President’s Address

**Presented by:**
Karen M. Ryle, MS, RPh

Good afternoon. I’m pleased to be able to share with you the National Association of Boards of Pharmacy’s® (NABP’s®) developments and accomplishments over the past year.

It has been an incredible year serving as your president. Throughout my seven years on the NABP Executive Committee, I have been amazed at the dedication and commitment shown by the members of this Association. Without all of us working together, NABP would not be able to achieve the many things that we do. And moving forward I see that we will need to work together even more closely to protect public health.

**Compounding Training**

The last two years have reinforced to me how interconnected NABP and the boards of pharmacy are. For me, the revitalization of the relationship between NABP and the boards began in December 2012 at the Interactive Executive Officer Forum. It was inspiring to see the passion of the attendees as we discussed and brainstormed on shared solutions for preventing future compounding tragedies. One of the key components of the solutions was for NABP to facilitate the necessary connections between the boards of pharmacy. Since that time, NABP has built tools to assist boards of pharmacy in sharing important pharmacy license and inspection information. If we all utilize these tools, we will have access to complete information about pharmacies seeking licensure in our states. Joe will be talking more about these valuable, easy-to-use tools on Tuesday.

Another outcome of that meeting was the call for compounding inspection training for board staff. In October, NABP sponsored the first Sterile Compounding Inspection Training event.

Thirty-eight boards of pharmacy, including three Canadian associate members, sent a total of 61 compliance staff. The training provided in-depth information on sterile compounding inspections, including how to conduct a sterile compounding pharmacy inspection and identify dangerous and/or improper compounding techniques.

How many of you here would like the opportunity to participate in this training – for the first time or as a repeat attendee?

We will be providing this training again in the fall. And as in the past, NABP will provide the funds for one person from each board to attend. NABP staff will be sending more information about this training through the Electronic Mailbag in the near future.

In addition, working with the compounding experts at Critical Point, NABP has made training webinars available to board staff all year round at no cost.

While classroom training can be beneficial, NABP recognizes that training in the field is also very valuable. Therefore, NABP facilitates training through its inspection services conducted on behalf of boards. Understanding the importance of state involvement in this process, NABP notifies the boards of pharmacy when an inspection
will be done in their state. This allows the board to send a state inspector to accompany the NABP surveyor for observation or training.

**Drug Quality and Security Act**

Of course, we can’t talk about compounding without discussing the Drug Quality and Security Act, or DQSA.

Before the passage of this bill, NABP provided testimony in several congressional hearings to discuss the need for compounding to remain under board of pharmacy oversight. We also stressed the need for federal regulation of compounders operating as manufacturers.

Coincidentally, Food and Drug Administration (FDA) held a conference call to discuss the DQSA on the first day of the 2013 Interactive Compliance Officer and Legal Counsel Forum. NABP opened the meeting room early for all who wanted to participate in the call. This provided a unique opportunity for NABP to get feedback from the members. And yet again, compounding became one of the main topics of discussion for the forum as we adjusted the programming to meet your needs.

The DQSA requires enhanced communications between state boards of pharmacy and FDA, and calls for NABP to facilitate this communication in several cases. Specifically, it calls for the establishment of a reporting system for state boards of pharmacy to report the following activities:

- suspensions, revocations, disciplinary actions, sanctions, warning letters taken against pharmacies for compounding violations;
- recall activities by a pharmacy for issues related to the purity or quality of a compounded product; and
- concerns that a pharmacy may be exceeding the scope of Section 503A of the Federal Food, Drug, and Cosmetic Act.

In addition, the law calls for a memorandum of understanding between the states and FDA that must be developed in consultation with NABP.

NABP is committed to ensuring that the processes and systems developed meet the needs of the state boards of pharmacy. Therefore, since the passage of the bill, NABP has been in frequent discussions with FDA regarding implementation.

In addition, NABP provided the boards of pharmacy with suggested points of consideration for the multi-state meeting held by FDA in March. As a follow-up to this meeting, tomorrow at noon we will be holding a session in this room to review the outcomes of the multi-state meetings as well as discuss next steps.

Finally, NABP has nominated several representatives of boards of pharmacy for the Pharmacy Compounding Advisory Committee that is being formed. The law provides for FDA to consult with this committee prior to issuing certain regulations pertaining to outsourcing facilities.

**Pharmacy Inspections**

The interconnectedness of the boards and NABP is further highlighted in the work done by the Task Force on Pharmacy Licensure Standards. Members of the task force reviewed existing state pharmacy inspection forms. Their purpose was to compile a list of requirements that are consistent across the states. From there, we were able to create a uniform inspection form that can assist states with inspections of resident and nonresident pharmacies.

Before I get into the recommendations of the task force, I have a quick quiz for you. Does someone want to take a guess as to what is the average number of inspectors our boards have?

There is an average of 6.5 inspectors for each board of pharmacy, according to the 2014 Survey of Pharmacy Law. And the total number of inspectors for all the boards is 308. This is a daunting fact when you consider that the combined number of in-state pharmacy licenses in the United States totals more than 74,000.

In addition to the in-state licensees that they must keep track of, board inspectors are also charged with oversight of nonresident pharmacies. Does anyone have a guess for what the total number of out-of-state pharmacy licenses issued in the US is?

According to the 2014 Survey, when you add up each state’s out-of-state pharmacy licenses, the total comes to 24,740.
licenses. I think we can all agree that a substantial amount of time and resources are needed to ensure these licensees are adhering to pharmacy practice rules and regulations.

In the face of these numbers, a uniform inspection form seems like a pretty good way to help streamline the inspection process for your board, especially when you are considering licensure of a nonresident pharmacy and hoping to use a recent resident inspection report. In its recommendation to establish a standardized inspection form, the task force recognized that doing so would allow boards to rely on one another's inspections in evaluating licensure applications for nonresident pharmacies.

The new uniform inspection form is now available for boards’ use. I strongly encourage you to take advantage of this tool, as it provides boards a variety of benefits, including saving time and money.

During their discussions, the task force members stressed the importance of maintaining the boards’ decision making authority. Therefore, the form only serves as a means to collect inspection data and record observations. Determinations regarding a pharmacy’s compliance with state laws and regulations remain with the respective board of pharmacy.

In addition to the general inspection form, the task force recommended that supplemental inspection modules be developed to support additional kinds of inspections. Recommended forms include

- sterile compounding,
- nuclear pharmacy,
- mail order,
- hospital/institutional, and
- central fill.

The task force also recommended that NABP encourage the release of pharmacy inspection reports to inspected facilities and boards of pharmacy. Providing inspection reports to the facility allows personnel to correct any deficiencies.

I know I said this before, but it is worth repeating: Allowing all states access to reports will eliminate duplication of efforts and reduce costs for the boards. NABP is currently drafting an agreement to facilitate the sharing of inspection data. I encourage all of you to push for the signing of the agreement. We understand that many of you have challenging legislative systems that you will have to work through. So, if there is any way that NABP can assist you, please contact the Member Relations and Government Affairs Department.

**Pharmacy Benefit Managers**

Another task force held in 2013 was on the regulation of pharmacy benefit managers (PBMs). The task force is pursuant to Resolution 19-3-13, which was passed at the 109th Annual Meeting.

During the meeting, task force members reviewed the 1999 Task Force on Licensing of PBMs. They affirmed that the 1999 task force recommendation stating that PBMs engaged in the practice of pharmacy should be licensed and regulated by state boards of pharmacy.

The task force also recommended that, wherever possible, states institute an ombudsman for PBM issues to assist patients and ensure that their interests and complaints are appropriately received and managed. Additionally, the task force recommended that NABP study outcomes of new regulations of PBMs by state boards of pharmacy to determine the outcome of these efforts. By observing these efforts, once the area is more fully evolved, it can be better determined if expansion of the boards’ authority is warranted.

The task force also recommended that NABP provide education related to PBMs to consumers and licensees through the AWARXE program.

The full reports from both task forces are posted in the Member section of the NABP website.

**Interactive Forums**

In addition to the single-issue task forces, NABP was further supported by the volunteers who served on the following committees:

- the Advisory Committee on Examinations
- the competency assessment content expert and review committees,
- the Committee on Constitution and Bylaws,
the Committee on Law Enforcement/Legislation,

• the NABP InterConnect Steering Committee, and

• the gTLD Advisory Committee.

Through the leadership, expertise, and commitment of the committee and task force volunteers, several significant issues were addressed this year. Please join me in a round of applause for those individuals who gave up their time and provided us their expertise by serving the Association this way.

Today I have said a lot about the interconnectedness of the boards and NABP. The last three interactive forums have provided an avenue to foster the benefits of that interconnectedness. Seeing the critical discussions that have been held at the forum the past couple of years made it easy for us to decide to continue holding forums in 2014.

The two scheduled forums are:

• The Interactive Executive Officer Forum, to be held October 14-15, and the

• Interactive Member Forum, to be held December 2-3.

As with the previous interactive forums, the meeting content will be built around the topics that you are interested in. Prior to the forum, NABP will circulate a survey to determine what issues are important to the boards of pharmacy to ensure that the sessions are relevant to you. Also, NABP will again provide funding for travel, meals, and accommodations to facilitate participation by as many boards as possible.

Please be sure to send a representative to each meeting. These forums are a wonderful opportunity to interact with your colleagues.

I would again like to express my appreciation for the commitment you all show to NABP. Without your support, NABP would not be able to make a difference for the benefit of the public health. I have enjoyed serving as your president during this exciting time.

To say this year has been a challenging year would be an understatement. I would not have been able to commit my time as your president without support from my employer, Mass General Hospital, or as we say “Man’s Greatest Hospital.” They have allowed me to take the time necessary to travel to all the district meetings, executive committee meetings, and meetings with other pharmacy stakeholders. I have to say the district meetings were my favorite; getting to know many of you on a personal level and the hospitality that you have shown me has been the highlight of my presidency. Besides attending great programs at the district meetings, I got to visit the Country Music Hall of Fame, ride a Pedal Tavern through the streets of Nashville, attend a baseball game in Winnipeg, visit Rocky Mountain National Park, cruise Lake Michigan with a view of the Chicago skyline, and eat lobster for breakfast, lunch, and supper in Bar Harbor, ME. It doesn’t get much better than that.

Another highlight this past year was when I was invited to lead the students at the University of Rhode Island into the “Oath of a Pharmacist” at the white coat ceremony, and my daughter Amanda was one of those P1 pharmacy students.

I am grateful to have had such a successful year, and I could not have done this without the support from my husband John and my daughter Amanda.

I am going to leave you with a quote from Ralph Waldo Emerson, who happens to be from Boston, MA. “Do not go where the path may lead; go instead where there is no path and leave a trail.”

I think all of us here at NABP have left a very big trail.

Thank you.