regulatory program, the Amendment does not save a law that "obstructs" federal law. "Federal law may preempt state law even where the federal government may not compel a state government to enact or administer a federal legislative or regulatory scheme."

The Defendants cited cases regarding marijuana legislation; however, the court held that such cases are not on point as the federal government included a savings clause in the Controlled Substances Act that expressly provided that Congress did not intend to occupy the field. Thus, the previous jurisprudence involving marijuana laws that allow for the enactment of state statutes was not subject to a field preemption analysis.

This case addresses the very important issue of preemption as related to states' rights and the importation of prescription drugs on a state-by-state basis. Pursuant to this judicial ruling, states are preempted from legislating in this arena. It is likely that additional state statutes will be enacted and challenged. Stay tuned.

Ouellette v. Mills, 2015 US Dist. LEXIS 21137 (US District Ct ME 2015)

Pharmacy Robberies and Thefts Task Force

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provide a CPE session on preventing pharmacy robberies and thefts by nationally recognized experts in this field at future NABP meetings. Further, the task force recommended that the CPE session be recorded and made available to other audiences. During the discussion, task force members focused on the need to disseminate information about best practices to prevent drug loss and the joint responsibility of PICs and pharmacy owners to detect and report drug loss as required by state and federal laws and regulations.

In addition to these recommendations, there were two recommendations from the Task Force on Prescription Drug Abuse that the NABP Executive Committee determined were better exemplified with the recommendations set forth during the pharmacy robberies task force. Following a discussion of the many opportunities for pharmacists to identify warning signs of potential misuse, abuse, or diversion related to patient prescriptions, the Task Force on Prescription Drug Abuse recommended that NABP amend the pharmacist section of the consensus document to add additional "red flags" and cautions for pharmacists and other stakeholders. Information added to the document included a red flag indication for phoned-in prescriptions received at unusual times and another for prescriptions filled inconsistently or obtained from more than one pharmacy by parents of children prescribed attention deficit hyperactivity disorder medication.

The Task Force on Prescription Drug Abuse also recommended that NABP amend the pharmacist section of the consensus document to additionally include "red flags" that may be signs of internal diversion. Warning signs that were added to the document included frequent visits from an employee's boyfriend or girlfriend and employees who leave the pharmacy multiple times during a shift. The task force stressed that pharmacists should recognize that employee diversion occurs in varying degrees in almost all settings.

The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts was established in response to Resolution 110-2-14, which was passed by the NABP membership at the Association's 110th Annual Meeting in May 2014. The task force met on October 22-23, 2014, at NABP Headquarters.

Task force members included Anthony Rubinaccio, RPh, chair; Jody Allen, PharmD, RPh, FASHP; Mindy Ferris, RPh; Cathryn Lew, RPh; Edward Maier, RPh; Jeenu Philip, BPharm; Pam Reed, RPh; Nona Rosas, CPhT; Gary A. Schnabel, RN, RPh; and Stuart Williams, JD. The Executive Committee liaison was Richard B. Mazzoni, RPh.

The full task force report was approved by the NABP Executive Committee in February 2015. The task force's *Model Act* amendments were reviewed by the Committee on Law Enforcement/Legislation in January 2015 and approved by the NABP Executive Committee during its May 2015 meeting. The task force report is available in the Members section of the NABP website at *www.nabp.net.*

VPP Enhancements Now Available to the Boards

Authorized board of pharmacy staff can now access pharmacy data through the enhanced Verified Pharmacy Program™ (VPP™) interface, which was made available for the state boards of pharmacy on July 15, 2015. In addition to existing features such as the tagging of VPP facilities, the improved VPP interface provides the states with an added level of access, allowing authorized users to link directly from a VPP facility e-Profile to more detailed disciplinary data, when applicable, relating to the facility and relevant pharmacists-in-charge. Boards may also see the most recent VPP inspection date for a facility when one exists, directly from the search page. Along with an updated look and feel, this enhanced interface provides boards additional functionality to further improve navigation within the facility e-Profiles. Additional features such as ownership details are also anticipated to be made available in future releases of the interface as more data becomes available.

Through VPP, board of pharmacy staff will continue to receive information on pharmacies including licensure, inspection, and disciplinary action information. The system also allows the states with the capability to upload and view their own state inspection reports.

Developed by NABP in conjunction with the state boards of pharmacy, the VPP interface is available to the member boards of pharmacy through the existing NABP e-Profile Connect system and allows the boards to communicate and share critical information, in addition to providing access to verified data collected directly through the program.

As an extension of NABP's existing pharmacist licensure transfer system, VPP is meant to serve as an enhancement to existing licensure processes by facilitating this data sharing capability.

At press time, at least 302 pharmacies have applied to VPP and currently, or soon will, have verified data available for the boards to view. This verified data is provided to the member boards in an effort to further support them in making informed licensure decisions for their nonresident pharmacies.

Of the 309 VPP facilities:

- 127 pharmacies engage in nonsterile compounding;
- 39 pharmacies engage in sterile compounding;
- 95 pharmacies engage in both sterile and nonsterile compounding;
- 39 pharmacies are general retail or mail-order pharmacies; and
- 2 pharmacies are nuclear pharmacies.

For more information about VPP, contact the NABP Accreditation department at vpp@nabp.net. Additional information is also available in the Programs section of the NABP website at *www.nabp.net.*

NABP Provides Inspection Services to Third-Party Program

To support safe compounding practice and protection of public health, NABP will be providing inspection services as part of a new compounding accreditation program offered by United Compounding Management (UCM). The United Compounding Accreditation Program (UCAP) is aimed at enhancing accreditation standards and processes for compounding pharmacies with a focus on protecting the public health.

NABP's experience in licensure and pharmacy review, and the Association's network of inspectors allows for a cost-effective and efficient review process for applicants seeking UCAP accreditation. The UCAP accreditation process includes a review of business and quality practices, attestation to a code of conduct, and compounding-specific requirements. More information about this program is available on the UCM website at *www.ucmrx.com.*

Newly Accredited VAWD Facilities

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

Smiths Medical ASD, Inc
Dublin, OH
Gary, IN

A full listing of more than 540 accredited VAWD facilities is available on the NABP website at *www.nabp.net.*

Expanded AWARxE Consumer Outreach Yields Exciting Results With Audience Reach of More Than 3.4 Million

The 2015 AWARxE® Prescription Drug Safety Program consumer outreach efforts have achieved significant results just three months into a 10-month consumer campaign – each month focuses on a different topic and uses a different strategy to reach the audience.

In March, proper medication disposal was the focus of a custom audience solution campaign. This type of campaign is based on a consumer's online activity. If a consumer went to a search engine and typed in keywords related to medication disposal, he or she saw one of four digital banner advertisements about proper disposal. These ads allowed consumers to click through to AWARxE's drug disposal site locator tool (*www.AWARERx.org/disposal-sites*). Behavior on the AWARxE website was also tracked so that consumers who left the program's website would see banner ads leading them back to the website for another visit. Additionally, consumers saw the banner ads if they visited certain websites, searched for related products, or bought those related products online.

Banner ad text included "Use AWARxE's drug disposal locator tool to find a disposal site in your area today," and "Disposal sites for tossing unneeded medications are located throughout the country." The results were impressive. The overall click-through rate was three times the standard results for similar campaigns. More than 2.5 million people viewed the banner ads and AWARxE's Locator Tool page visits skyrocketed.

April focused on the secure storage of medications. With spring being a busy time for the real estate market, AWARxE recorded radio public service announcements (PSAs) to alert consumers about the dangers of leaving medications in easy-access locations when they open their homes for showings or open houses. Unlike most radio advertisements, PSAs are aired for free at the discretion of a radio station's manager. The PSAs were sent to radio stations across the country and aired during April in markets like Portland, Nashville, Sacramento, Baltimore, and Chicago. Top airings include WYPL-FM (News) in Memphis, TN, which played the PSA 120 times and KBZZ-AM (Talk) in Reno, NV, which played the PSA 90 times. More than 550 airings enabled the PSA to reach nearly 900,000 listeners for close to $30,000 in donated media value. It is expected that the PSAs will continue to play throughout the summer.

Facebook was the delivery platform for May's campaign, which alerted parents about the potential for teens to misuse and abuse prescription medications during finals and prom. Three types of Facebook ads were utilized: page likes ads, which were used to build audience/page likes on the AWARxE Facebook page; click to website ads, which prompted consumers to visit the AWARxE website; and boosted posts, which increased activity on the AWARxE Facebook page through likes, comments, and shares.

Ad text ranged from "The majority of teens who abused prescription drugs say they're easy to get and often free," to "Teens often combine prescription and over-the-counter drugs with alcohol, which can be potentially fatal. Protect your children." The ads ran throughout May and the results were noticed immediately. Within one day, the AWARxE Facebook page received roughly 800 new likes and by the end of May the page had gained approximately 4,500 likes.

AWARxE continues to roll out monthly campaigns in third quarter 2015. Through these consumer outreach efforts, NABP hopes that the program will produce more exciting results and opportunities to prevent prescription drug misuse and abuse.

AWARxE Facebook Ads Alert Parents During Finals and Prom Season

In May 2015, the AWARxE® Prescription Drug Safety Program ran Facebook ads to alert parents of the potential for teens to abuse or misuse prescription drugs during finals and prom. The ad pictured left increased activity on the AWARxE Facebook page through likes, comments, and shares.

Around the Association

Executive Officer Changes

- **Kamlesh "Kam" Gandhi, PharmD, RPh,** is serving as the executive director of the Arizona State Board of Pharmacy, replacing Hal Wand, MBA, RPh, who retired in late May 2015. Mr Gandhi currently serves as a district manager for Albertson's in the Nevada, Utah, and California districts. Prior to joining the Arizona Board, Mr Gandhi served as a board member of the Nevada State Board of Pharmacy. He received his doctor of pharmacy degree from the University of Illinois at Chicago College of Pharmacy.
- **Dane Ishihara** is serving as the bureau manager of the Utah Board of Pharmacy, replacing Steven Duncombe who was serving as the interim bureau manager. For the last 10 years, Mr Ishihara has worked for the Utah Department of Commerce, Division of Occupational and Professional Licensing where he worked extensively on policy analysis and implementation. Mr Ishihara received his bachelor of arts degree in economics and his master's degree in community leadership from Westminister College.

Board Member Appointments

- **Leif Holm, PharmD, RPh,** has been appointed a member of the Alaska Board of Pharmacy. Holm's appointment will expire March 1, 2019.
- **Jason Hansel, PharmD, RPh,** has been appointed a member of the Iowa Board of Pharmacy. Hansel's appointment will expire April 30, 2018.
- **William Cox, CPhT,** has been appointed a pharmacy technician member of the Massachusetts Board of Registration in Pharmacy. Cox's appointment will expire October 31, 2017.
- **Jason Penrod, PharmD, RPh,** has been appointed a member of the Nevada State Board of Pharmacy. Penrod's appointment will expire October 31, 2017.
- **Robert Graves** has been appointed a public member of the North Carolina Board of Pharmacy. Graves' appointment will expire April 30, 2020.

Board Member Reappointments

- **Edward McKenna, RPh,** has been reappointed a member of the Iowa Board of Pharmacy. McKenna's appointment will expire April 30, 2018.
- **Robert Haneke, PharmD, RPh,** has been reappointed a member of the Kansas State Board of Pharmacy. Haneke's appointment will expire April 30, 2019.
- **Chad Ullom, RPh,** has been reappointed a member of the Kansas State Board of Pharmacy. Ullom's appointment will expire April 30, 2019.
- **Susan DelMonico, JD, RPh,** has been reappointed a member of the Rhode Island Board of Pharmacy. DelMonico's appointment will expire November 30, 2017.

NABP PMP InterConnect Steering Committee Convened for a Meeting in July 2015

The NABP PMP InterConnect® Steering Committee met in Northbrook, IL, on July 15-16, 2015, to discuss recent state participation updates and issues related to the administration and function of the program. In addition, in an effort to encourage the ability to share data on a national scale, additional state prescription monitoring programs (PMPs) not currently connected to PMP InterConnect were invited to attend. More information about the meeting is forthcoming in future NABP communications.

Ohio Board Now Lists Licensed Outsourcing Facilities on Website

The Drug Quality and Security Act, signed into law on November 27, 2013, created a new Section 503B in the Federal Food, Drug, and Cosmetic Act. Under Section 503B, a compounder can become an "outsourcing facility." These facilities are permitted to provide non-patient-specific compounded sterile drug products that must meet current Good Manufacturing Practice requirements. Pursuant to Ohio Administrative Code 4729-16-02, an outsourcing facility is prohibited from selling compounded products in Ohio unless it holds a valid license as a wholesale distributor of dangerous drugs with an outsourcing facility classification. To identify these properly licensed entities, the Ohio State Board of Pharmacy has posted a list of approved sites to its web page at *https://pharmacy.ohio.gov/outsourcing*. This list will be updated as new outsourcing facilities are licensed by the Board.

New Virginia Laws Address Drug Distribution, Compounding, and Dispensing

In Virginia, several bills that may affect the practice of Virginia licensees became law on July 1, 2015.

House Bill (HB) 1736 requires a wholesale distributor or nonresident wholesale distributor that ceases distribution of Schedule II through V drugs to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances (CS) to notify the Virginia Board of Pharmacy within five days of the cessation.

HB 1737 creates a new regulatory framework for permitting outsourcing facilities that compound sterile drugs and are located within the Commonwealth, along with registering nonresident outsourcing facilities shipping their product into the Commonwealth. The bill also amends §54.1-3410.2 of the Drug Control Act by limiting the circumstances under which a pharmacy may provide compounded drugs to practitioners of medicine, osteopathy, podiatry, or dentistry for office use. Effective July 1, 2015, a pharmacy may only provide a reasonable amount of compounded drugs to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded drug products to practitioners of veterinary medicine for office-based administration to their patients.

HB 1914 provides that a prescriber may authorize pharmacists, pursuant to an oral or written order or standing protocol, to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

HB 1458, among the allowances, expands the former naloxone pilot by authorizing pharmacists to dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber and in accordance with protocols developed by the Board of Pharmacy in consultation with the Virginia Board of Medicine and the Virginia Department of Health, and authorizes a person to possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opiate overdose. Because an emergency exists, the act is in force from its passage.

Additional details on these and other bills are available on the Virginia General Assembly's website at *http://leg1.state.va.us* and may be searched by bill number or keywords.

Kansas Sees Increase in PMP Utilization

The Kansas State Board of Pharmacy is proud of the increase in utilization of Kansas Tracking and Reporting of Controlled Substances (K-TRACS), and K-TRACS is continuing to prove to be the most powerful patient care tool to prevent and deter prescription drug abuse. Specifically, the number of pharmacy registrants and requests made by pharmacy registrants has increased substantially during the past year. The Board is also pleased that Oklahoma is now using NABP PMP InterConnect® so that K-TRACS users are able to check Oklahoma's records as well as Kansas records.

K-TRACS staff has been working with its technology vendor to provide unsolicited patient alerts on the website through the use of the prescription monitoring program (PMP) software system PMP AWAR$_X$E™. K-TRACS will alert the pharmacy by providing a history of those patients who have been identified as users of multiple pharmacies and prescribers. This will take the place of the threshold letters that are currently mailed to pharmacists and prescribers.

K-TRACS users will also see an improved error description for National Drug Codes that do not match and that are rejected. There will be a better description, and the errors will be easier to fix.

The Board will have an easier time determining whether a pharmacy that dispenses CS or drugs of concern to patients in Kansas is delinquent in uploading or providing zero reports. The Kansas law requires data to be submitted within 24 hours of the dispensing.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model. Additional information is available on the course website at *http://health.gov/hcq/training.asp#pathways.*

Compounding Restrictions on Four Drugs Reviewed by FDA

The Pharmacy Compounding Advisory Committee of Food and Drug Administration (FDA) held a public meeting that included discussions regarding revisions to the list of drug products that may not be compounded under the exemptions provided by the Federal Food, Drug, and Cosmetic Act. Specifically, FDA is considering whether to add aprotinin, ondansetron hydrochloride, bromocriptine mesylate, and acetaminophen to the list of drugs that may not be compounded, according to a *Federal Register* announcement. The announcement also notes that the "list may specify that a drug may not be compounded in any form, or, alternatively, may expressly exclude a particular formulation, indication, dosage form, or route of administration from an entry on the list because an approved drug containing the same active ingredient(s) has not been withdrawn or removed from the market." The committee meeting was held June 17-18, 2015, in Silver Spring, MD, and was open to the public. More details are available in the *Federal Register* announcement, which can be viewed at *www.federalregister.gov/articles/2015/05/22/2015-12512/pharmacy-compounding-advisory-committee-notice-of-meeting.*

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2.4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body-building aid. The "Orange Notice" warning about DNP was published after a woman in the United Kingdom died and a man in France was left seriously ill after taking the substance. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet. Unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL. Additional details on this drug can be viewed on the INTERPOL website at *www.interpol.int/News-and-media/News/2015/N2015-050.*

September DEA Drug Diversion Conference Open to Pharmacy Personnel in Maine

Drug Enforcement Administration (DEA) is offering two regional one-day Pharmacy Diversion Awareness Conferences (PDACs) in South Portland, ME, with one on Saturday, September 12, 2015, and another on Sunday, September 13, 2015. Each one-day conference is open to pharmacy personnel (pharmacists, pharmacy technicians, or loss prevention personnel) who are employed by pharmacies or hospitals/clinics that are registered with DEA in the state of Maine. The conference is designed to assist pharmacy personnel in identifying and responding to potential diversion activity. Location details, a conference agenda, and a link to the online registration form are available on the DEA website. There is no registration fee for these conferences. Upon completion of the one-day conference, pharmacists and pharmacy technicians may receive seven hours (0.7 CEUs) of Accreditation Council for Pharmacy Education-accredited continuing pharmacy education. Additional information on this and other upcoming PDACs is available on the Office of Diversion Control website at *www.deadiversion.usdoj.gov/mtgs/pharm_awareness.*

nabp newsletter

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

Next PARE Testing Window Will Be August 10-21, 2015

The next available Pharmacist Assessment for Remediation Evaluation® (PARE®) testing window is scheduled during the two-week time period of August 10-21, 2015.

Member boards of pharmacy are encouraged to take advantage of this web-based assessment that was created to assist the boards as part of their decision-making process when considering cases of remediation or brief departures from practice. To pre-register an individual for the PARE, boards of pharmacy may use the NABP Clearinghouse via NABP e-Profile Connect or they may contact the NABP Competency Assessment department via email at NABP_Comp_Assess@nabp.net.

An additional PARE testing window for 2015 is scheduled during the two-week period of November 2-13, 2015. More information about the PARE may be found in the Programs section of the NABP website at *www.nabp.net.*