newsletter
National Association of Boards of Pharmacy®

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Upcoming Events

September 28, 2015
FPGEE Administration

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

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

November 2-13, 2015
PARE Administration

November 4-6, 2015
NABP/AACP District 4 Meeting
Milwaukee, WI

November 17-18, 2015
Task Force on the Implementation of VPP
NABP Headquarters

December 1-2, 2015
NABP Interactive Compliance Officer and Legal Counsel Forum
Northbrook, IL

Updated *Model Act* Available; Amended Language Addresses Timely Pharmacy Practice Topics

NABP recently amended the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to provide the state boards of pharmacy with model language that may be used for developing state laws or board rules for purposes of protecting the public health. Amendments to the *Model Act* were incorporated as a result of the NABP Executive Committee-approved recommendations suggested by the Task Force on Standards for the Use of PMP Data, the Task Force on Medication Synchronization, the Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts, a resolution adopted at the NABP 110th Annual Meeting, and the recommendations of the 2014-2015 Committee on Law Enforcement/Legislation. The following is a summary of the *Model Act* changes.

PMP Data Use

To address the importance of interoperability between state prescription monitoring programs (PMPs) in curbing prescription drug abuse and diversion, the Task Force on Standards for the Use of PMP Data determined that revisions were needed to Appendix G, the Model Prescription Monitoring Program Act, of the *Model Act*. The Committee on Law Enforcement/Legislation agreed with the task force's recommendation to add a section on interoperability to the *Model Act* and to include a definition for electronic health information systems. Addressing the section devoted to establishing a PMP, the committee also agreed with the task force's recommendation to include language that notes the board should be responsible for overseeing PMPs, promulgating PMP rules, and establishing PMP policies to increase interoperability and ensure the most effective and appropriate use of PMP information.

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The committee also agreed with the task force's recommendations to revise language regarding PMP reporting requirements. Therefore, the *Model Act* was updated to increase reporting frequency to "within 24 hours." In addition, new reporting fields were added and "Drug Enforcement Administra-

(continued on page 158)

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.

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Model Act

(continued from page 157)

tion" number was changed to "Identification" number throughout. Also, footnotes were added to the *Model Act* to recommend that boards use practitioners' National Provider Identifier number for identification purposes, and to clarify that "date prescription was dispensed" means the date of drug delivery to patient.

Medication Synchronization

As recommended by the Task Force on Medication Synchronization, the *Model Act* was updated to include a revised definition of medication synchronization. The revised definition aims to recognize the authority of pharmacists to provide better patient-centered care through the implementation of medication synchronization programs. In addition, the definition now reflects an emphasis on the value of enhanced communication between patients and pharmacists to improve medication adherence and improve patient outcomes. The *Model Act* was also updated to note that pharmacists may adjust refill schedules without having to seek approval from the prescriber for each scheduling adjustment. The Committee on Law Enforcement/Legislation agreed with the task force's recommendations and its subsequent revisions to the comments section, but amended language to recommend that patients receive synchronized refills by regular appointment rather than monthly appointment. Additional changes were also made to the comment section to clarify that the new definition, while extending the pharmacist's authority to adjust medication use and quantities, should adhere to the medication regimen permitted by law. The *Model Act* was also updated to state that medication synchronization programs are specifically tailored for maintenance medications, but do not apply to controlled substances (Schedules II-V) or prescriptions that are taken on an as-needed basis.

Pharmacy Robberies and Thefts

Additional amendments to the *Model Act* were also implemented based on recommendations from the Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts. Based on the task force's recommendation, a new security section was added to the *Model Act,* which 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. In addition, new policies and procedures were added under the duties and responsibilities of the pharmacist-in-charge (PIC). The *Model Act* now states that the PIC, in conjunction with the owner/facility permit holder, should be responsible for developing and reviewing actions to be taken to prevent and react to pharmacy robberies and thefts. In addition, the PIC and owner/facility permit holder should also be required to have policies and procedures in place for monitoring and guarding access to locks, barriers, and other diversion prevention mechanisms in the pharmacy.

Veterinary Education

The *Model Act* was also updated in response to Resolution 10-5-14 Veterinary Pharmacy Education, which was adopted at the NABP 110th Annual Meeting and calls for NABP to encourage the development and availability of veterinary pharmacology education at schools and colleges of pharmacy in collaboration with schools of veterinary medicine. Additionally, the resolution supports ensuring that pharmacists dispensing medications for veterinary patients possess the competence and have access to resources necessary to appropriately dispense and provide patient care. To fulfill the mandate of the resolution, the Committee on Law Enforcement/ Legislation added a facility requirement for a veterinary drug therapy reference for pharmacies that engage in veterinary drug dispensing. Keeping in mind the monetary cost of acquiring such reference, the committee clarified that the requirement should only apply to pharmacies that engage in veterinary drug dispensing.

Additional Updates

Pursuant to comments in the footnotes developed

(continued on page 162)

Board of Pharmacy Staff Invited to Network, Collaborate at NABP Interactive Forums This Fall

Providing an opportunity for networking with peers while discussing challenges faced by their boards, the NABP Interactive Forum series will return this fall and focus on the theme "Reconnect, Recharge, Revitalize – Strengthening Board of Pharmacy Collaboration."

The first of the forum series to return is the NABP Interactive Executive Officer Forum that will take place October 13-14, 2015. The forum, which invites all executive officers from the state boards of pharmacy, will include presentations on timely and relevant topics developed directly from suggestions submitted by the board executive officers. In addition, NABP support services available to the boards of pharmacy will be reviewed.

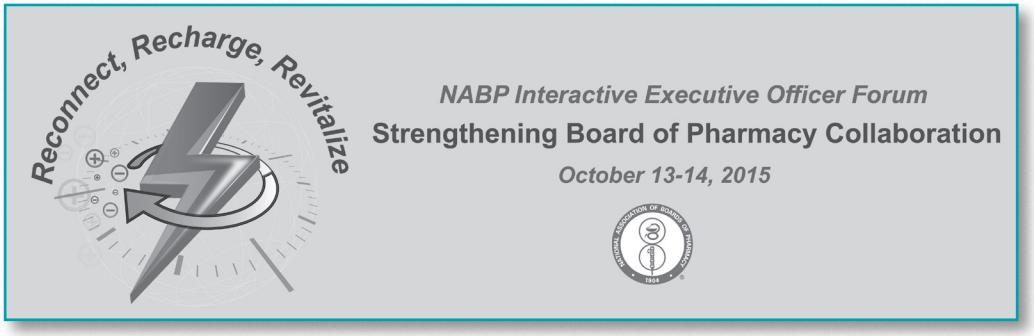
Invitations to attend the Executive Officer Forum were sent in August. As with the previous forums, travel, hotel accommodations, and meals will be paid by NABP. In addition, there is no registration fee for the meeting.

Following the Interactive Executive Officer Forum, NABP will hold another forum tailored for board of pharmacy compliance officers and legal counsel on December 1-2, 2015. The annual NABP surveyor workshop will be held at the same time and surveyors will also participate in some of the forum sessions. Invitations to attend the NABP Interactive Compliance Officer and Legal Counsel Forum will be sent to board of pharmacy executive officers in October. Each executive officer may select one compliance officer from his or her board and one attorney who serves as the board's legal counsel to participate in the forum. Like the Interactive 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. The Compliance Officer and Legal Counsel Forum is held biannually, alternating with the forum geared toward board members, which will return in fall 2016.

The goal of the Interactive Forums is to facilitate interaction among boards from the across the country and provide closed sessions to discuss important and timely issues related to pharmacy regulation.

Both forums will take place at the Hilton Chicago/Northbrook in Northbrook, IL.

For more information about the forums, please contact NABP Executive Office at exec-office@nabp.net, or at 847/391-4406.



Executive Committee

Joseph L. Adams
Chairperson
One-year term

Edward G. McGinley
President
One-year term

Hal Wand
President-elect
One-year term

Jeanne D. Waggener
Treasurer
One-year term

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

Susan Ksiazek
Member, District 2
Serving third year of a three-year term

Jack W. "Jay" Campbell
Member, District 3
Serving second year of a three-year term

Philip P. Burgess
Member, District 4
Serving second year of a three-year term

Gary Dewhirst
Member, District 5
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John A. Foust
Member, District 6
Serving first year of a three-year term

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.

Defamation Case SLAPPED on Pharmacies

By Dale J. Atkinson, JD

Pharmacists must exercise professional judgment when assessing the validity of a prescription and determining whether to dispense medications. The board of pharmacy may become involved to the extent a pharmacist is accused of violating the relevant standards of practice related to filling prescriptions. In addition to the administrative authority of the board of pharmacy, civil and criminal consequences to the licensee may be relevant under certain factual scenarios. Consider the following.

A physician (Physician) specializing in endocrinology had numerous patients for which he prescribed the human growth hormone (HGH). According to the pleadings in a lawsuit eventually filed, the HGH prescriptions were based upon independent evaluations and each determined to be "medically necessary." However, sometime starting in 2010, the mail service pharmacies previously dispensing the medications began refusing to honor the HGH prescriptions. The refusal to fill the prescriptions was based on concerns related to federal law, specifically the criminal consequences of knowingly distributing HGH for use in humans "other than for the treatment of a disease or other recognized medical condition, where such has been authorized by the Secretary of Health and Human Services . . . and pursuant to the order of a physician." In addition, one of the mail service pharmacy affiliates had previously entered into a deferred prosecution agreement that resulted in the development of the protocols utilized under the current circumstances. Indeed, the deferred prosecution agreement and resulting protocols were intended to shield the pharmacists from potential criminal liability. Finally, the mail service pharmacies based the refusal to fill on due diligence and a good faith belief that the prescriptions were written for a non-medically acceptable reason(s) or were "associated with organizations that advocate for off-label uses of HGH." It is alleged that the representatives of the mail service pharmacies made defamatory statements to multiple patients attempting to fill the prescriptions.

As a result of the refusal to fill the prescriptions, the Physician and eight of his patients (collectively Plaintiffs) filed a federal lawsuit in the United States District Court for the Northern District of Indiana against several mail-order pharmacies (Defendants). The Plaintiffs alleged multiple causes of action including a breach of duty to honor prescriptions, defamation, and breach of settlement agreement. The Defendants filed a motion for judgment on the pleadings as to the breach of duty to honor prescriptions claim, arguing that Indiana law does not provide for a private cause of action under the relevant state law.

The Defendants also filed motions to dismiss the defamation and breach of settlement agreement claims under the Indiana statute that protects against Anti-Strategic Lawsuits Against Public Participation (SLAPPs). Anti-SLAPP statutes are designed to "reduce the number of lawsuits brought primarily to chill the valid exercise of the constitutional rights of freedom of speech and petition for the redress of grievances." Judicial dismissal under anti-SLAPP is generally premised upon disposing of litigation that is meritless, aimed at silencing the activities of the defendants, and/or designed merely to divert the resources of such defendants.

Under the breach of duty to honor prescriptions, the Plaintiffs relied upon Indiana law that:

A pharmacist shall exercise his or her professional judgment in the best interest of the patient's

health when engaging in the practice of pharmacy, and that a pharmacist has a duty to honor all prescriptions from a practitioner or from a physician, podiatrist, dentist, or veterinarian licensed under the laws of another state. Before honoring a prescription, the pharmacist shall take reasonable steps to determine whether the prescription has been issued in compliance with the laws of the state where it originated. The pharmacist is immune from criminal prosecution or civil liability if he or she, in good faith, refuses to honor a prescription because, in his or her professional judgment, the honoring of the prescription would:

- be contrary to law;
- be against the best interest of the patient;
- aid or abet an addiction or habit; or
- be contrary to the health and safety of the patient.

The Defendants argued that the above statute does not confer a private cause of action and, therefore, judgment should be awarded in favor of the mail service pharmacy. Conversely, the Plaintiffs argued that the statute does in fact provide for a private cause of action. The District Court noted that no Indiana court has ever considered the issue of whether the relevant statute provides for a private right of action. Citing previous jurisprudence, the court noted that a private right of action can be created either explicitly or impliedly. The explicit creation of a private right specifically references such in the statute by, for example, stating the right of an aggrieved person to file a civil action in the circuit or superior court located in the county where the alleged wrongdoing took place. In this case, the court quickly held that the relevant statute did not explicitly create a private cause of action.

The implicit conferring of a private cause of action can be inferred where a statute imposes a duty for a particular individual's benefit, but will not be inferred where the legislature imposes a duty for the public's benefit. In short, ". . . a private party may not enforce rights under a statute designed to protect the public in general and containing a comprehensive enforcement mechanism." In determining that the relevant statute is contained in the pharmacy practice act and benefits the public as a whole through regulation of the profession on behalf of the public interest, the court found that the law does not implicitly confer a private right of action. In so holding, the court, citing previous case law, rejected the arguments of the Plaintiff that the practice act provides immunity to a pharmacist who in good faith refuses to honor a prescription. As argued by the Plaintiff, the provision of immunity implicitly indicates that a private right exists, otherwise no such immunity would need to be referenced.

Next, the court rejected an argument that previous duty to warn cases citing the relevant statute held that pharmacists owe a duty to patients when filling a prescription and thus conferred a private right of action. In rejecting this argument, the court noted that not only were such previous cases brought under a common law claim for negligence, but such cases involved the actual filling of a prescription and the responsibilities of a pharmacist to warn the patient of identified side effects, rather than the refusal to fill prescriptions based upon professional judgment. Accordingly, the court held that the relevant statute did not confer a private right of action and count one of the complaint must be dismissed. The court also noted that the Plaintiffs are not left without a remedy as mechanisms exist whereby a complaint can be filed with the Consumer Protection Division of the Indiana Attorney General's Office and/or the Indiana Board of Pharmacy.

The Defendants also sought dismissal of the additional counts of the complaint under the anti-SLAPP statute. The Indiana anti-SLAPP statute is, according to the court, "typical" of other anti-SLAPP statutes. Such laws provide a defense in a civil action against a person that an act or omission complained of is a right

(continued on page 162)

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Legal Briefs

(continued from page 161)

of petition or free speech under the US Constitution in connection with a public issue and an act or omission taken in good faith and a reasonable basis in law and fact. Prevailing parties under a motion to dismiss under the anti-SLAPP statutes are entitled to attorney's fees.

In this matter, the court found that the Defendants did not establish that they were acting in furtherance of their right to free speech in connection with a public issue. The Defendants argued that their statements were related to their offer of pharmaceutical services and that the legislature declared the occupation of pharmacy to be a matter affecting the public health, safety, and welfare. However, in agreeing with the Plaintiffs, the court found a "logical disconnect between the proffered public interest and the context, form, and content of the statements at issue . . . " Rather than a broad public interest in pharmaceutical services, the court noted the statements at issue here were several explanations to a single patient with respect to why the prescriptions could not be filled. There is no public health benefit to the medical needs of individual patients. The court noted no evidence that the pharmacist or patients were in the public eye, nor that the alleged conduct by the Physician "could affect large numbers of people beyond the direct participants." The court further stated, "Without this more narrow focus on the public interest at issue, the Court believes that the anti-SLAPP protections would paint with too broad a brush, providing immunity to any statement made by pharmaceutical personnel simply by virtue of the fact that the industry in which they practice is one of general concern to the public."

Finally, the Defendants made clear in their pleadings that the statements were made for the limited purposes of communicating the reason(s) for declining to fill the prescriptions and to protect themselves from potential liability under federal law. Thus, the court denied the motion to dismiss the defamation claims of the Plaintiffs under the anti-SLAPP statute. However, the court held that the motion to dismiss by the Defendants was neither frivolous nor intended to cause unnecessary delay in the litigation and, consequently, refused to award attorney's fees to the Plaintiffs.

Next, the Defendants moved for dismissal of the defamation claims arguing a defense of a qualified privilege. A qualified privilege applies to communications made in good faith, based upon an interest or duty, and made to a party with a corresponding interest or duty. Only the issue of whether the communications were made in good faith was at issue. Defining good faith as "a state of mind indicating honesty and lawfulness of purpose; belief in one's legal right; and a belief that one's conduct is not unconscionable," the court declined to dismiss the defamation count, holding that there was not enough information of record thereby necessitating the need for a trial.

Finally, the court ruled in favor of the Defendants and dismissed the count of the complaint alleging a breach of the settlement agreement, finding that the current Defendants were not parties to the agreement. In total, the court dismissed the duty to fill the prescriptions count as not creating a private right of action and dismissed the breach of the settlement agreement because the Defendants were not parties to the agreement. However, the court denied the motion to dismiss the defamation count because the anti-SLAPP statute did not provide relief. Thus, the case continues and a trial on the merits will be held unless a settlement is reached.

This case presents interesting analyses regarding the potential civil consequences to refusing to fill prescriptions, including what justifications may (or should) be affirmatively stated in expressing the reasons for such refusals. Pharmacists must apply professional judgments as to verifying the validity of the prescriptions before dispensing the product. Under certain circumstances, refusal to fill may be justified. How to express such refusal to the patient and any related justifications must be carefully considered along with what rights the patient has to have the prescription returned.

Kadambi v. Express Scripts, Inc, 2015 US Dist. LEXIS 13607 (N.D. IN 2015)

Model Act

(continued from page 158)

by the 2008-2009 Task Force on Standardized Pharmacy Technician Education and Training, the *Model Act* was amended to require that all pharmacy technicians be certified. The model language now refers to pharmacy technicians as either certified pharmacy technicians or certified pharmacy technician candidates. In addition, the *Model Act* was also updated to reflect the provisions contained in Title II of the Drug Quality and Security Act (DQSA). Specifically, references to "pedigree," "repackagers," "manufacturers," and "third-party logistics providers" were removed. The Committee on Law Enforcement/Legislation recommended that NABP staff draft further revisions to the *Model Act* to reflect Titles I and II of the DQSA and noted that a separate task force may be warranted as well. Lastly, as approved by the NABP Executive Committee, the *Model Act* was updated to provide licensure exemption for manufacturers that dispense dialysate, drugs, and devices to home dialysis patients.

The updated *Model Act* is now available for free download in the Publications section of the NABP website at *www.nabp.net.*

Survey Results Give Insights Into State Board Responsibilities and Resources Including Support Staff and Fiscal Data

Results from the NABP 2015 Resources and Responsibilities Survey provide a current snapshot of the boards of pharmacy, focusing on what duties the boards perform and the resources with which they operate.

The data collected from the biennial survey give insight into the functioning of NABP's 54 active member boards as they perform their regulatory duties and work to protect the public health.

The survey asked the boards of pharmacy to provide information in such areas as licensure and disciplinary functions, fiscal issues, emergency preparedness, human resources, and inspectors and inspections. Forty-five, or 83% of active member boards, participated in the 2015 survey.

General Structure and Responsibilities

Twenty of the 45 responding boards of pharmacy characterized their organization as "independent" – that is, operating independently of other professional boards, with an executive officer whose primary responsibility is to the pharmacy board. Twenty-four boards, or slightly more than half of respondents, indicated their status as part of an umbrella organization, with an executive officer whose primary responsibility is to the umbrella organization rather than the pharmacy board. One board reported that it had no executive director.

Virtually all the responding boards of pharmacy stated that they are responsible for various licensing and disciplinary functions, either alone or in conjunction with an umbrella or other agency. All but one of the 45 responding boards, for example, indicated that they have sole (39) or shared (5) responsibility for licensure of pharmacists, and sole (40) or shared (4) responsibility for discipline of pharmacists. The majority of boards also have responsibility for licensing (28 sole, 4 shared) and disciplining (27 sole, 2 shared) pharmacy technicians, and licensing (35 sole, 4 shared) and disciplining (28 sole, 3 shared) pharmacy interns. A smaller number of pharmacy boards reported sole (5) or shared (7) responsibility for licensure of dispensing prescribers; while no boards reported sole responsibility for the discipline of dispensing practitioners, 11 boards reported sharing this function with an umbrella or other agency.

The boards of pharmacy also usually handle the license, registration, or permit process for pharmacies and other entities that deal in the manufacture or distribution of prescription medications. Perhaps not surprisingly, the boards most predominantly reported this sole responsibility for various types of pharmacies; for example, more than 75% of responding pharmacy boards license or register community pharmacies (38); long-term care (37) and infusion/home care pharmacies (37); nuclear (36) and sterile compound-

(continued on page 164)

Board of Pharmacy Responsibilities

Function	Sole Responsibility of Boards	Shared Responsibility With Umbrella or Other Agency
Discipline of pharmacists	40	4
Licensure of pharmacists	39	5
Licensure of community pharmacies	38	3
Set practice standards	38	3
Determine penalties	36	7
Licensure of sterile compounding pharmacies	36	3
Evaluate qualifications of candidates for licensure	36	7
Make final determination whether law/regulation violated	36	7
Hold disciplinary hearings	35	8
Licensure of pharmacy interns	35	4
Licensure of nonsterile compounding pharmacies	35	3
Conduct investigations	29	11
Licensure of wholesale distributors	29	4
Licensure of pharmacy technicians	28	4
Discipline of pharmacy interns	28	3
Receive complaints	27	12
Discipline of pharmacy technicians	27	2
Rulemaking	25	8
Issue examination scores	21	10
Administer examinations	17	8
Issue controlled substances licenses to pharmacy licensees	15	6
Issue controlled substances licenses to non-pharmacy licensees	12	6
Issue licenses to dispensing prescribers	5	7
Discipline of dispensing prescribers	0	11

The table above represents a select portion of reported board of pharmacy responsibilities. A total of 45, or 85% of active member boards participated in the survey; however, not all 45 boards provided responses to every question.

2015 Board Survey Results

(continued from page 163)

ing pharmacies (36); and institutional (35), nonsterile compounding (35), and nonresident pharmacies (35). (Not all states issue separate licenses to each category, but some group different types of pharmacy into one license category.) But a majority of boards also license or register wholesale distributors (29) and manufacturers (25), as well as Internet pharmacies (27), veterinary pharmacies (26), specialty pharmacies (25), and telepharmacies (23). Nearly half (22) of responding boards are also responsible for licensing or registering nonresident wholesale distributors and reverse distributors.

Other functions carried out solely by most of the boards of pharmacy include setting practice standards (38), evaluating the qualifications of candidates for licensure (36), making a final determination whether a law or regulation has been violated (36), determining penalties (36), and holding disciplinary hearings (35). More than half the boards reported sole responsibility for conducting investigations (29), receiving complaints (27), and rulemaking (25). Some boards issue examination scores (21) or administer examinations (17), and 12 boards, or roughly one-quarter of respondents, reported responsibility for certifying or accrediting schools and colleges of pharmacy.

Preventing the abuse and diversion of prescription drugs has become a focus in many states in recent years, as is reflected by other duties carried out by the boards of pharmacy. Nineteen boards are responsible for their state's prescription monitoring program; 28 boards have responsibility to enforce their state's wholesale drug distribution licensing act, while 12 boards enforce their state's methamphetamine precursor control act.

Twenty-five boards indicated that enforcement of their state controlled substances act (CSA) fell solely under board purview, and a number of boards process licenses related to controlled substances (CS). Responsibility for the federal CSA falls to fewer boards, with 18 pharmacy boards having sole responsibility. Fifteen boards reported issuing CS licenses to pharmacy licensees, while 12 issue CS licenses to non-pharmacy licensees. Processing renewals of CS licenses, meanwhile, was the sole responsibility of 14 pharmacy boards for pharmacy licensees and 12 boards for non-pharmacy licensees.

Those boards that do not hold sole responsibility for a licensing or disciplinary function often share that responsibility with an umbrella or other agency. The most commonly shared functions, according to survey respondents, include receiving complaints (12), conducting investigations (11), and issuing examination scores (10).

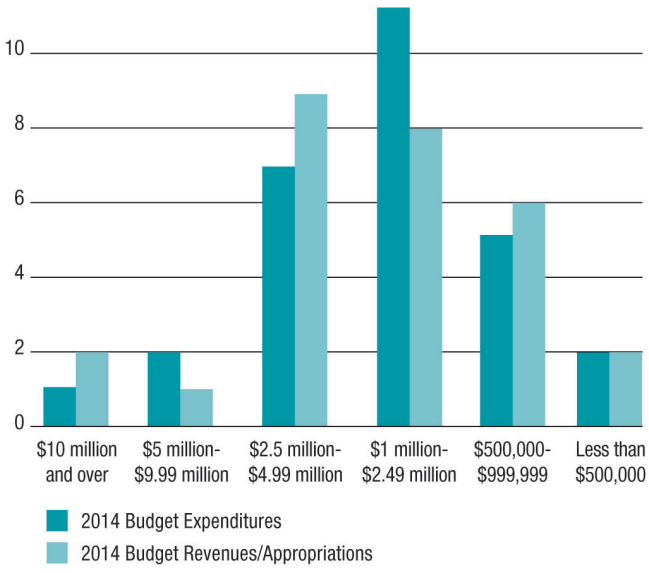
Roughly 73% of 41 responding boards reported having a preparedness or response plan for both external and internal disasters or emergencies that would impede the board's ability to operate normally.

Fiscal Data

Forty-three boards gave information regarding the fiscal functions they perform. Of 42 responding boards, 90% reported that they are responsible for one or more of the following: developing the board of pharmacy's budget (25), setting fines (31) and fees (25) (in some states, the state legislature sets maximum fees and fines), collecting fines (22) and fees (27), and making purchasing decisions (27). About 43% of the responding boards (18) process accounts payable and receivable. Those fiscal functions not fulfilled by the board generally fall to an umbrella agency; for some pharmacy boards, functions are handled by board and agency together.

Ninety-three percent of 43 responding boards reported that they are allowed to impose fines for infractions of laws or regulations; only four percent stated they could not. The maximum fine amount that boards could levy ranged from $500 per violation to no limit. Of the 42 responding boards, about 48% reported that their budget was fixed by legislative appropriation; 52% reported that it was not. Just over half of 41 respondents (51%) reported that other state agencies

Figure 1 – Board of Pharmacy Fiscal Data



Twenty-eight boards provided information on their 2014 budgeted expenditures and revenues/appropriations. Of those 28 states, the most common range was between $1 million and $5 million for both 2014 budgeted expenditures and budgeted revenues/appropriations.

(such as the state department of health, state attorney's office, or drug control agency) were allowed to impose fines for infractions of pharmacy or wholesale drug distributor laws or regulations; 49% reported that they were not.

Twenty-eight states provided information on their 2014 budgeted expenditures and appropriations. Of these, seven boards reported budgeted expenditures under $1 million, 18 boards reported expenditures between $1 million and $5 million, and three boards reported expenditures over $5 million. On the other side of the balance sheet, eight boards reported revenues or appropriations under $1 million, 17 boards reported revenues or appropriations between $1 million and $5 million, and three boards reported revenues or appropriations over $5 million. (See Figure 1.)

Twenty-one states provided details on their revenue sources; of these, states reported that anywhere from 10 to 100% of their budgeted revenues derived from permit or license fees, with two-thirds (14) reporting that at least 70% of their budgeted revenue came from this source. Other common revenue sources include examination and reciprocity fees, fines, and state appropriations. Two-thirds of responding boards reported that revenues were utilized by the board itself; about eight percent reported that revenues were utilized by the state government or legislature. About 26% indicated that revenues were split between the pharmacy board and a more general fund (such as a state general fund, or a funding pool with other professional boards).

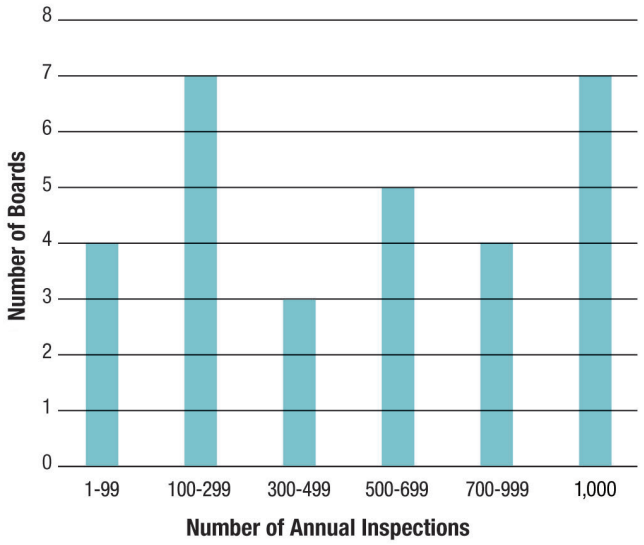
Board of Pharmacy and Support Staff

The number of support staff utilized by boards of pharmacy ranges widely, from one to 27, with one board reporting 70 support staff. Almost all reporting boards have an executive officer, usually on a full-time basis (34 of 39 responders); four boards reported an executive director devoted to the board less than full time. Nearly 95% of responding boards reported that they have administrative staff other than an executive officer or inspectors: 13 boards reported between one and four full-time support staff members, 18 boards reported between five and 10 full-time staff, and six boards reported 11 or more full-time staff. Ten boards indicated that, of these support staff positions, at least one – and up to four – serves as an information technology specialist.

Of 39 responding boards, most indicated that executive officers (38), board administrative staff (37), and inspectors (34) are eligible for state employment benefits. Benefits are most likely to include health insurance for self and family, life insurance, and a retirement plan with both employee and (somewhat less commonly) state contributions. Disability insurance is also common, as is reimbursement of traveling expenses. Several states indicated that inspectors have access to a state car to carry out inspections.

Of 38 responding boards, only two indicated that board of pharmacy members receive no compensation for their participation on the board. Other states provide compensation to board members, largely in the form of per diem or per meeting payment, and in some cases travel or even lodging reimbursement. Reported per diem rates vary from about $30 to $200. One state reported that board members receive $100 per month.

Figure 2 – Annual Community Pharmacy Inspections



Four boards noted that they do not have separate categories for pharmacies and they inspected 1,000, 992, 2,715, and 956 pharmacies in 2014. Another board noted that it inspects all of that state's licensed community pharmacies (which includes long-term care pharmacies and infusion/home care pharmacies) every 14 months. Another board indicated that they inspect all state pharmacies every other year, half one year, and the other half the next year. These numbers are not reflected in Figure 2.

Inspectors and Inspections

The survey also sought details from the boards of pharmacy regarding their inspection functions. Of 36 responding boards, one board reported having no inspectors, 31% (11) reported having between one and three full-time inspector positions dedicated to supporting the board of pharmacy, 44% (16) reported having between four and six, and 22% (8) reported having seven or more. Twenty-three boards reported that inspectors are employed directly by the board of pharmacy, 10 boards indicated that the inspectors are employed by

(continued on page 166)

2015 Board Survey Results

(continued from page 165)

an umbrella agency, and four boards stated that they are employed by another state agency. One board indicated that it also uses one inspector employed by someone else, a contracted private investigator.

Sixteen boards, or 42% of respondents, reported that they are legally required to hire pharmacists as inspectors; 22 boards (58%) are not. Thirty-one of 35 responding boards, however, have one or more inspectors who are pharmacists. Three boards stated that board of pharmacy members act as inspectors, while 10 boards stated that their executive officer acts in that capacity. Seventeen boards (47% of respondents) stated that inspectors have civil service status, while 19 (53%) reported that they do not.

Reflecting continuing concerns about compounding oversight, 88% (29) of responding boards reported that their inspectors have training in pharmaceutical sterile compounding, and 82% (27) stated their inspectors are trained in pharmaceutical nonsterile compounding. Eighteen percent (6) of boards reported that their inspectors receive training in current Good Manufacturing Practices.

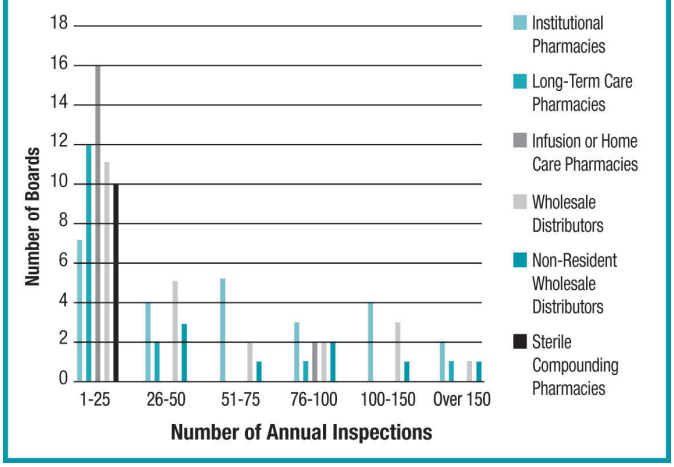
Seven boards reported that they have one or more inspectors who are commissioned peace officers. Nearly one-quarter (9) of responding boards stated that their inspectors are authorized by the state to bear arms; four boards indicated that any of their inspectors actually do so.

Twenty-nine boards, or 76% of respondents, reported having procedures in place to monitor the effectiveness of their inspectors' field work; 9 boards (24%) do not. Monitoring methods include review of inspection reports and data, regular reports and/or quality reviews, and ride-alongs.

Thirty-four boards provided details on the number of inspections performed in a typical year, though these numbers vary widely. For example, boards report performing from a low of zero to a high of 1,500 inspections of community pharmacies. (See Figure 2.) Reported numbers of institutional pharmacy inspections ranged from zero to 300, long-term-pharmacy inspections ranged from zero to 219, and infusion or home-care pharmacy inspections ranged from 0 to 89. Boards reported that they or their agency performed from 0 to 150 inspections of wholesale distributors; one board reported inspecting 550 wholesalers biennially. (See Figure 3.)

Boards of pharmacy may contact NABP at exec-office@nabp.net to obtain a printed version of the 2015 survey results.

Figure 3 – Annual Inspections of Other Licensees



One board inspects their 80 institutional pharmacies on a biannual basis, inspecting about 40 each year. One board indicated that it inspected 60 wholesale distributors in the last 15 months, and one indicated that it inspects 550 wholesalers biannually. These numbers are not reflected in Figure 3.

Newly Accredited DMEPOS Facilities

The following facilities were accredited through the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program:

Health Treasures Pharmacy, Inc
Brooklyn, NY

The Apothecary P.S.C
Richmond, NY

A full listing of over 500 accredited DMEPOS companies representing nearly 28,000 facilities is available on the NABP website at *www.nabp.net.*

Pharmacy Organizations Take Actions to Integrate JCPP Patient Care Process to Optimize Medication Outcomes and Promote Consistency

In May 2014, the Joint Commission of Pharmacy Practitioners (JCPP) released a resource document aimed at promoting consistency in the pharmacists' process of patient care service delivery. The document is applicable to any practice setting where pharmacists provide patient care and for any patient care services provided by pharmacists.

Developed by a group of national pharmacy organizations working in partnership with JCPP, The Pharmacists' Patient Care Process is based on a pharmaceutical care model developed in the 1990s. The pharmaceutical care model was developed by Drs Charles D. Hepler and Linda M. Strand by examining a number of key source documents on pharmaceutical care and medication therapy management. These key documents were cataloged and compared to create a patient care process consistent with best practice models in pharmacy. The patient care process is articulated in a manner aligned with the patient care processes of other health care professionals while detailing the unique medication-related aspects of pharmacists' training.

In July 2013, JCPP's vision statement for the pharmacy profession and strategic plan for reaching this vision were revised to reflect the need for pharmacists to be patient-centered and accountable for patient outcomes while working collaboratively with other members of the health care team.

The Pharmacists' Patient Care Process uses a patient-centered approach that depends on the pharmacist having an established relationship with the patient. This relationship supports engagement and effective communication with the patient, family members, and caregivers throughout the process. The process also involves the pharmacist working with prescribers and other practitioners to optimize patient health and medication outcomes.

The patient care process includes a follow-up step to be repeated with each and every patient encounter, and the frequency of follow-up depends on the acuity of the patient and the nature of their care. The level of intensity for each step will vary with the service provided, but the process should not vary. The process is intended to be used in all patient care settings, and while one pharmacist might be responsible for all the steps in some settings, in other settings, there may be more than one pharmacist involved at different stages of the process.

NABP President, Edward G. McGinley, MBA, RPh, is sharing with member boards of pharmacy information about the JCPP Pharmacists' Patient Care Process in his report at the 2015 NABP district meetings. In his report, President McGinley stresses that this patient-centered approach is "foundational to the value pharmacists bring to the health care system," and that it creates the "perfect environment for pharmacists to become more actively involved and impactful in educating patients and furthering the protection of public health."

Other national pharmacy organizations are currently working to facilitate implementation of the process across the profession, including developing case examples for different practice settings. The Accreditation Council for Pharmacy Education (ACPE) has incorporated the Pharmacists' Patient Care Process into the *2016 Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree*. With the ACPE standards revision, schools and colleges of pharmacy are working to incorporate the process into their curricula.

To facilitate the adoption of this process, JCPP encourages pharmacists to think closely about the patient care process used in their practices and to compare it to the JCPP process. JCPP also encourages pharmacists to speak with colleagues at their practices to promote awareness of the process and to discuss how the practice can increase patient care consistency.

JCPP brings together the chief executive officers and elected officers of national pharmacy associations, including NABP, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice. More information on the JCPP process and its growing role in pharmacists' patient care activities will soon be available on the new JCPP website.

Newly Accredited VAWD Facility

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

Emerson Ecologics, LLC
Colonial Heights, VA

A full listing of more than 530 accredited VAWD facilities is available on the NABP website at *www.nabp.net*.

New Resources Address Adverse Drug Events Related to Errors

Adverse drug events (ADEs) are among the most common cause of health care-related harm. According to the *National Action Plan for Adverse Drug Event Prevention,* developed by the United States Department of Health and Human Services, ADEs affect approximately 2 million hospital stays, and account for an estimated 3.5 million physician office visits and 1 million emergency department (ED) visits annually. The plan suggests a four-pronged approach to reducing ADEs and identifies three initial targets – anticoagulants, diabetes agents, and opioids; the plan also emphasizes the role of the pharmacist in preventing ADEs.

NCC MERP Algorithm

A new resource to help providers properly analyze and categorize ADEs and medication errors has been created by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The algorithm, titled "Contemporary View of Medication-related Harm, A New Paradigm," provides a method for categorizing ADEs and medication errors and outlines decision points health care providers can use to help determine if an ADE is preventable, so that efforts can be focused on eliminating preventable harm.

NCC MERP notes that the tool may aid in developing policies and procedures to mitigate harm, and may be useful for future research and those who work on medication safety.

Resources for Preventing ADEs

National Action Plan for Adverse Drug Event Prevention
www.health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf

Contemporary View of Medication-related Harm, A New Paradigm
www.nccmerp.org/sites/default/files/nccmerp_fact_sheet_2015-02-v91.pdf

VPP Online Application Launches, Offers Streamlined Process

To further streamline Verified Pharmacy Program™ (VPP™) processes, the VPP online customer application was launched on July 15, 2015. The new application will facilitate a more efficient application process and further support the program's goal to make pharmacy licensure, inspection, and disciplinary action information available to the boards of pharmacy to support licensure decisions.

Developed by NABP in conjunction with the state boards of pharmacy, the recently enhanced 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. The system also allows boards the capability to upload and view their own state inspection reports.

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

At press time, at least 314 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 314 VPP facilities:

- 133 pharmacies engage in nonsterile compounding;
- 39 pharmacies engage in sterile compounding;
- 100 pharmacies engage in both sterile and nonsterile compounding;
- 39 pharmacies are general retail or mail order pharmacies;
- 2 pharmacies are nuclear pharmacies; and
- 1 pharmacy is an outsourcing facility.

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 to Convene Committee Meeting in November 2015 to Discuss Implementation of the Multistate Pharmacy Inspection Blueprint

In November 2015, NABP will convene a committee meeting to discuss the implementation of the Multistate Pharmacy Inspection Blueprint.

The committee will discuss plans on how to best work with the state boards of pharmacy to help implement the blueprint into their inspection processes, and discuss the development of a structured process for receiving feedback on the blueprint.

In addition, the committee will discuss when blueprints for other types of facilities are needed, including blueprints for nuclear and institutional pharmacies, as well as for wholesale distributors.

Developed by member boards, the Multistate Pharmacy Inspection Blueprint allows states to ensure their own inspection forms and processes cover the minimum requirements agreed upon by the states, largely focusing on general areas of pharmacy and references to existing national compounding standards, such as United States Pharmacopeia (USP) Chapters <795> and <797>. As more states implement the common requirements included in the blueprint, increased uniformity is expected to assist boards in making nonresident licensure decisions. Training and educational resources to help states use the documents are currently available through NABP.

Using the development of NABP's examination blueprints as a model, NABP facilitated the development of the Multistate Pharmacy Inspection Blueprint. During the January 2015 working group meeting, board of pharmacy representatives from 42 jurisdictions contributed to the finalized development of the inspection blueprint document.

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The Association has also worked to update existing inspection tools based on feedback from the Verified Pharmacy Program™ (VPP™) Working Group and Inspection Blueprint Development Workshop. Intended for the boards' reference and use, these tools include a general inspection form, as well as nonsterile and sterile compounding inspection forms that record compliance with USP Chapters <795> and <797>. To assist the states, NABP also plans to develop and provide a list of standard definitions for the items referenced within the blueprint. Additionally, NABP plans to establish a governance body that will continue to oversee the blueprint and ensure it remains a timely and useful resource for the boards. Individuals with related questions or concerns may contact NABP Member Relations and Government Affairs at 847/391-4406 or by email at Government Affairs@nabp.net. Further details on VPP are available in the Programs section of the NABP website at *www.nabp.net.*

Newly Approved e-Advertisers

The following entities were granted approved e-Advertiser status through the NABP e-Advertiser Approval℠ Program:

Allina Health System
www.allinahealth.org

Banfield Pet Hospital
www.banfield.com

Dobbs Ferry Pharmacy
www.dobbsferrypharmacy.com

PharmEZ Medical, LLC
www.pharmez.com

Potentis Capital, LLC, dba Acquire Health
www.pharmaquotes.com

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

NABP Hosts Annual Program Review and Training for Board Staff to Network and Learn About NABP Programs and Services

To further familiarize themselves with NABP programs and services, boards of pharmacy staff – both new employees and those seeking a refresher course – attended the NABP Annual Program Review and Training session on July 21-22, 2015, at NABP Headquarters.

Seventeen participants representing 16 state boards of pharmacy attended this two-day interactive session that provided board staff with information about NABP's examinations, licensure transfer, accreditation programs, and more. In addition, these informational sessions provided board staff with a unique opportunity to network with other board of pharmacy staff.

The event began with a group dinner on July 21, which provided board of pharmacy staff the opportunity to network with each other and NABP representatives.

On July 22, participants convened for breakfast and a brief welcome. After the welcome, the educational portion of the meeting began, which provided attendees with an overview of the following NABP programs and services:

- Electronic Licensure Transfer Program® (e-LTP™) and license verification
- NABP Clearinghouse/ National Practitioner Data Bank
- Verified Pharmacy Program™ (VPP™) and inspection sharing network
- North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®)
- Pharmacist Assessment for Remediation Evaluation® (PARE®)
- NABP e-Profile Connect: NAPLEX/MPJE eligibility; score reporting and Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification; and online reporting to candidates
- FPGEC Certification Program, including information on the application, examination, and certification process
- Pharmacy Curriculum Outcomes Assessment® (PCOA®) program
- Verified Internet Pharmacy Practice Sites® (VIPPS®); Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®); Verified-Accredited Wholesale Distributors® (VAWD®), durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation; and the NABP e-Advertiser Approval℠ Program
- Community Pharmacy Practice Accreditation
- Internet Drug Outlet Identification program and .Pharmacy Top-Level Domain Program
- AWAR$_X$E® Prescription Drug Safety Program
- CPE Monitor® service and the continuing pharmacy education (CPE) reporting tool for the boards
- NABP PMP InterConnect®
- Member Relations and Government Affairs
- Professional Affairs
- Communications

For more information about future training sessions or to obtain training materials provided at the session, please contact NABP at custserv@nabp.net.

Board Staff Attend Training to Learn About NABP Programs and Services

On Wednesday, July 22, 2015, attendees of the Annual Program Review and Training were provided with informational materials detailing all NABP programs and services to accompany presentations made by NABP staff throughout the day. Pictured from left to right: Chrisy Hennigan, office manager, Oregon State Board of Pharmacy; Beverly Fontaine, administrative specialist, Wyoming State Board of Pharmacy; Michael R. Dupuis, MHA, RPh, executive director, New Hampshire Board of Pharmacy; Christine Mast, administrative specialist III, Delaware State Board of Pharmacy; and Tammy Siebert, administrative coordinator, Missouri Board of Pharmacy.

Executive Board Addresses Strategy, Standards for Use of .Pharmacy Domain

NABP's .Pharmacy Executive Board convened on July 29, 2015, via teleconference to address matters of strategy and standards pertaining to the .pharmacy Internet domain. Among the topics of discussion was NABP's global outreach to make the .pharmacy Top-Level Domain (TLD) available to eligible pharmacies and related entities worldwide. In so doing, NABP is extending its patient safety mission to address shared, international concerns about illegal online drug sellers distributing products that endanger patient health.

NABP has been in contact with regulators in Canada, France, Great Britain, Hong Kong, Ireland, and Spain in an effort to determine how best to evaluate .pharmacy applicants located or doing business in those countries. Discussions are also under way with regulators in multiple other countries. Meanwhile, NABP continues to monitor the European Union's implementation of a mandatory "common logo" for legally operating online pharmacies/retailers and to explore potential relationships with regulators in EU member states. Use of the common logo will help consumers in the EU identify legally operating websites selling medicines online.

The .Pharmacy Executive Board also reviewed NABP's public outreach efforts to date, as well as additional opportunities for consumer education, and further engagement with the boards of pharmacy to spread the word about the .pharmacy TLD initiative. The Executive Board members noted that the boards of pharmacy are ideally positioned to promote the program to their licensees and, in turn, to inform patients in their jurisdictions about the dangers illegal online drug sellers pose and the importance of obtaining medicine and related services only from legitimately licensed pharmacies and credentialed pharmacists. To assist boards of pharmacy that may have limited website design resources, the board has encouraged NABP to create a template, model text, or criteria for optimal use of a .pharmacy domain name by the boards.

To help raise consumer awareness of the dangers posed by rogue Internet drug outlets, NABP continues to publicize the launch of its .pharmacy TLD through multiple channels, including internationally distributed news releases. The .pharmacy TLD website, *www.safe.pharmacy,* has become a hub of information not only for potential registrants but also for consumers. The site includes the "Buying Safely" section for consumers, presented in both English and Spanish. New to the .pharmacy website is the "Find a .Pharmacy Website" page, which lists all .pharmacy domain name registrants. An online form to report abuse is also available on the .pharmacy website, *www.safe.pharmacy/buying-safely/report-abuse.* Alternatively, such reports can be emailed to NABP at abuse@safe.pharmacy.

The .Pharmacy Executive Board was established by the NABP Executive Committee in accordance with NABP's contractual agreement with the International Corporation for Assigned Names and Numbers. Informed, in part, by the expertise and strategic input provided by the .pharmacy advisory committees, the Board makes recommendations for review and approval by the NABP Executive Committee concerning strategy, national and international standards that are consistent with the mission and purpose of the .pharmacy TLD and the interests of the global public health.

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 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.

Organizations that receive authorization to obtain a requested domain name will be able to register through an approved registrar.

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 them for a period of five years. Thirty-two boards of pharmacy have registered their .pharmacy domain name. 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 454 .pharmacy domain name requests and registered 215 domains for 33 boards of pharmacy and 45 companies including 26 pharmacies, 12 veterinary pharmacies, three manufacturers, and two informational sites.

Additional details about the .Pharmacy TLD Program, including a list of approved .pharmacy sites, are available at *www.safe.pharmacy.*

New Test Delivery System for Pre-NAPLEX to Begin October 2015

In October 2015, NABP will deploy two new forms of the Pre-NAPLEX® created using the Pallet Assembly℠ computer process, and delivered via a new NABP-hosted test driver. The Pallet Assembly process uses questions from a program's item bank and builds a "pallet" of psychometrically equivalent forms. The use of Pallet Assembly to create the Pre-NAPLEX will be informative as the Association expects to employ the system for other NABP examinations.

Pallet Assembly, a patent pending software application, allows NABP to build many equivalent forms of an examination by controlling item selection usage and examination specifications, while complying with the examination blueprint and targeted psychometric properties. This enables NABP to better control item usage, and adds to the security of the examination program's content.

In addition, NABP has developed a new test delivery model including a secure browser for taking the Pre-NAPLEX. The secure browser will prohibit other programs from running during the execution of the examination and will be required to take the Pre-NAPLEX.

The Pre-NAPLEX is the only North American Pharmacist Licensure Examination® (NAPLEX®) practice examination written and developed by NABP. It is designed to help familiarize students with the NAPLEX testing experience. The items on the Pre-NAPLEX are actual items that have previously appeared on the NAPLEX. The Pre-NAPLEX score is intended to provide candidates with information on their performance under pre-testing conditions when answering a subset of test questions similar to those that may be included on the NAPLEX. Additional information on the Pre-NAPLEX and other competency assessment resources is available on the NABP website at *www.nabp.net/programs.*

Ohio Pilot Program Synchronizes CPE Monitor Data With Board Data

At the request of the Ohio State Board of Pharmacy, NABP has created a pilot program to allow for the upload of CPE Monitor® data into the Board's licensing software system. Through this system, the Board is now able to integrate CPE Monitor data with its own Board-approved continuing pharmacy education (CPE) information through NABP e-Profile Connect. Integrating the data will help the Board to better evaluate compliance of licensees, by creating a nearly complete picture of a licensee's CPE status. The initial synchronization of the Board licensee data with the NABP e-Profile data was completed in the summer of 2015. Ongoing updates will keep the systems synchronized.

CPE Monitor is a national collaborative service from NABP, the Accreditation Council for Pharmacy Education (ACPE), and ACPE providers that allows licensees to track their completed CPE credits electronically. ACPE-accredited providers have been transmitting CPE data to support CPE Monitor since 2013, and require pharmacists and pharmacy technicians to submit their NABP e-Profile ID and date of birth in order to obtain ACPE-accredited CPE credit. The ability to access CPE activity records electronically streamlines the verification process for boards of pharmacy, and will eventually eliminate the need for boards to collect printed statements of credit for ACPE-accredited CPE.

Boards who are interested in synchronizing their own CPE tracking systems with CPE Monitor may contact NABP at custserv@nabp.net or at 847/391-4406 for more information.

Additional details on CPE Monitor are available on the NABP website at *www.nabp.net/programs.*

PCOA Informational Resources on New Processes Provided to Schools and Colleges to Support Expanded Demand Due to ACPE Requirement

NABP continues to partner with the schools and colleges of pharmacy to ensure the effective implementation of the Pharmacy Curriculum Outcomes Assessment® (PCOA®), and the Association has provided several sources of information regarding new registration processes. Changes in the PCOA registration process have been made to accommodate the anticipated increase in participating schools due to the Accreditation Council for Pharmacy Education (ACPE) *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (Standards 2016)* requirement, and to ensure that PCOA administrations remain streamlined.

Comprehensive Information Packet

On September 1, NABP sent the schools and colleges of pharmacy details about accessing new informational materials intended to lead administrators through the PCOA process from start to finish. This information will be available on the NABP website and will include:

- PCOA Registration Form for Schools and Colleges of Pharmacy
- *PCOA Registration and Administration Guide for Schools and Colleges of Pharmacy:* The guide will include instructions for registering the school/college for the PCOA; and obtaining, analyzing, and using score reports; among other topics.
- PCOA Informational Flyer (for students): The flyer will provide an overview of the PCOA and the student registration process. The flyer is available on the website so that schools/colleges may distribute to students.

With the inclusion of the PCOA requirement in the ACPE *Standards 2016*, NABP will provide the assessment at no cost for all students nearing the completion of their didactic curriculum. Students in this group qualify to take the PCOA one time at no cost. If the school/college chooses to schedule an additional administration for students eligible to take the PCOA at no cost, the current fee of $75 per student will apply.

If schools and colleges administer the PCOA to students other than those nearing the completion of their didactic curriculum, the current fee of $75 per student will apply.

The school/college is responsible for providing the testing facility, meeting the technical requirements for computer-based testing, and ensuring that all students have the appropriate hardware for the assessment.

Additional details are available under PCOA for Schools in the Programs section of the NABP website. Questions regarding the PCOA registration or administration processes may be directed to the PCOA manager, or the Competency Assessment senior manager, at PCOA@nabp.net or 847/391-4406.

FPGEE/PCOA 2015 Curricular Survey Complete

NABP has completed the administration of the 2015 United States PharmD Curricular Survey that was distributed to all accredited pharmacy programs. The results of this survey inform the competency statements for the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) and the Pharmacy Curriculum Outcomes Assessment® (PCOA®). Survey results are used to create weights for the competency statements; these weights drive the examination's blueprint, which determines the number of questions on each topic covered on the examination.

Both examination programs target the subject areas taught in US pharmacy programs and are reflective of the Accreditation Council for Pharmacy Education (ACPE) *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (Standards 2016)*, Appendix 1 (Required elements of the didactic Doctor of Pharmacy curriculum) and the Center for the Advancement of Pharmacy Education (CAPE) Educational Outcomes 2013.

NABP received responses from 104 schools and colleges of pharmacy, providing a robust data set to evaluate and update the examination blueprints.

All participating programs were entered in a lottery to receive 25 Pre-NAPLEX® vouchers for distribution to their students. NABP would like to congratulate Wilkes University Nesbitt School of Pharmacy, Wilkes-Barre, PA, the school selected in a random drawing to receive the vouchers.

The Association also expresses its appreciation to the deans, faculty, and staff from all of the participating programs for supporting this important NABP initiative.

Have You Taken the Pledge to Help Prevent Prescription Drug Abuse in Your Community?

NABP President Edward G. McGinley, MBA, RPh, announced his goal of encouraging fellow pharmacists to take more steps to prevent prescription drug abuse among patients and in local communities during his speech at the NABP 111th Annual Meeting in May 2015. McGinley invited pharmacists to reevaluate all that their job entails and take advantage of the educational resources that the AWAR$_X$E® Prescription Drug Safety Program offers. In order to further spread this important message, McGinley created a pledge that pharmacists can sign to show their support for making meaningful changes within the profession.

The pledge reads, *"I pledge that I will make a difference, as a pharmacist and member of my community to help with the drug abuse epidemic. I will provide information about prescription drug abuse in my pharmacy, office, or other practice setting to make my patients and colleagues aware of the epidemic facing our nation. I will address prescription drug abuse as a pharmacist should by applying my knowledge, skills, and experience. I will be involved. I will take action. I will be a pharmacist who saves peoples' lives!"*

The pledge is a wonderful way to reinforce AWAR$_X$E's main goal of reaching consumers through education. The hope is that these powerful words will encourage positive changes in the practice of pharmacy. AWAR$_X$E has made getting involved easy; simply visit the Pharmacists page on the AWAR$_X$E website at *www.AWARERX.ORG* to sign the pledge.

If you are ready to become part of the movement to increase patient safety and prevent prescription drug abuse in the spirit of the pledge, you can start by implementing the 10 steps provided in this article. The list is also available on the AWAR$_X$E website by clicking on the link under Live the Pledge in the Pharmacists section.

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Show your support for safe prescription drug use by signing the pledge today and taking action in your community!

10 Steps for Implementing the Pharmacist's Pledge

1. **Share the pledge with colleagues and encourage them to sign it.**
2. **Learn more about prescription drug abuse and misuse.**
3. **Check prescription monitoring programs regularly when filling prescriptions.**
4. **Learn your pharmacy's protocol for assisting a patient who may be abusing prescription drugs so that you can take action if needed.**
5. **Educate patients on medication safety issues such as safe use, handling, and storage of medication.**
6. **Promote proper medication disposal:**
   - Set up a disposal box on site at your pharmacy; or
   - Have a disposal site that you can recommend to patients.
7. **Remind patients to securely store their medications.**
8. **Download and print AWAR$_X$E® flyers for patients who would like detailed information about:**
   - proper disposal;
   - secure medication storage;
   - buying medicine safely online; and
   - statistics about the abuse and misuse of prescription drugs.
9. **Hang AWAR$_X$E posters (available to download and print) in your pharmacy, office, or other practice settings.**
   - The striking images can alert patients and colleagues to prescription drug abuse at a glance.
   - A proper medication disposal poster is also available.
10. **Give presentations using AWAR$_X$E's PowerPoint slides, which include presenter notes.**

NABP Report Stresses Need for Accountability in Enforcing Internet Policies to Protect the Public From Rogue Internet Pharmacies

In July 2015, NABP issued a report urging greater accountability by the stakeholders charged with ensuring that action is taken against websites illegally selling medications online. As detailed in the *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: July 2015,* thousands of websites illegally distribute medications and avoid retribution. Such sites often distribute dangerous counterfeit drugs, putting at risk the health of the consumers who use them. Many of these rogue sites use domain names obtained from a small number of registrars who turn a blind eye to their illegal activity. The report highlighted the need for the Internet Corporation for Assigned Names and Numbers (ICANN) and domain name registrars – the stakeholders responsible for facilitating the use of Internet domain names – to enforce policies forbidding illegal use of websites and to take more accountability for shutting down rogue sites.

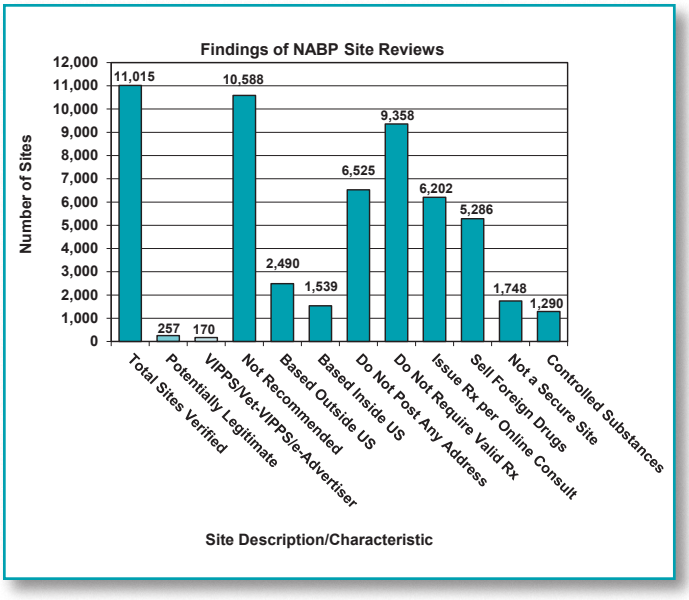
As noted in the report, NABP holds online drug sellers accountable to the laws and standards that govern pharmacy practice and, since 2008, the Association has been collecting data on websites selling medicine illegally online to United States patients. NABP has reviewed over 11,000 Internet drug outlets, finding that 96.13% of the sites reviewed operate out of compliance with US pharmacy laws and practice standards, and identifying these sites as "Not Recommended." Approximately 85% of Not Recommended sites are selling prescription drugs without requiring a valid prescription. Nearly 50% offer drugs that are either foreign, or not approved by the US Food and Drug Administration. Further, of the 10,588 Not Recommended sites, 87% can be traced to affiliate networks of rogue Internet drug outlets.

> Websites illegally selling drugs to patients in the US and in other countries hide behind the anonymity of the Internet, and in the gray areas between enforcement boundaries where the questions of who should take responsibility for enforcing Internet policies goes unanswered.

Websites illegally selling drugs to patients in the US and in other countries hide behind the anonymity of the Internet, and in the gray areas between enforcement boundaries where the question of who should take responsibility for enforcing Internet policies goes unanswered. Many stakeholders, however, believe that domain name registrars and ICANN could play a greater role in protecting consumers. Registrars can make an impact by fulfilling their responsibility to shut down domains that are being used for illegal activities, and ICANN can hold registrars accountable for meeting this obligation.

The risk to public health posed by these illegally operating sites was the impetus for NABP launching the global .Pharmacy Top-Level Domain (TLD) Program. Only legitimate Internet pharmacies and pharmacy-related websites will qualify for .pharmacy domains, giving consumers worldwide a way to distinguish safe and legal online pharmacies and resources from rogue sites. More information about the .pharmacy TLD is available on page 171 of this *Newsletter.* Additional information, including a list of approved entities with registered .pharmacy domain names, is available on the .pharmacy website at *www.safe.pharmacy.*

For the full report with detailed findings on the characteristics of rogue websites and the list of Not Recommended sites, visit *www.AWARERx.org/get-informed/safe-acquisition/not-recommended-sites.*



The above NABP site review findings are taken from the *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: July 2015.*

NABP PMP InterConnect Participation Reaches Record Number; Thirty States Now Sharing Secure Prescription Drug Data

NABP is pleased to announce that 30 state prescription monitoring programs (PMPs) are securely sharing prescription drug data through the NABP PMP InterConnect® program, with Maryland being the latest state to go live in August 2015.

The Maryland Prescription Drug Monitoring Program joins the following participating states in the fight against prescription drug abuse: Arizona, Arkansas, Colorado, Connecticut, Delaware, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Nevada, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, West Virginia, and Wisconsin.

PMP InterConnect is expected to see continued growth in 2015 as one additional state has signed a memorandum of understanding (MOU) to participate and four other states/jurisdictions have MOUs under review.

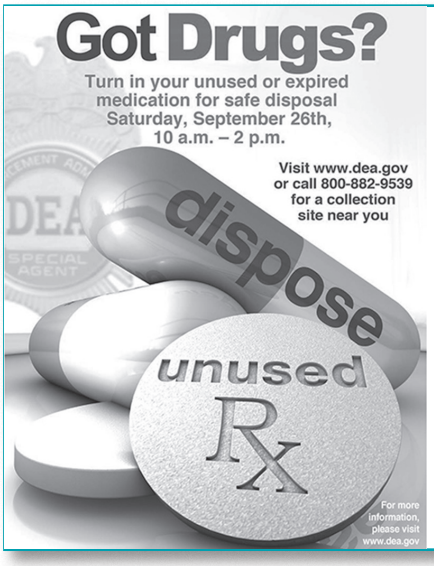
Additional states have also shown interest in connecting to the system. On July 15-16, 2015, the NABP PMP InterConnect Steering Committee, which serves as the governing and advisory body of the program, convened to discuss participation updates and other information related to the administration and function of the program. NABP invited state PMPs to the meeting that are not currently connected to PMP InterConnect, with some of those states seeking interest in reviewing an MOU.

Also during the meeting, the Steering Committee discussed new workflow integration projects that would streamline access to the state PMPs and new program policy issues. Additional details from this meeting will be provided in future NABP communications.

Since 2011, PMP InterConnect has been successfully facilitating national interoperability and secure interstate data sharing between state PMPs and providing health care providers with access to a more complete record of a patient's controlled substance medication history. To date, PMP InterConnect has processed more than 14 million requests from authorized users, and is now processing an average of over 1 million requests per month for a consolidated multistate PMP report.

Recognizing the program's value in assisting the states' efforts in the fight against prescription drug abuse and diversion, NABP recently approved continued funding to support participation in PMP InterConnect at no cost to the state PMPs through June 2018.

Additional information about PMP InterConnect, including the most up-to-date information about state participation is available in the Programs section of the NABP website at *www.nabp.net*. States seeking more information about PMP InterConnect may contact the NABP Member Relations and Government Affairs staff at Government Affairs@nabp.net or by calling 847/391-4406.



DEA to Hold 10th Prescription Drug Take-Back Day on Saturday, September 26, 2015

Drug Enforcement Administration (DEA) has announced that it will hold a 10th National Prescription Drug Take-Back Day event on Saturday, September 26, from 10 AM to 2 PM, at participating locations nationwide. Take-Back days for the states of Pennsylvania and Delaware will be held on Saturday, September 12. DEA will list collection sites on its website; a link to the list of sites will also be available on the AWAR$_X$E® Prescription Drug Safety Program website, *www.AWARERX.ORG/get-informed/find-disposal-information/option-2-dea-nationwide-drug-take-back-sites.*

Consumers who are unable to visit a location on the Take-Back Day can use AWAR$_X$E's drug disposal locator tool, which allows consumers to search for disposal sites year round.

Around the Association

Executive Officer Changes

- **Ted Cotterill, JD,** is serving as the director of the Indiana Board of Pharmacy, replacing Robert "Rob" Kendall. Prior to this position, Mr Cotterill served on the Indiana General Assembly and also served as deputy director for the Indiana Archives and Records Administration (IARA). While with IARA, he served as the legislative liaison and ethics officer, chairman of the IN.gov User Council, and as a member of the IN.gov Governance Council and Governor's Constitutional Review Committee. Mr Cotterill earned his bachelor of science degree from Ball State University and his juris doctorate degree from Indiana University Robert H. McKinney School of Law.
- **Michael R. Dupuis, MHA, RPh,** is serving as the executive director of the New Hampshire Board of Pharmacy, replacing Charles Fanaras, RPh. Prior to this position, he served as vice president of support services for Crouse Hospital and Elliot Hospital. In addition, he served as director of pharmacy for Catholic Medical Center. Mr Dupuis received his bachelor of science degree in pharmacy from Massachusetts College of Pharmacy and Health Sciences and his master of health care administration degree from Bellevue University.

Board Member Appointments

- **Lemrey "Al" Carter, PharmD, RPh,** has been appointed a member of the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy. Carter's appointment will expire April 1, 2020.
- **Despina Kotis, PharmD, RPh**, has been appointed a member of the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy. Kotis' appointment will expire April 1, 2020.
- **George "Phil" Ayers, PharmD, RPh**, has been appointed a member of the Mississippi Board of Pharmacy. Ayers' appointment will expire June 30, 2020.
- **Mark St Cyr, DPh**, has been appointed a member of the Oklahoma State Board of Pharmacy. St Cyr's appointment will expire June 30, 2020.
- **Matthew Ronayne, RPh**, has been appointed a member of the Washington State Pharmacy Quality Assurance Commission. Ronayne's appointment will expire January 19, 2019.

Board Member Reappointments

- **Thaddeus Schumacher, PharmD, RPh**, has been reappointed a member of the Wisconsin Pharmacy Examining Board. Schumacher's appointment will expire July 1, 2019.

Awards and Honors

- **Lloyd K. Jessen, JD, RPh,** former executive director of the Iowa Board of Pharmacy and former member of the NABP Executive Committee, was awarded the Food and Drug Administration Leveraging Collaboration Award. The award recognizes Jessen for his use of effective cooperation and collaboration among federal and state partners, which has resulted in the removal of potentially harmful injectable drugs from the United States marketplace.

Item Writers Gather for June 2015 Workshop

In June 2015, item writers gathered at NABP Headquarters for a workshop to develop new questions for the Foreign Pharmacy Graduate Equivalency Examination® and the Pharmacy Curriculum Outcomes Assessment®. These dedicated volunteers consist of pharmacists in all areas of practice and faculty from schools and colleges of pharmacy. Pictured from left to right: Ana Quiñones-Boex, MS, PhD, Midwestern University Chicago College of Pharmacy and Stephanie Peshek, MDEd, MBA, PharmD, FASHP, Lake Erie College of Osteopathic Medicine School of Pharmacy.

New Kentucky Laws Support Medication Synchronization

In Kentucky, Senate Bill 44 regarding medication synchronization passed and was signed by Governor Steve Beshear during the 2015 Legislative Session. Any individual or group health benefit plan that provides benefits for prescription drugs shall provide a program for synchronization of medications when it is agreed among the insured, a provider, and a pharmacist that synchronization of multiple prescriptions for the treatment of a chronic illness is in the best interest of the patient for management or treatment of a chronic illness, provided that the medications:

- Are covered by the individual or group health benefit plan;
- Are used for treatment and management of chronic conditions that are subject to refills;
- Are not Schedule II or III controlled substances (CS) containing hydrocodone;
- Meet all prior authorization criteria to the medications at the time of the synchronization request;
- Are of a formulation that can be effectively split over required short fill periods to achieve synchronization; and
- Do not have quantity limits or dose optimization criteria or requirements that would be violated in fulfilling synchronization.

This bill also includes language requiring the Kentucky Department for Medicaid Services or a managed care organization to provide a program for synchronization for patients covered under these plans. This bill takes effect January 1, 2016.

North Dakota to Implement CS Disposal Program

In 2014, Drug Enforcement Administration (DEA) released a final rule on the ability of pharmacies, along with other DEA registrants, to participate in a take-back program for patients' unused CS. After hearing from multiple stakeholders, the North Dakota State Board of Pharmacy decided to move forward with a program that will provide North Dakota pharmacies the option to implement a take-back program. The Board agreed to provide the funding for at least a year for pharmacy participation in the take-back program.

The Board will be providing information about how licensees may modify their DEA registration to be eligible as a disposal site, and also information from Yellow Jug Old Drugs, whom the Board has agreed to work with, to get a take-back box and proper security and storage requirements for the receptacle and containers.

The Board encourages all applicable pharmacies to participate in this opportunity and provide a resource for patients to properly dispose of CS, which will hopefully help to eliminate one of the largest sources of diversion by our youth across the state.

New Mexico Now Requires Safe Opioid Use CPE

Pharmacists in New Mexico are required to obtain two contact hours in the continuing pharmacy education (CPE) area of patient safety. Beginning January 1, 2015, a minimum of two contact hours per renewal period must be in the area of safe and appropriate use of opioids. An educational program consisting of a minimum of two contact hours that addresses both patient safety as applicable to the practice of pharmacy and the safe and appropriate use of opioids will satisfy both requirements. The New Mexico Medical Society (NMMS) has a course that will meet the patient safety requirement in the area of opioids. The courses produced by the NMMS are Accreditation Council for Continuing Medical Education-accredited and, therefore, approved for use by New Mexico pharmacists. A link to the course is found at *www.nmms.org/nm-medical-board-requirements.*

Immunization Authority Expanded in West Virginia

Rules adding the meningococcal vaccine to those permitted to be administered by immunizing pharmacists, as well as rules permitting properly certified interns to do immunizations under the immunizing pharmacist's personal supervision, passed the West Virginia Legislature during the 2015 Regular Legislative Session, and were final-filed by the West Virginia Board of Pharmacy. The rules became effective May 17, 2015. Pharmacists with an immunizing pharmacist permit, and properly trained and certified interns under their personal supervision, can now do immunizations for influenza; pneumococcal; hepatitis A; hepatitis B; herpes zoster; tetanus; tetanus diphtheria; tetanus, diphtheria, and pertussis; and meningococcal disease.

The rules now provide that a licensed pharmacy intern may perform all of the immunizations an immunizing pharmacist can administer so long as the intern has completed all of the same training and current certification required of a pharmacist and the intern is under the personal supervision of an immunizing pharmacist. Additional details are in the June 2015 *West Virginia State Newsletter,* available under Publications on the NABP website.

Dispensers Get Four More Months to Meet DSCSA Provisions

Food and Drug Administration (FDA) has granted dispensers an additional four months to comply with provisions of the Drug Supply Chain Security Act (DSCSA) that call for tracking and tracing drug packages across the drug supply chain. As explained in an FDA guidance document, some dispensers' electronic systems for tracking product information will not be operational by the original July 1, 2015 deadline. Therefore, dispensers now have until November 1, 2015.

Specifically, "FDA does not intend to take action against dispensers who, prior to November 1, 2015, accept ownership of product without receiving the product tracing information, as required by section 582(d)(1)(A)(i) of the FD&C Act," states the agency. FDA also notes that "this compliance policy does not extend to transactions in which dispensers must provide the subsequent owner with product tracing information, including transaction history, as required by section 582(d)(1)(A)(ii). If a dispenser has not received product tracing information prior to or at the time it takes ownership of a product, FDA recommends that the dispenser work with the previous owner to receive this information. FDA believes that product tracing information serves as an important tool for dispensers to meet their obligation under section 582(d)(4) to identify suspect product, quarantine the product, and investigate whether that product is illegitimate." Drug manufacturers, wholesale distributors, and repackagers were still expected to meet the original July 1 deadline. The FDA guidance document is available at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM453225.pdf.*

FDA Advises Caution Against Codeine for Treating Colds in Young Patients

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.*

Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns

In June, FDA warned health care providers and consumers that Daytrana®, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color due to repeated exposure to specific chemical compounds, according to an FDA Safety Alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in an FDA Safety alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.*

Mylan Expands Recall of Certain Injectable Products Due to Particulate Matter

In June 2015, Mylan N.V., of Hertfordshire, England and Pittsburgh, PA, expanded an earlier recall to the hospital/user level of certain lots of injectable products, including gemcitabine and methotrexate, due to the presence of visible particulate matter observed during testing of retention samples. Administration of a sterile injectable product contaminated by foreign particulates can lead to adverse health effects, such as emboli, myocardial infarction, respiratory failure, and loss of renal and hepatic function, depending on the means of administration, as detailed in a news release on the FDA website. To date, Mylan has not received any reports of adverse events related to the recall, the news release notes. Mylan is notifying its distributors and customers by letter and is arranging for return of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program. More details are included in a news release on the FDA website, available at *www.fda.gov/safety/recalls/ucm450140.htm.*

nabp newsletter

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Mount Prospect, IL 60056

Missouri Board Wins *Survey of Pharmacy Law* Luncheon Drawing

NABP would like to congratulate the Missouri Board of Pharmacy for winning the 2016 *Survey of Pharmacy Law* Luncheon Drawing. The Board was awarded $175 toward a Board member and staff luncheon for returning updates to the Survey by the July 22 deadline. These important updates are requested annually by NABP from all boards of pharmacy for inclusion into each updated issue of the *Survey*. NABP would like to thank all boards for their participation, which makes the publication a valuable resource for many.

Revised and published each December, the *Survey of Pharmacy Law* serves as a convenient reference source for individuals seeking an overview of laws and regulations that govern pharmacy practice in 54 jurisdictions. For more information about the *Survey*, visit *www.nabp.net/publications*.