

The Handwriting is on the Wall

By Dale J. Atkinson, JD

In order to promote uniformity, take advantage of expertise, and to promote financial savings through economies of scale, regulatory boards, including boards of pharmacy, rely upon outside entities for certain programs and services related to the licensure and renewal process. Examples include accrediting bodies that establish and review standards related to education, continuing education providers and programs, licensure transfer programs that collect, store, and disseminate practitioner information, and, of course, uniform licensure examination programs designed to assess entry-level competence as one criterion of licensure.

Boards of pharmacy are created and empowered to enforce the practice acts in furtherance of the public protection mandates of the legislation. As a governmental process that impacts an individual's right to practice a chosen profession, the licensure process and rights of licensees are subject to numerous legal protections and mandates related to the issuance, denial, and removal of the practice privileges. To take advantage of the numerous benefits of uniform programs, boards of pharmacy justifiably defer a certain amount of responsibility to NABP and the Accreditation Council for Pharmacy Education. Without addressing the complex issues of delegation of authority of required criteria in the

licensure process, boards of pharmacy, as the entities ultimately responsible for licensure decisions, are encouraged to understand and participate in NABP activities. As governmental agencies and to encourage public protection perspectives, boards of pharmacy are also cloaked with immunity protections. Consider the following:

The Illinois State Board of Education is empowered by law to set standards for teaching, supervising, and holding other certificated employment in the public schools. The Board administers the certification process, approves and evaluates teacher and administrator preparation programs, establishes standards for the issuance of new types of certificates,

enters into agreements with other states for reciprocal approval of teacher and administrator preparation programs, and takes actions relating to improving teaching in the public schools. Adhering to the nomenclature of regulation of those in the education community, "certification" is used throughout this article as governmental recognition of authority to practice, which is akin to "licensure" in other professions.

In Illinois, individuals can receive a substitute teaching certificate allowing employment on a substitute basis for up to 120 days per year. A substitute teaching certificate is not a full teaching certificate. To receive a full teaching certificate, applicants must complete an approved program at an accredited university. Further, applicants must pass the Illinois Certificate Testing System's Basic Skills Test, Content Area Test, and Assessment of Professional Teaching Test (collectively referred to as teaching tests). Newly certified teachers receive an initial certificate that is valid for four years. During that four-year period, teachers must complete certain professional development. Thereafter, the teacher receives a standard certificate that is renewable every five years. Teachers must receive an initial certificate before receiving a standard certificate.

To maintain employment in the public schools, substitute and full-time classroom teachers must be certified by the Board.

The teaching tests are administered by the National Evaluations Systems (NES). NES administers the tests, analyzes the test scores, and notifies the Board of examination results. In addition, the NES notifies the Board of anomalies regarding the teaching test scores, including low to high score variances of an identified candidate from one test administration to another.

A particular applicant was educated in Alabama and completed her master's degree in urban teaching in Illinois in 1994. Based upon notice from the school in Illinois, the applicant completed a few additional classes in order to qualify for and submit her application to the Board for a teaching certificate in Illinois. During the years leading up to her sitting for the Basic Skills Test, the applicant worked in a variety of public schools as a substitute teacher, a classroom teacher, and a provisional teacher (which is a substitute teacher who works every day at the same school).

The applicant received notice from her employer, the Chicago Public Schools (CPS), that all teachers needed to become fully certified by a certain date.

As a result, the applicant was required to successfully complete the teaching tests. Previous to this notice, the applicant had taken and failed the Basic Skills Test four times. In February 2004, the applicant again took the Basic Skills Test and NES discovered a statistical discrepancy between her February 2004 administration and her previous unsuccessful attempts. NES notified the Board of the discrepancy, which identified a significant increase from low to high in the applicant's examination score. The Board notified the applicant of the discrepancy and the fact that a handwriting analysis would be undertaken. The applicant responded to the Board correspondence with a possible explanation for her score increase, including her participation in a preparation course.

A forensic scientist with the Illinois State Police analyzed the handwriting of the applicant and that of the Basic Skills Test and determined that his analysis "failed to establish that [the applicant] took the February 2004 Basic Skills Test. The Board forwarded notice to the applicant informing her that "no person may be granted a teaching certificate who has knowingly altered, misrepresented his or her teaching qualifications" and that her claim that the February 2004 examination results

were hers constituted a misrepresentation of her qualifications based upon the handwriting analysis. Eventually, the applicant was provided with a copy of the Illinois State Police report regarding the handwriting analysis and was asked to respond in writing to defend the charges.

The applicant submitted a handwriting sample which, after analysis, did not change the Illinois State Police analyst's opinion that the applicant's handwriting did not match the handwriting of the February 2004 test administration. As a result, the Board by letter informed the applicant that the February 2004 examination score was voided, she was not eligible for an initial teaching certificate, and that she would be denied all future applications for certification. In July 2007, the applicant's substitute teaching certificate expired and the Board denied her application for renewal.

The applicant filed a complaint in United States District Court against the former Illinois Superintendent of Education and the Chairman of the Illinois State Board of Education (defendants) in their official capacities arguing that they denied the applicant's liberty interests without due process of law and seeking equitable and monetary relief in the

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Transfer of Pharmacist Licenses

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Gary A. Schnabel, RN, RPh, executive director, Oregon State Board of Pharmacy. In 2008, the Oregon State Board of Pharmacy amended OAR 855-019-0100.

(4) Effective April 1, 2009, any pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the Board in accordance with the following rules, except that a mail-order pharmacy located in another state is only required to have the

pharmacist-in-charge, or similar position, licensed by the Oregon Board of Pharmacy.

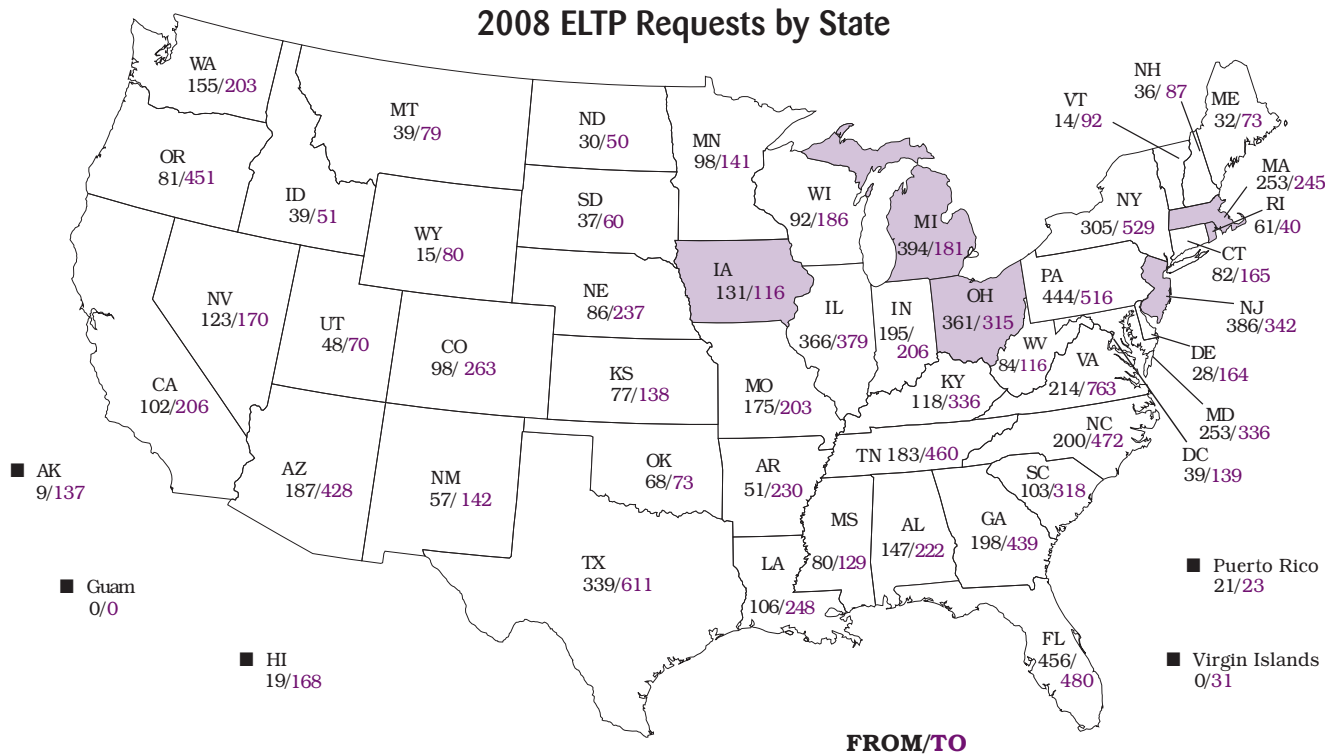
“We did anticipate a large increase but didn’t consider it remarkable because we counted up the number of nonresident pharmacies and remote and telepharmacy projects we already have operating in the state,” Schnabel states in regard to the 2008 increase. “With the new rule traditional mail-order pharmacies are required to have only one pharmacist licensed in Oregon,” he says, “however, all out-of-state pharmacists performing duties beyond those that would take place in traditional mail-order

pharmacies such as drug regimen review, remote order entry, and prescription management services are required to obtain licensure in Oregon. The Board is reviewing this new rule to identify whether the language is being appropriately interpreted or whether some change to the language is needed clarify its intent.”

In addition to Virginia and Oregon’s noteworthy changes, Florida’s recent law revision may have also affected the overall licensure transfer numbers of pharmacists seeking licensure in other states. In June 2008, Florida rescinded its requirement for license transfer applicants to have passed the North American Pharmacist Licensure

Examination® (NAPLEX®) within 12 years from the date the transfer application was filed with the Florida Board of Pharmacy. As a direct response, several states began to review and update their requirements to allow pharmacists to reciprocate their licenses from Florida without condition. Prior to this, many states either did not accept license transfers from Florida or held specific requirements. (See January 2009 *NABP Newsletter* article, “Several States Update Regulations in Response to Florida’s Rescinding of 12-Year Licensure Transfer Law.”) Though the number of requests to transfer a license from Florida decreased in 2008 by about 13%, Florida still saw the

2008 ELTP Requests by State



Shaded areas denote states where the number of applications for transfer from the state is greater than the number of applications requesting transfer to the state.

largest overall number of requests to transfer licenses from the state, with 456. In addition, Florida had the fifth highest number of requests to transfer to the state, with 439. By eliminating its 12-year requirement for licensure transfer, Florida's legislative change removed barriers for pharmacists wishing to transfer to and from the state.

As in the past, three states continue to experience high totals in licensure transfer requests. After Virginia, Texas had the second most requests from pharmacists to transfer their licenses to the state, with 611; New York had the third most requests, with 529; and Pennsylvania had the fourth most, with 516.


Future Expectations

The upward trend in licensure transfer requests can be expected to continue as the overall national demand for pharmacists persists. This level of demand is evident in the Aggregate Demand Index (ADI) survey, which is supported by Pharmacy Manpower Project, Inc. The ADI survey reports the level of demand for pharmacists by state and region monthly, and in 2008, included Wisconsin as a state with one of the highest levels of unmet demand for the last half of the year. This may explain the 118.8% increase in requests to transfer pharmacy licenses to Wisconsin. The

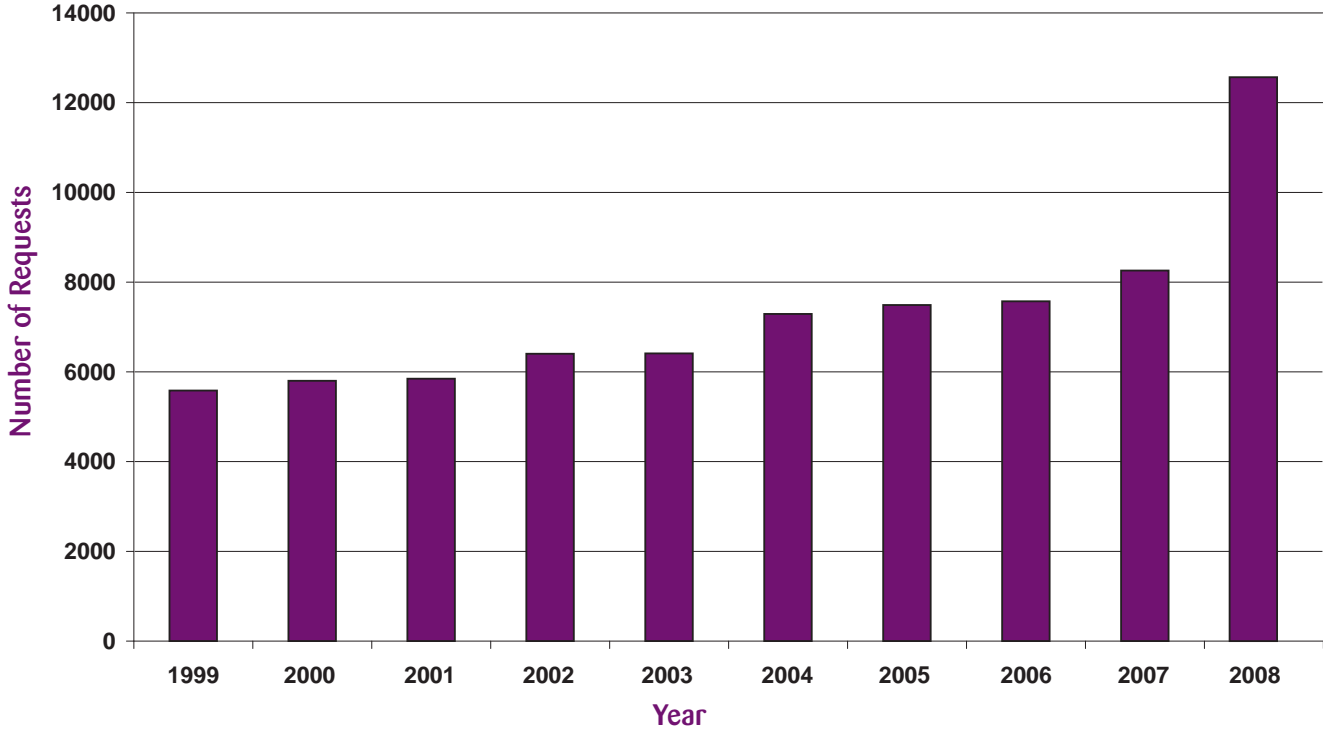
most recent ADI survey is available at www.pharmacymanpower.com.

With the anticipation that ELTP numbers will continue to escalate, the boards normally would expect to be faced with an elevated number of inquiries from applicants. However, development of the Internet-based ELTP application has not only created a user-friendly and accelerated application process but has enabled applicants to check the status of their applications online, freeing up more time for the boards to focus on important regulatory matters. (See January 2008 NABP Newsletter article

"New Internet-based ELTP Application Accelerates Processing, Eliminates Incomplete Applications.")

"NABP is diligently working to further enhance the services and support it provides to the state boards of pharmacy," states NABP President Rich Palombo, RPh. "The Association's ultimate goal is to provide an organized and comprehensive licensure database to relieve board staff of resource-intensive tasks." This improved database will allow boards to access ELTP, licensure verification, score retrieval, and eligibility reports in one convenient location. 

ELTP Requests by Year, 10-year Trend



A total of 12,334 licensure transfer requests were submitted in 2008, which is an increase of 54.7% when compared to the 5,583 requests submitted in 1999.

Patient-Centered Information Focus of Task Force on Uniform Prescription Labels

Recognizing that prescription drug labels may currently require and highlight information pertinent for pharmacists rather than clearly displaying information critical to what the patient needs to know, the Task Force on Uniform Prescription Labeling Requirements agreed that major changes must be made to labels to ensure that information is provided in a uniform, patient-centered format. Keeping this in mind as they considered changes to prescription drug labeling, the task force, which met December 6, 2008, in Tucson, AZ, undertook the following charges.

1. Evaluate current state and federal laws and regulations addressing prescription label format and content.
2. Review the results of the findings of both state and federal studies regarding prescription labeling.
3. Study the feasibility of implementing standardized state requirements for prescription label format and content and for patient medication information.
4. Recommend revisions, if necessary, to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* addressing these issues so as to increase readability and comprehension of labels by patients.

Early on in their discussions, the task force members agreed that it was important to create a clear, concise statement regarding the focus and purpose of their recommendations for prescription labeling. The members recommended that this statement be endorsed by the NABP Executive Committee and distributed to interested stakeholders. Through this statement, the task force members communicated their belief that labels should be used solely to provide patients with important information about medication use. The statement also included the assertion that prescription labels should not replace critical pharmacist care responsibilities.

The task force members identified some critical pharmacist care responsibilities as (1) patient identification and (2) patient counseling. Patient identification encompasses patient data elements, such as the address. These elements are important identifiers for matching the prescription to the patient but do not warrant inclusion on the label, as this type of information should be contained in other patient identification systems. The task force members agreed that patient counseling is the single most effective component to increase and improve patient compliance and avoid medication errors. Because of this, they believe that prescription labels should be designed to supplement patient counseling, but not replace it in any way.

Numerous studies cite 12-point, sans-serif fonts as providing the best readability; therefore, the task force members included this feature in its recommended amendments to the *Model Act* language addressing prescription drug labeling. Recognizing the relatively small

real estate afforded by 2" by 4" labels for prescription bottles, the task force identified critical information that should be presented in this larger, 12-point font versus important information for patients that could be provided in a smaller font size. Additionally, the task force identified several pieces of data, such as the pharmacy fax number, that could be removed from prescription drug labels because that information can be found through other sources and is not vital to patient safety.

The task force agreed that the following information is critical and must appear on the label with emphasis (either highlighting or bolding) in a sans-serif font, with a minimum point size of 12, and which must never be truncated:

- Patient name
- Directions for use and, if included on prescription drug order, the purpose/indication
- Drug name and strength
- Date by which the medication should be used

The task force also recommended that the following information be included in the *Model Act* as mandatory data elements for labels, but that this data should not supersede the aforementioned

critical information in size or emphasis.

- Pharmacy name
- Pharmacy telephone number
- Prescriber name
- Fill date (the date the prescription was dispensed)
- Prescription number
- Drug quantity
- Number of refills
- Product description
- Auxiliary information


In addition, the task force recommended the *Model Act* be amended to note that the following additional data elements may appear on the prescription label:

- Bar codes
- Pharmacy address
- Pharmacy store number

Through its discussions on which information should be included on prescription labels, the task force recognized that its recommendations represent a significant change in the philosophy of what defines a prescription label and the purpose of the prescription label. Because the *Model Act* is not intended to contravene state and federal laws or regulations, the task force supports NABP working with relevant agencies and organizations to allow implementation of the patient-centered label the task force developed.

Finally, the task force also recommended

that NABP work with the American Medical Association, the Federation of State Medical Boards, the Centers for Medicare and Medicaid Services, and other relevant organizations to require that medication indications be included on written and electronic prescription drug orders. The task force members discussed how providing on a prescription the purpose for which a drug was prescribed is an important tool for protecting patients. With this tool, pharmacists can better counsel patients on how and why they are taking the medication. This concept has a history of support among NABP members as evidenced by NABP Resolution No. 100-7-04, Medication Indication on the Prescription, which was passed by the membership at its Annual Meeting in 2004; the task force members felt that with the profession's focus on patient-centered labels that the time was well suited to pursuing this change.

The recommendations of the task force were approved by the NABP Executive Committee during its February 2009 meeting. The full report of the task force is available on the NABP Web site at www.nabp.net under News/Press. 

Obama Administration Ushers in ‘New Day in Health Care’; Reform on the Horizon

“We are going to see a new day in health care,” says Philip P. Burgess, RPh, MBA, chairperson of the Illinois Division of Professional Regulation – State Board of Pharmacy. Health care reform has been a major tenet for President Barack Obama since his campaign began. In the next four years, we can expect to see myriad changes in the health care environment, many of which are likely to have an impact on the practice and regulation of pharmacy.

While some elements of these plans are clearer cut than others, over all, Burgess says he is optimistic about the changes to come under the leadership of Obama. “He really has reached out to experts in the field of health care and in other areas,” says Burgess, who recently retired as national director of pharmacy affairs for Walgreen Co. “He will bring a fresh look at a lot of things, and I think pharmacy will benefit, and the patient will benefit.”

Prevention, Outcomes in Focus

Pharmacy experts foresee a significant role for pharmacists in the prevention of illness with the long-term end result of lowering health care costs. States in which pharmacists routinely administer immunizations, for instance, show increased rates of immunization in those populations. The profession may

see the new administration fostering those kinds of initiatives and encouraging regulations to maximize the use of other health care professionals, as well as more walk-in clinics opening in retail pharmacies.

Gary Matzke, PharmD, professor and associate dean for clinical research and public policy at Virginia Commonwealth University School of Pharmacy, says he envisions pharmacists becoming “health care coaches who are involved in their communities to advocate for better lifestyles.” He describes this practice as a logical extension of medication adherence counseling that would not require any legislation but, rather, a business model transformation. If this role for pharmacists is valued by those who receive it as indicated by direct payment for services, the new administration may consider providing a mechanism to make these services

more broadly accessible and economically feasible.

The coming years will also likely bring a growing emphasis on evidence-based medicine and attention to outcomes. Obama said in a campaign speech, “in our new national health care plan and other participating plans, we will require coverage of evidence-based, preventive care services . . . We’ll also start measuring what’s effective and what’s not when it comes to different drugs and procedures . . . And instead of rewarding providers and physicians only by the sheer quantity of services and procedures they prescribe, we’ll start rewarding them for the quality of the outcomes for their patients.”

As boards of pharmacy continue to focus on implementing and optimizing continuous quality improvement programs in their states, the new administration may provide additional impetus to measure patient care outcomes in assessing the success of those programs.

Importation Back on the Table

One of Obama’s campaign promises is to reduce health care costs for the average family by up to \$2,500 as reforms phase in. He promotes several strategies for achieving this savings, including the importation of “safe”

prescription medications from other developed countries. How such a plan would ensure the safety of imported drugs, however, remains a complex question, the answer to which lies in a tangled web of domestic and international regulations.

Obama's appointment of US Representative Rahm Emanuel as White House chief of staff is a strong indication that the administration is serious about pursuing this option. Emanuel, an Illinois Democrat, has been a vocal supporter of importation. Emanuel released a statement at a September 2004 press conference "debunking the myth that prescription drugs from abroad are unsafe."

Previous attempts to legislate importation have failed due to the, as of yet, inability to ensure the safety of imported medications. FDA repeatedly has warned that, unless medications have been purchased from a state-licensed pharmacy in the US, the safety and efficacy of these medications cannot be guaranteed. Currently, no safeguards exist to protect shipments of foreign medications entering the US from infiltration by counterfeit and substandard drugs. Whether the Obama administration would be able to implement such safeguards, or what form those safeguards might take, remains to be seen.

With the safety of imported goods being such a concern over the past year, stakeholders have expressed doubts that addressing importation will be a top priority for the new administration. "If there could be a way of ensuring those drugs could be safe, [Obama] would support the concept of importation," Burgess says, adding, "I don't think there's any way we can bring in drugs from outside the United States and ensure the same level of safety."

On the other hand, some experts note that recent changes in Congressional leadership point to a higher likelihood that legislation allowing commercial importation could pass this time around, as it does fit in with Obama's focus on reducing costs and increasing access to affordable health care.

Health Information to Enter 21st Century

The new administration will likely bring with it a renewed push for the universal implementation of health information technology, including the use of electronic patient medical records and electronic prescribing. Such a move, Obama has said, would ultimately help to lower health care costs by diminishing paperwork, reducing errors, and eliminating redundant diagnostic testing.

"By moving to electronic medical records, we can give doctors and nurses easy access to all the necessary information about their patients, so if they type-in a certain prescription, a patient's allergies will pop right up on the screen," Obama said during a campaign speech in Iowa. "This will reduce deadly medical errors, and it will also shorten the length of hospital stays, ensure that nurses can spend less time on paperwork and more time with patients, and save billions and billions of dollars in the process."

E-prescribing is touted for its potential to decrease paperwork, reduce prescription forgery, prevent prescription errors caused by illegible handwriting and misunderstood oral prescriptions, and enable more direct integration of prescription records with other medical records. It also dovetails with the use of electronic medical records by keeping patient profiles together with their medication history.

Obama has advocated requiring a standard for electronic health records, as well as a plan to invest \$10 billion per year for five years to move the US health care system to broad adoption of standards-based electronic health information systems and will phase

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Transition to Internet-Based MPJE State-Specific Review Provides Flexibility for State Boards of Pharmacy

In an effort to increase the involvement and oversight of the Multistate Pharmacy Jurisprudence Examination® (MPJE®), as well as offer a more convenient and flexible approach for state boards of pharmacy to participate, NABP will conduct the MPJE State-specific Review meeting using an Internet-based format in October 2009.

Constructing a more convenient and flexible approach for the boards, the new Internet-based State-specific Review will allow boards to examine test questions without having to leave the office, an advantage for boards with shrinking staffs and budgets.

NABP hopes the meeting's transition to an Internet-based format will enable boards that may have limited resources available to increase their involvement and oversight. The increase in participation will ensure that the MPJE has the highest potential and validity standards with the most

up-to-date questions on the examinations, and allow boards of pharmacy to have access to the largest pool of valid examination items.

The new Internet-based format promotes the two primary responsibilities and goals of the meeting as the boards review items specific to their own state:

1. review all the newly developed questions to determine which of them apply to their state; and
2. review all questions currently approved for their state to ensure all the items are appropriate.

To ensure the new remote MPJE State-specific Review runs smoothly and safely, NABP will be utilizing a secure Web site where NABP will post each participating state's operational pool and new pretest questions. Each board will have its own log-in and password, and will be able to designate multiple representatives to complete the work. If needed, multiple people

will be able to access the secure Web site simultaneously.

While the time frame for boards to complete the MPJE review is more flexible with the Internet-based format, boards will still have a defined period of time to access their information. All MPJE items will be available for two full weeks on the secure Web site. For examination security purposes, NABP will close the Web site at the end of the two weeks.

As of today, 46 boards utilize the MPJE and are asked to participate in at least one State-specific Review meeting each year to determine the appropriateness of items in the MPJE for candidates seeking licensure. In the past, the meetings were held as a three-day event that took place in different locations throughout the US, and boards were provided the opportunity each year to attend a session. In October 2008, representatives of the state boards of pharmacy gathered in Rosemont, IL, with 65 participants in attendance from 34 jurisdictions.

The MPJE is based on a nationally uniform content blueprint with questions that are tailored to assess the

MPJE Development Timeline

The following activities occur annually during the development of the MPJE:

- New items are written during an item-writing workshop.
- MPJE Review Committee members review and edit the test items that were written at the item-writing workshop. Members also assign all new items to the proper competency/sub-competency on the MPJE blueprint.
- Appointed board representatives select new pretest items for the year and review their state-specific scored items. ⓘ

pharmacy jurisprudence requirements of individual states.

Specific review dates and details on the new Internet-based MPJE State-specific Review will be sent out to participating boards in July 2009. ⓘ

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Escalating Numbers of US Pharmacy School Graduates Continue to Impact NABP Examinations

As expected, the increase of pharmacy school graduates in the United States directly effected the 2008 administration numbers for the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®).



NAPLEX

The steady increase in pharmacy school graduates continues to positively impact the annual total number of candidates who sit for the NAPLEX. From January 1, 2008 to December 31, 2008, there were a total of 13,038 NAPLEX administrations compared to 12,785 administrations in 2007. With a 1.98% growth (253 administrations), the number of NAPLEX administrations remains consistent in its upward trend. In addition to the continual increase in the number of graduates at long-established pharmacy schools, there were four schools of pharmacy that graduated their first classes in 2008, further adding to the total number of NAPLEX candidates. Of the 13,038 candidates who sat for the examination, a total

of 10,618 (81.4%) candidates took the NAPLEX for the first time.

In addition to the increasing number of pharmacy school graduates, the Bureau of Labor Statistics recently reported in its *Occupational Outlook Handbook* (2008-09 Edition) that employment of pharmacists is expected to grow by 22% between 2006 and 2016. This growth, which is much larger than the average for other occupations, correlates with increasing demands for prescription medications and scientific advances creating more drug products. This prediction of growth supports the annual NAPLEX administration numbers as well as the belief that the number of candidates who sit for the examination will continue its upward trend in the coming years.

The number of individuals who utilized the Pre-NAPLEX™, the only practice examination for the NAPLEX developed by NABP, also continues to grow. In 2008, a total of 6,944 individuals took the Pre-NAPLEX, an increase of 686, or 11%, from the 6,258 individuals who took the practice examination in 2007. It is expected that the numbers for both the NAPLEX and Pre-NAPLEX will continue to increase proportionately.



MPJE

A total of 18,856 candidates sat for the MPJE in 2008 compared to 18,076 administrations in 2007, representing an increase of 780 individuals, or 4.32%. As also witnessed with the NAPLEX, this increase may be directly attributed to the high demand for pharmacists mentioned by the *Occupational Outlook Handbook*. In addition, the growth in MPJE administrations may directly relate to the increase in the number of Electronic Licensure Transfer Program® (ELTP®) requests received in 2008, since in most cases, pharmacists are required to take the MPJE specific to the state in which they are seeking licensure. (See page 43 for details on ELTP statistics.)



FPGEE

In 2008, a total of 3,045 applicants sat for the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), a decrease of 796, or 20.7%, when compared to the 3,841

applicants who sat for the examination in 2007. This decrease may relate to changes in the requirements for applicants wishing to obtain Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification. In 2003 the FPGEC began requiring that foreign-educated pharmacists earn their professional degrees from five-year curriculum programs. Since many of the foreign universities do not have a five-year program or are still in the process of transitioning to one, it is possible that fewer foreign graduates are eligible for the FPGEC program. The decline in FPGEC applicants impacts the number of individuals who are eligible to sit for the FPGEE. This is supported by comparing the number of first-time FPGEE takers to the number of repeat test takers. Though very slight, over the past few years the number of first-time test-takers has gradually decreased, while the number of repeat test-takers has slowly increased.

In addition to degree requirements, the ability to obtain a visa has become increasingly difficult. The FPGEC reported that it received at least 150 requests from applicants last year asking for an additional opportunity to test due to the inability to obtain a visa.

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State Rules Distinguish Compounding for Office Use from Manufacturing, Wholesaling

Florida is the latest of 26 states to adopt rules allowing and setting standards on pharmaceutical compounding for office use. Such rules have attempted to distinguish the circumstances in which pharmacies are permitted to prepare compounded medications for practitioners, without a prescription drug order for a specific patient, and without falling into the realm of manufacturing or wholesale distribution.

According to Food and Drug Administration (FDA) guidelines, pharmacy compounding is permissible if it is done on the basis of a prescription written by an authorized practitioner for a specific patient for a drug that is not available on the market. Preparing large quantities of compounded drugs without a prescription, compounding drugs for third parties who resell to individual patients, or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale, on the other hand, cross the line into manufacturing and/or wholesaling, FDA says in the pharmacy compounding section of its “Compliance Policy Guidance for FDA Staff and Industry.” FDA states that such activities “raise the kinds of concerns normally associated with a drug manufacturer

and result in significant violations of the new drug, adulteration, or misbranding provisions of the [Federal Food, Drug, and Cosmetic] Act.”

Several states do allow pharmacies to prepare compounded drugs in small quantities to fill orders for practitioners, who then *administer* the drug to their patients in the practitioners’ offices or other health care institutions.

California, however, is one of the few states to allow practitioners to *dispense* limited quantities of compounded medications to their patients. The rule in this state defines *prescriber office use* as “application or administration in the prescriber’s office, or for *distribution of not more than a 72-hour supply to the prescriber’s patients* as estimated by the prescriber” (emphasis added).

According to Florida’s rule, as well as those of several other states, a pharmacist may prepare compounded medications as prescribed by a practitioner for a specific patient, or for “provision and administration . . . to a patient by the practitioner in the practitioner’s office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy.”

In Florida, as in several other states, compounded medications may not be dispensed by the practitioner to the patient. The rule specifies, “[t]he preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities *for purposes of dispensing or distribution* is not compounding and is not within the practice of the profession of pharmacy” (emphasis added).

Florida’s rule, as well as those of several other states, permit pharmacies to prepare compounded medications “in anticipation of prescriptions based on routine, regularly observed prescribing patterns,” and to deliver a quantity of a compounded drug to a practitioner for office use by the practitioner with the following provisions:

- (a) The quantity of compounded drug does not exceed the amount a practitioner antici-

- pates may be used in the practitioner's office before the expiration date of the drug;
- (b) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;
 - (c) The quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.


Kentucky is in the process of developing a similar rule to address compounding for office use. Depending on the outcomes of a public hearing, written comments, and a hearing before the Administrative Regulation Review Subcommittee, the proposed rule was scheduled to be sent to the Health and Welfare Committees of both the House and Senate in March. If passed by these committees, it is expected to become law at or near the end of March.

Several states' rules, including Oklahoma's rule and Kentucky's proposed rule, do not permit the compounding of medications containing controlled substances for office or institutional administration. Colorado, on the other hand, allows compounded controlled substances to be distributed to practitioners pending verification of the practitioners' current Drug Enforcement Administration (DEA) registration. The Colorado rule specifies, however, "[c]ontrolled substances may not be distributed outside of the United States unless the pharmacy has obtained registration with DEA as an exporter."

Several states, including Alabama, Arkansas, Colorado, Kentucky, and Texas, also specify information to be included on the labels of medications compounded for office use. Along with several states, the Pharmacy Compounding Accreditation Board (PCAB) requires its accredited compounding pharmacies to include on the label of each package compounded for use in the prescriber's office, "[t]his medicine was compounded in our pharmacy for use by a

licensed professional only. This compounded preparation may not be resold."

In addition to laws pertaining specifically to compounding for office use, several states have regulations on the provision of prescription drugs, compounded or otherwise, to practitioners. Pharmacies must comply with these regulations so as to distinguish their practices from those of wholesalers.

Some states, including Arizona, Georgia, Illinois, Indiana, Maryland, New Jersey, Oregon, and South Dakota, explicitly distinguish the provision of drugs for office use from wholesale distribution. Arizona's Practice Act defines wholesale distribution as "distribution of a drug to a person other than a consumer or patient," excluding "the sale of prescription drugs by a pharmacy, not to exceed five percent of the pharmacy's gross sales, to practitioners for office use." The rules pertaining to *wholesale distribution* in Georgia, Illinois, Oregon, and South Dakota allow the sale of prescription drugs by retail pharmacies to licensed practitioners for office use. Minimal quantities are defined in each state's rules. 

New Day In Health Care

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in requirements for full implementation of health information technology.

Assuming pharmacists will be able to input information regarding individual patient's use of all prescription and over-the-counter medications into electronic health records, they may be positioned to take a more active role in the coordination of patient care and medication reconciliation, stakeholders say.

One of the wrinkles yet to be ironed out in the transition to health information technology pertains to e-prescribing of controlled substances. In an effort to contain the diversion and abuse of controlled substances, Drug Enforcement Administration (DEA) has been cautious about allowing the e-prescribing of these medications. On June 27, 2008, DEA published in the *Federal Register* a proposed rule to revise its regulations to allow e-prescribing of controlled substances. If finalized, the rule would give practitioners the option to transmit prescriptions for controlled substances electronically and would permit pharmacies to receive, dispense, and archive such e-prescriptions.

Yet another wrinkle concerns the need to ensure patient privacy and the security of sensitive information. Consumer groups have continued to raise these concerns, and Obama has vowed to make the security of these records a

priority, although how, and how effectively, that will be accomplished remains to be seen.

Medicare to Negotiate Prices

Obama has indicated he intends to repeal the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which bans the government from negotiating prescription drug prices with pharmaceutical manufacturers for the Medicare Part D program. This change will likely result in a cost savings for the Medicare program and its beneficiaries. One concern raised by opponents, however, is that pharmacies may continue to pay the same amount for these drugs but will be reimbursed less when those drugs are dispensed to Medicare patients.

Health care under the new administration also will strive to eliminate the so-called doughnut hole that some patients currently face, when Medicare halts drug benefits until the beneficiaries have paid a certain amount out of pocket before the benefits resume.

Generic, Therapeutic Substitutions Eyed

Obama also has said he plans to increase the use of generic drugs in public health programs to control medical costs. Currently, according to the 2009 *Survey of Pharmacy Law*, 38 jurisdictions give pharmacists the option to substitute generic medications for name-brand drugs, while 14

states require it. Nine states have designated a list of drugs that are not substitutable, such as drugs with a narrow therapeutic index.

The new administration will likely bring with it a renewed push for the universal implementation of health information technology, including the use of electronic patient medical records and electronic prescribing.

Obama's emphasis on generics may extend to regulation and practice. Burgess says he expects to see more states requiring pharmacists to substitute generic drugs for their brand-name equivalents. He also says he expects to see generics coming to market faster in the coming years and with fewer hurdles to overcome than in the past.

Also on the horizon may be an increased prevalence of therapeutic substitutions, ie, replacing a prescribed medication with another, lower-cost medication in the same drug class, and regulations to encourage this practice, such as the program introduced in the state of Washington. Washington's Therapeutic Interchange Program has developed a process allowing physicians and other prescribers to endorse the Washington State Preferred Drug List, for use by applicable state

agencies as the basis for the purchase of medications in state-purchased health care programs. Endorsing practitioners agree to allow the therapeutic interchange of a preferred drug for any non-preferred drug in a given therapeutic class for patients in state-purchased health care programs. The program requires pharmacists to automatically substitute the preferred drug for the non-preferred drug prescribed by these practitioners, unless the practitioner specifies "dispense as written" or the prescription is for a refill of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug, in which case the pharmacist must dispense the prescribed non-preferred drug.

Moving forward, experts expect to see therapeutic interchanges encouraged and obstacles to generic substitution removed. While the main concern of the boards of pharmacy is the protection of the health and well being of patients in their states, as opposed to drug costs, it is a concern of the boards when costs preclude patients from having access to needed medications.

While Obama supports saving money on mass-manufactured drugs, he also welcomes continued research and development of personalized medicine based on genomics, as demonstrated by his appointments of Harold Varmus, MD, and Eric

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VIPPS: Ten Years

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Verified Internet Pharmacy Practice Sites™ (Vet-VIPPS™) program, which serves as a means to evaluate and accredit legitimately operating online veterinary pharmacy practice sites that dispense medications for companion animals as well as non-food producing animals and ensure that a patient/client relationship exists. This program was developed to assist the states in their efforts to maintain control over the Internet-based distribution of prescription drugs and devices for non-food producing animals as well as hold

Internet veterinary pharmacies accountable for meeting patient/client safety practice standards. The Vet-VIPPS criteria, which is based on the Association's original VIPPS criteria, also incorporates new criteria specific to veterinary pharmacies.

Additionally, to educate patients on the potential dangers of buying medicine online and empower them to make informed choices, in May 2008, the Association created the Internet Pharmacies section of the NABP Web site. Here NABP lists the Not Recommended Internet drug outlets, which do not appear to meet state and



federal laws and NABP patient safety and pharmacy practice standards, as well as the Recommended sites encompassing those Web sites that are VIPPS accredited. See page 64 of this *Newsletter* for an update on the Not Recommended Internet drug outlets.

In conjunction with these programs, NABP also offers the Report-a-Site capability, which is accessible on the Association's Web site. This feature allows

consumers to report any suspicious Internet pharmacy sites to NABP. In turn, NABP will follow up with this report and notify the appropriate regulatory authorities of the suspicious site. The Report-a-Site feature can be accessed under the Resource Links section of the NABP Web site, which is located at the bottom left of the home page.

Additional information on the VIPPS program and a listing of VIPPS accredited pharmacies, as well as details on the other programs mentioned in this article are available on the NABP Web site at www.nabp.net. ⓘ

NABP Sees Huge Growth in Number of DMEPOS Accreditation Applications

Since the launch of its durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program two years ago, NABP has seen incredible growth in the number of applications received. In 2008, NABP received 309 applications, more than doubling the 145 applications received in 2007, and in 2009, the Association received an astounding 303 applications in just one month's time. The deadline for DMEPOS accreditation, as mandated by Centers for Medicare and Medicaid Services (CMS), is September 30, 2009. The NABP DMEPOS program

includes a rigorous accreditation process in support of the CMS quality standards governing this program. Due to the length of time required to conduct DMEPOS accreditation respective of the CMS requirements, and in service to those suppliers already enrolled in the NABP program whose accreditation bids must be completed by the CMS deadline, NABP reserved the right to cease accepting new applications for this program as of January 31, 2009. More information is available under Accreditation Programs on the NABP Web site. ⓘ



NEWLY ACCREDITED DMEPOS FACILITIES

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

Heena Vital Rx, Inc
Chicago, IL
Accredited January 28, 2009

**M&A Pharmacy Corporation,
dba Medex Pharmacy**
Woodhaven, NY
Accredited December 29, 2008

Tech Pharmaceuticals, Inc
Hialeah, FL
Accredited December 29, 2008

**Texas Community Pharmacy
Services, Inc,
dba Community Pharmacy**
Denton, TX
Accredited January 28, 2009

A full listing of accredited DMEPOS facilities is available on the NABP Web site at www.nabp.net. ⓘ

Task Force Recommends Maintenance of TOEFL iBT Passing Standards as a Means of Protecting Patient Safety

After careful deliberation and examination of the current passing standard for the speaking portion of the TOEFL® iBT (Test of English as a Foreign Language™ Internet-based Test), the Task Force to Review TOEFL iBT Score Requirements unanimously agreed during its October 28-29, 2008 meeting to sustain the speaking requirement score of 26.

The task force was charged with determining whether the passing standard required by NABP (1) was equivalent to the requirements for graduates of pharmacy programs accredited by the Accreditation Council for Pharmacy Education (ACPE); (2) represented the appropriate communication skills needed to enter pharmacy practice; and (3) was congruent with the standards required by other, similar health programs such as medicine, nursing, and the allied health professions.

After thorough review and discussion, the task force members presented five recommendations to the NABP Executive Committee.

The **first** recommendation of the task force was that NABP continue to accept the TOEFL iBT as the only English language proficiency testing device for Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification.

In reviewing the possibility of utilizing a different

English proficiency examination as a requirement for the FPGEC, the task force looked at the availability of two alternatives, the University of Michigan's Michigan English Language Assessment Battery (MELAB) and the International English Language Testing System (IELTS). A study conducted by NABP in early 2008, found that the MELAB is only offered three times a year and is available in only two countries and that IELTS, though offered 30 to 40 times per year, is limited to 121 countries. The task force members found these numbers to be less beneficial to applicants than the TOEFL iBT's availability of 30 to 40 times per year in 178 different countries.

In addition, though the IELTS is offered as a face-to-face examination and the TOEFL iBT is provided via computer, only one rater scores each applicant's speaking portion in the IELTS scoring process compared to four raters per applicant in the TOEFL iBT scoring process. The task force felt that the use of four raters provides better odds for well rounded scoring of applicants' proficiency in the English language. In addition, they concluded that the TOEFL iBT's integrated test format provides the best method for determining English proficiency as it tests an applicant's ability to combine

all of his or her communications skills, demonstrating a true understanding of the language.

... task force members discussed the role of today's pharmacists, stressing the necessity for pharmacists to be able to communicate well with patients as the importance of patient counseling takes increasing precedence in the practice of pharmacy.

The **second** recommendation of the task force was that NABP maintain the current passing standard requirement of 26 for the speaking portion of the TOEFL iBT. Task force members conducted a thorough review of the passing standards set by other health care professional organizations including the Commission on Graduates of Foreign Nursing Schools, Educational Commission for Foreign Veterinary Graduates, Federation of State Boards of Physical Therapy, International Commission on Healthcare Professionals, and National Board for Certification in Occupational Therapy, and found the NABP standard to be directly in line with the requirements of these organizations.

During the meeting, task force members discussed the role of today's pharmacists, stressing the necessity for pharmacists to be able to communicate well with patients as the importance of patient counseling takes increasing precedence in the practice of pharmacy.

The **third** recommendation of the task force stated that NABP review the passing standard-setting process in conjunction with other health care professions at an appropriate time to ensure the standards remain valid and psychometrically sound as it had done in May 2005 and March 2008. The task force agreed that the appropriateness and timing of the review should be left to the discretion of the NABP Executive Committee. (More information on the passing standard-setting process is available in the September 2008 *NABP Newsletter* article "NABP Revisits TOEFL iBT Standards for FPGEC Certification, Convenes Task Force to Assess Findings.")

After thoroughly discussing the passing standard-setting process, the task force determined that the TOEFL iBT, which was introduced in 2005, has not been utilized for a sufficient period of time to warrant a reevaluation of the entire standard, hence the members' recommendation for the Executive Committee to decide the appropriate time to convene another standard-setting meeting.

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Model Act Amendment to Require Technician Certification by 2015

NABP will amend its model rules to recommend that the state boards of pharmacy require all pharmacy technicians to be certified by 2015 in accord with the vision for pharmacy practice adopted by the member organizations of the Joint Commission of Pharmacy Practitioners. This upcoming change to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* was among the outcomes of the NABP Task Force on Standardized Pharmacy Technician Education and Training, which met September 9-10, 2008, at NABP Headquarters. The recommendations of the task force were reviewed by the NABP Executive Committee during its February 2009 meeting and subsequently revised to include additional specifications.

New language modifies the definitions section (105) of the *Model Act*, adding a comment, which indicates, “[t]he term Pharmacy Technician will continue to be utilized until 2015.” At that time, the *Model Act* will be amended to require that all pharmacy technicians be certified and to replace the term Pharmacy Technician. The Executive Committee specified the revised term to be Candidate for Certified Pharmacy Technician, which will be defined to provide a path to certification for non-certified pharmacy technicians. The new provisions will al-

low a one-time renewal of the candidate for certified pharmacy technician registration after which, such candidates must become certified pharmacy technicians in order to continue to perform their duties.

The task force encouraged NABP, in the mean time, to maintain its position that boards of pharmacy should license or register pharmacy technicians. In their discussion, task force members recognized that pharmacy technicians are among the few ancillary personnel in the health care field that remain unlicensed in several states. They further remarked that pharmacy technician-attributable medication errors have increasingly gained national media attention, and they voiced concern that this trend has shed a negative light on the regulation of pharmacy practice, particularly in states lacking licensure or registration of pharmacy technicians.

Viewed as a crucial step toward standardization, licensure or registration translates to accountability for pharmacy technicians, which, the task force members agreed, is in the interest of the public health and improved patient care and safety, and addresses the growing problem of diversion by unlicensed pharmacy personnel.

In regard to pharmacy technician certification, task force members concluded that certification

would be a progressive step only if it included some measure of competency. Toward this end, the task force recommended that NABP encourage states, subsequent to implementing a pharmacy technician registration or licensure system, to require technician certification. Upon review, the Executive Committee amended this recommendation to further specify that NABP encourage states that certify technicians to recognize certification by the Pharmacy Technician Certification Board (PTCB). The basis for this decision by the Executive Committee is the fact that PTCB certification and, specifically, the Pharmacy Technician Certification Examination, have been reviewed and approved by NABP pursuant to Resolution 96-1-2000, adopted by the member boards of NABP at the 96th Annual Meeting in 2000.

As part of a system of accountability for pharmacy technicians, the task force also advised NABP to encourage states to continue reporting pharmacy technician disciplinary information to the NABP Disciplinary Clearinghouse. Members discussed the importance for boards of pharmacy to report disciplinary information to the Clearinghouse, especially in light of the prevalence of diversion cases. Disciplinary reporting, members stressed, will make it more difficult for technicians who

have been subject to disciplinary actions in one state to obtain pharmacy employment in another state.

The task force further recommended that NABP expand its licensure transfer program to include pharmacy technicians who have been certified by a program that uses a nationally recognized competency assessment examination. Expanding the licensure transfer program, members determined, would ensure a national pool of pharmacy technicians who have achieved an accepted level of competency and professionalism. Members agreed that technicians must be certified to participate in the NABP licensure transfer program.

Recommended modifications to the *Model Act* include requirements for the registration of certified pharmacy technicians. Revisions to Section 308, Registration of Certified Pharmacy Technicians, include the requirement to “have graduated from a competency-based pharmacy technician education and training program approved by the Board of Pharmacy,” to have “successfully completed a site-specific, competency-based education and training program approved by the Board of Pharmacy,” and to “have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved

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ACE Convenes, Committee Member Honored

On March 9, 2009, the Advisory Committee on Examinations (ACE) convened at NABP Headquarters to oversee the development and administration of the Association's examination and certification programs. **Pictured above from left to right:** Kendall M. Lynch, DPh, vice president, Maxor Correctional Pharmacy Services; Richard K. "Mick" Markuson, RPh, former executive director, Idaho State Board of Pharmacy; Betty Dong, PharmD, professor of clinical pharmacy, University of California, San Francisco; David Todd Bess, PharmD, member, Tennessee Board of Pharmacy; Judy Gardner, PharmD, member, Georgia State Board of Pharmacy; Tom Houchens, RPh, FASCP, director of pharmacy services, Laurel Housing Inc; Michael A. Burleson, RPh, NABP Executive Committee liaison; Kevin Rynn, PharmD, FCCP, clinical assistant professor, Rutgers University; Arthur I. Jacknowitz, MS, PharmD, professor and distinguished chair, West Virginia University School of Pharmacy; and Richard "Dick" Morrison, RPh, pharmacy investigator, Washington State Board of Pharmacy. **Pictured at left:** ACE Chairperson Tom Houchens (right) presented Richard "Mick" Markuson (left) with an award for his dedication and contributions as a member of ACE.



NEWLY ACCREDITED VAWD FACILITIES

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

**Cardinal Health 100, Inc dba
Cardinal Health**
Lakeland, FL
Accredited January 12, 2009

Cutis Pharma, Inc
Woburn, MA
Accredited January 13, 2009

Direct Relief International
Goleta, CA
Accredited January 7, 2009

Intervet, Inc
Omaha, NE
Accredited January 7, 2009

**McKesson Corporation dba
McKesson Drug Company**
LaVista, NE
Accredited January 12, 2009

**McKesson Corporation dba
McKesson Drug Company**
Livonia, MI
Accredited December 17, 2008

**McKesson Corporation dba
McKesson Drug Company**
Memphis, TN
Accredited January 12, 2009

Metro Medical Supply, Inc
Reno, NV
Accredited December 12, 2008

**Midwest Veterinary Supply,
Inc**
Burnsville, MN
Accredited December 17, 2008

**PSS World Medical, Inc dba
Physician Sales & Service**
Rogers, MN
Accredited December 12, 2008

**Teva Pharmaceuticals USA,
Inc**
Chalfont, PA
North Wales, PA
Accredited January 15, 2009

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



NABP 105th Annual Meeting • May 16–19, 2009 • Hyatt Regency Miami Hotel • Miami FL

Meeting Program

Saturday, May 16, 2009

9 AM - 7 PM

Registration/Information Desk Open

1:30 - 4:30 PM

Pre-Meeting CPE

Maxims, Monarchy, and Sir Thomas

More

ACPE #205-000-09-001-L03-P
(0.275 CEUs – 2.75 contact hours)

5 - 6 PM

Annual Meeting Orientation

7 - 10 PM

President's Welcome Reception

Honoring NABP President

Rich Palombo and his wife Sandra

Dinner will be served.

Dress: business casual

Sunday, May 17, 2009

6:30 AM - 5:15 PM

Registration/Information Desk Open

7:30 - 8:30 AM

Fun Run/Walk

8 - 11:30 AM

Joint CPE

Educational Poster Session –

CQI on Fire

ACPE #205-000-09-002-L05-P
(0.1 CEU – 1 contact hour)

8 - 11:30 AM

Hospitality Brunch and Educational Table

Top Display

Noon - 4 PM

First Business Session

12:30 - 1:30 PM

Keynote Address

Tucker Carlson, Senior Campaign

Correspondent, MSNBC

4 - 5 PM

Joint CPE

DEA Update

ACPE #205-000-09-003-L03-P
(0.1 CEU – 1 contact hour)

Monday, May 18, 2009

7 AM - 2 PM

Registration/Information Desk Open

7 - 8:15 AM

NABP/USP Breakfast

8:15 - 10:15 AM

Joint CPE

Patient Counseling – Catch the Wave

ACPE #205-000-09-004-L03-P
(0.2 CEUs – 2 contact hours)

10:30 AM - noon

Second Business Session

Noon - 12:30 PM

Informal Member/Candidate Discussion

1:30 - 5 PM

Magic City Tour

(Afternoon free)

Tuesday, May 19, 2009

7:30 AM - 4:15 PM

Registration/Information Desk Open

8 - 9 AM

Continental Breakfast

9 - 10:30 AM

Executive Officer and Board Member CPE

Compounding Inferno – “For Office Use”

ACPE #205-000-09-005-L03-P
(0.15 CEUs – 1.5 contact hours)

9 - 10:30 AM

Compliance Officer CPE

e-Tools “Out of Hand!”

ACPE #205-000-09-006-L03-P
(0.15 CEUs – 1.5 contact hours)

10:45 AM - 12:15 PM

Joint CPE

Standardization of Technician

Education – Want it? Need it?

ACPE #205-000-09-007-L04-P
(0.15 CEUs – 1.5 contact hours)

12:15 - 1:30 PM

Lunch Break *(On your own)*

1:30 - 4 PM

Final Business Session

5:45 - 6:45 PM

Awards Dinner Reception

7 - 11 PM

Annual Awards Dinner

Dress: semiformal

Note: The 105th Annual Meeting schedule is subject to change.



NABP and the NABP Foundation is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. ACPE Provider Number: 205. Participants may earn up to 9.75 contact hours (0.975 continuing education units) of ACPE-approved continuing pharmacy education credit from NABP. Participants in continuing pharmacy education programs will receive credit by completing a “Statement of Continuing Pharmacy Education Participation” and submitting it to NABP. A validated Statement of Continuing Pharmacy Education Credit will be sent as proof of participation within approximately six weeks. Full attendance and completion of a program evaluation form for each session are required to receive continuing pharmacy education credit and a Statement of Continuing Pharmacy Education Credit.

Continuing Legal Education (CLE) Policy: NABP staff will be available to assist attendees on an individual basis to apply for CLE credit for attending CPE sessions. To apply for CLE credit, attendees must initiate the program approval process in their own states by completing and submitting the appropriate application materials and forms. NABP will provide documentation as necessary.

Registration Available for 105th Annual Meeting in Miami

Register now to attend the 105th Annual Meeting, “NABP MIAMI: Quality Care – *It’s Hot! Hot! Hot!*” to be held May 16-19, 2009, at the Hyatt Regency Miami Hotel in Florida.

Prospective attendees can register directly online using the new and improved online

registration form by visiting the Meetings section of the NABP Web site at www.nabp.net. A printable registration form can also be downloaded by anyone wishing to mail or fax the form to NABP. Both types of registration offer attendees three payment options: (1) mailing in the

payment, (2) using a credit card, or (3) paying in Miami.

New this year, NABP now accepts American Express, as well as MasterCard and Visa.

Registration and additional information about the 105th Annual Meeting is available in the Meetings section of the NABP Web site. ⓘ

NABP Travel Grant Offered to Assist State Boards in Sending Voting Delegates to Annual Meeting

NABP is once again offering the Annual Meeting Travel Grant to qualified state board of pharmacy voting delegates for the 105th Annual Meeting to be held May 16-19, 2009, at the Hyatt Regency Miami Hotel in Florida. The travel grant was established by NABP in an effort to assist boards in sending representatives to the Annual Meeting so that they may participate in important business sessions, including discussing and voting upon resolutions,

electing NABP Executive Committee members and officers, and attending educational sessions regarding current issues facing pharmacy regulators.

This travel grant defrays the costs for designated voting delegates by providing funds for travel expenses, including airfare, hotel rooms, meals, taxis, parking, and tips. Qualified voting delegates will have the opportunity to receive up to \$1,200 in grant monies to attend the NABP 105th

Annual Meeting. The grant does not include Annual Meeting registration fees.

Last year, NABP was able to provide 30 state boards of pharmacy with grants to attend the NABP 104th Annual Meeting.

Grant applications and submission instructions may be obtained from NABP upon the direct requests of executive officers of the state boards of pharmacy. NABP requests that applications be submitted by executive of-



ficers to NABP Headquarters prior to the Annual Meeting.

Questions may be directed to exec-office@nabp.net. All applicants will be informed of whether or not they have qualified for the grant. ⓘ

Announcing the 2009 Symposium – Same Time, Same Place, Entirely New Continuing Pharmacy Education!

NABP invites board of pharmacy executive officers, members, and compliance officers as well as state and federal regulators and other stakeholders to unite December 3-4, 2009, for the NABP 2009 Symposium. A fast-paced,

one-and-a-half-day workshop, the Symposium will once again be held at the JW Marriott Starr Pass Hotel in Tucson, AZ, and will offer attendees the opportunity to discuss current issues in pharmacy. In addition, attendees may

earn Accreditation Council for Pharmacy Education-approved continuing pharmacy education. More information to follow in future issues of the *NABP Newsletter* and on the NABP Web site at www.nabp.net. ⓘ

Miami's Optional Events are Hot! Hot! Hot! – Exciting Networking Opportunities Available to Attendees

Attendees of the NABP 105th Annual Meeting will be provided with exciting opportunities to network and share information with their fellow state board of pharmacy members and other pharmacy professionals during the meeting's programming and optional events. To be held May 16-19, 2009, at the Hyatt Regency Miami Hotel in Florida, attendees will be able to participate in the Optional Tour, the Fun Run/Walk, Hospitality Brunch, and the Annual Meeting Orientation.

The Magic City Tour

Miami is known for its beaches, nightlife, diverse cultures, and art, and attendees of the Magic City Tour will see highlights of these attractions as they are guided through the scenic city. The tour will take place Monday, May 18 from 1:30 - 5 PM when guests will board an air conditioned motor coach for an informative and exciting adventure through South Beach, Miami Beach, downtown Miami, Coconut Grove, and Calle Ocho.

The tour will begin with a visit to America's largest Art Deco district where pastel colors shimmer in the sun. Throughout the tour, professionally trained tour guides will narrate points of interest including the route of

the annual Orange Bowl Parade.

Tour participants will also travel through the Coral Gables neighborhood, famous for its Venetian-like canals, winding roads, wrought iron work, and sculptures. The Biltmore Hotel and Venetian pool are also just a couple of highlights within Coral Gables.

The cost of the tour is \$49 per person. Advanced registration is required by **Monday, April 27**, as space is limited.

Annual Fun Run/Walk

NABP will offer its attendees a chance to warm-up for the day's Annual Meeting activities with the Fun Run/Walk on Sunday, May 17 from 7:30 to 8:30 AM. Sponsored by Pfizer Inc, this three mile run/walk will begin at the hotel and travel through Miami's historical and scenic Bayfront Park, which is in the heart of downtown Miami on Biscayne Bay. Designed by the innovative 20th Century American sculptor, Isamu Noguchi, Bayfront Park surrounds 32 acres of lush greenery, with a small sand beach, a tropical rock garden and waterfall, cascading fountain, a light tower, and many different monuments commemorating events and people

throughout history. Also, located within the park is the Bayfront Park Amphitheater and the Tina Hills Pavilion, which host many concerts and shows.

Participants will receive a Fun Run/Walk t-shirt when they check in for the meeting at the Registration/Information Desk, and bottled water and granola bars will be provided the morning of the event. Participants are asked to register (at no charge) by **Monday, April 27**.

Hospitality Brunch

Attendees of the 105th Annual Meeting will have another chance to network and gain knowledge during the Hospitality Brunch on Sunday, May 17. From 8 to 11:30 AM, attendees will be able to gather with colleagues supportive of the objectives of the boards of pharmacy, while partaking in a full buffet brunch.


In addition, educational table top displays that will be set up in the area by NABP, federal regulatory agencies, and other associations will highlight important issues and programs.

Just a few steps away from the brunch will be the Educational Poster Session – "CQI on Fire." Displays will provide in-

formation, such as a board of pharmacy's best or most noteworthy legislative issues, policy development, disciplinary cases, and research results that discuss continuous quality improvement. Universities and colleges of pharmacy will also display posters. Participants of the Poster Session can earn up to one contact hour (0.1 CEU) of Accreditation Council for Pharmacy Education-approved continuing pharmacy education (CPE) credit. Attendees will need to spend at least 60 minutes in the Poster Session area, discussing the displays and self-assessment questions with presenters in order to earn CPE credit.

Annual Meeting Orientation

Recently appointed board of pharmacy members attending their first NABP Annual Meeting are encouraged to attend the Annual Meeting Orientation from 5 to 6 PM on Saturday, May 16, where information will be provided regarding the procedures followed during the Annual Meeting.

Registration and more information about the 105th Annual Meeting are available in the Meetings section of the NABP Web site at www.nabp.net. 

NABP Announces 2009-2010 MPJE Review Committee

NABP is pleased to announce the Multistate Pharmacy Jurisprudence Examination® (MPJE®) Review Committee members for 2009-2010. Composed of faculty and/or pharmacists who are representative of the diversity of pharmacy practice, the MPJE Review Committee shares the responsibility for developing and reviewing the items in the MPJE. This team of dedicated volunteers, acting under the policy and planning guidance of the Advisory Committee on Examinations and the Executive Committee, convene to review the MPJE and safeguard the integrity and validity of the Association's examination. Responsibilities include reviewing the examination questions and attending and participating in meetings. NABP appreciates the assistance of these committee members as they evaluate examination content and ensure that it meets the specified competency assessment statements, which, in essence, determine the question pool. The MPJE Review Committee members are listed at right. Their terms began February 1, 2009.

Review Committee Members


- Alan M. Shepley, Mount Vernon, IA
- C. Richard Allen, Georgia State Board of Pharmacy
- Charles W. Sauer, Sycamore, IL
- Cynthia Benning, Milwaukee, WI
- Denise M. Frank, Princeton, MN
- Grace Cheung, Washington State Board of Pharmacy
- James D. Coffey, Massachusetts Board of Registration in Pharmacy
- John D. Taylor, Tallahassee, FL
- Michael A. Moné, O'Fallon, MO
- Richard Morrison, Washington State Board of Pharmacy
- Steve Morse, Pflugerville, TX
- Vance Alexander, Birmingham, AL
- Vickie Seeger, Richmond, VA 

List of Not Recommended Internet Drug Outlets Grows

The number of Internet drug outlets listed on the NABP Web site that do not appear to meet state and federal laws and NABP patient safety and pharmacy practice standards grew to 1,938 as of March 20, 2009. Of these:

- 1,848 sites do not require a valid prescription
- 1,026 sites offer foreign or non-FDA-approved drugs
- 745 sites are located outside the United States and selling drugs illegally to patients in the US

Sixteen sites are listed as Recommended. These sites are accredited through the NABP Verified Internet Pharmacy Practice Sites™ (VIPPS®) program.

A full listing of Recommended and Not Recommended sites, along with program criteria and related patient information, is available in the Internet Pharmacies section of the NABP Web site at www.nabp.net. 


NABP Examinations

(continued from page 53)

In 2008, approximately 90 countries were represented at the FPGEE administrations. Of those 90 countries, approximately 60% of the total applicants who took the FPGEE originated from five countries. India had the highest number of applicants, followed

by the Philippines, Korea, Egypt, and Nigeria. In addition to the FPGEE, a total of 487 individuals took the Pre-FPGEE™ in 2008. The Pre-FPGEE exhibits the types of questions provided on the FPGEE and offers applicants a chance to familiarize themselves with the examination.

Beginning with the April 14, 2009 administration, the FPGEE will be provided as

a computerized examination and the paper-and-pencil examination will be eliminated. The FPGEE will continue to be administered once in the spring and once in the fall; however, instead of only having three testing sites to choose from, applicants will be able to choose from more than 200 Pearson VUE testing sites located within the continental US. 

FDA Teams With WebMD for New Online Consumer Health Information

Food and Drug Administration (FDA) and WebMD have collaborated to expand patients' access to FDA's health information. The partnership includes a new online patient health information resource on WebMD .com. This resource provides information on the safety of FDA-regulated products, how to report problems involving the safety of these products, FDA public health alerts, and FDA's Consumer Updates. FDA Consumer Updates also will be featured at least three times a year in the bimonthly *WebMD The Magazine*. The partnership is described in a Memorandum of Understanding, posted in the *Federal Register* [Docket No. FDA-2008-N-0043].

FDA Accepting Comments on CMI Study Report

FDA is currently accepting comments on a consumer medication information (CMI) study report [Docket No. FDA-2008-S-0627], which found that the overall comprehensibility of printed CMI fails to meet target compliance levels. Comments will be accepted until June 1, 2009.

The study was released December 16, 2008, by FDA and found that CMI voluntarily provided with new prescriptions by retail pharmacies does not consistently provide easy-to-read,

understandable information about the use and risks of medications. NABP conducted the study to evaluate the progress of community pharmacies in meeting federally mandated goals for dispensing useful written CMI, with a grant provided by FDA. The study, Expert and Consumer Evaluation of Consumer Medication Information, shows that while most consumers (94%) received CMI with new prescriptions, only about 75% of this information met the minimum criteria for usefulness as defined by a panel of stakeholders. In 1996, Congress called for 95% of all new prescriptions to be accompanied by useful CMI by 2006. The study shows that the content, format, and overall comprehensibility of CMI lag far behind the target compliance levels set forth in Public Law 104-180. The full report is available on the FDA Web site.

RFID CPG Expiration Date Extended through 2010

FDA is extending the expiration date of compliance policy guide (CPG) section 400.210, "Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs," to December 31, 2010. The CPG, introduced in 2004, describes how FDA intends to exercise its enforcement discretion regarding certain regulatory requirements that might otherwise be applicable to studies involving RFID technology for drugs. The goal of the CPG is to fa-

cilitate performance of RFID studies and to allow industry to gain experience with the use of RFID technology and its effect on the long-term safety and integrity of the United States drug supply.

The Food and Drug Administration Amendments Act of 2007 includes a provision requiring the development of standards for the identification, validation, authentication, and tracking and tracing of prescription drugs. These new standards are to address promising technologies, which may include RFID technology. FDA is currently addressing such issues that may be relevant for the CPG. More information is available in the *Federal Register* [Docket No. FDA-2004-D-0298].

Pharmaceutical Industry Agrees to Moratorium on Drug Maker Gifts

Pharmaceutical companies have agreed to stop giving branded gifts, such as pens, mugs, and mouse pads, to practitioners starting January 1, 2009. Critics of this practice say it encourages doctors to prescribe more of the drugs, the *New York Times* reported on December 30, 2008. The Pharmaceutical Research and Manufacturers of America (PhRMA) Board of Directors unanimously adopted measures in June 2008 to enhance the PhRMA Code on Interactions with Healthcare Professionals to include this provision. "The revised, voluntary code reaffirms that interactions between pharmaceutical company representa-

tives and health care professionals should be focused on informing the health care professionals about products, providing scientific and educational information, and supporting medical research and education," according to a PhRMA statement naming 38 companies that signed on to the agreement as of December 19, 2008.

HHS Releases Guidance On Use of Pandemic Flu Drugs

Health care workers and emergency services personnel who could have direct contact with individuals who are ill during an influenza pandemic should be protected with antiviral drugs throughout the pandemic, even before these workers are exposed or become ill themselves, according to guidance released December 16, 2008, by the US Department of Health and Human Services (HHS). Stockpiling these antiviral drugs and planning for their use is the responsibility of employers as part of comprehensive pandemic preparedness, the guidance says.

The guidance also recommends preventive antiviral drug use for certain individuals following exposure to someone who is sick with pandemic influenza. HHS continues to recommend using antiviral drugs to treat people with pandemic influenza illness as a way to slow the spread of pandemic disease. National and state antiviral drug stockpiles, intended primarily for these uses, contain enough antiviral drugs for more than 72 million people. ③

Around the Association

Executive Director Changes

● **John A. Foust, DPh**, has been appointed the executive director of the Oklahoma State Board of Pharmacy replacing Bryan Potter, DPh, effective January 1, 2009. Prior to this, Foust was the director of pharmacy at INTEGRIS Grove General Hospital in Grove, OK, and Willow Crest Hospital in Miami, OK. He also served as a compliance officer with the Board in 1998, and has served on several Board rules committees over the years. In addition, Foust is a member of Oklahoma Pharmacists Association and Oklahoma Society of Health-System Pharmacists. He holds a bachelor of science degree in pharmacy from Southwestern Oklahoma State University and a doctor of pharmacy degree from the University of Oklahoma.

● **Kimberly A. Grinston, JD**, has been appointed the executive director of the Missouri Board of Pharmacy effective January 5, 2009. Grinston has more than 11 years of legal, legislative, and administrative

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Idaho Board Attends DEQ Pharmaceutical Waste Disposal Workshop

In September 2008, the Idaho Department of Environmental Quality hosted a Pharmaceutical Waste and Disposal Workshop that drew nearly 50 participants including representatives of the Idaho State Board of Pharmacy, Drug-Free Idaho, Boise State University, and various local governments and nonprofit groups throughout the state. The workshop was held to allow experts to present information on pharmaceutical waste disposal and for participants to contribute ideas and suggestions. Input from the workshop was the first step in learning about the issues and concerns related to developing a pharmaceutical waste and disposal program in Idaho. Follow-up meetings are planned to begin exploring potential legislative or regulatory changes needed, funding options, and public education and outreach efforts.

Currently, controlled substances and medications can be collected only by Drug Enforcement Administration or members of local law enforcement, the Board notes. In order to run a successful take-back program that includes controlled substances, law enforcement must maintain immediate custody during the take-back program and also be responsible for its disposal. Prescription medications "shall not be accepted for return by any

pharmacist or pharmacy." More details are available in IDAPA rule 27.01.01.156.05.

Kansas Board Reports Changes in Incident Reporting

On September 24, 2008, the Kansas State Board of Pharmacy held a public hearing on proposed changes to the Kansas Incident Report Regulation. These changes were necessary to ensure continuity between this regulation and the continuous quality improvement (CQI) statute passed by the Kansas Legislature in 2008, which required each pharmacy in Kansas to establish a CQI program no later than July 1, 2009. The purpose of the program is to assess errors in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence of any errors.

The new provisions in the Incident Report Regulation will delineate what constitutes a "reportable incident for purposes of preparing the incident report." A pharmacy must report preventable medication errors involving a prescription drug and resulting in the following:

1. the patient receiving the wrong drug;
2. the patient receiving an incorrect drug strength;
3. the patient receiving an incorrect dosage form;
4. the drug being received by the wrong patient;
5. inadequate or incorrect packaging, labeling, or directions; or

6. the dispensing of a drug to a patient in a situation that results in or has the potential to result in serious harm to the patient.

The pharmacist-in-charge (PIC) shall ensure that procedures exist requiring pharmacists who become aware of a reportable incident as defined above to alert the PIC of the incident as soon as practical so that a report can be prepared. The responsibility of preparing an incident report falls on each pharmacist involved in the incident and the PIC. Any employee involved in the incident must sign the incident report. Incident reports must be maintained for a minimum of five years. The incident reports should be reviewed at least once per quarter of each calendar year and a CQI report, according to the Board which takes the place of the Plan of Action Requirements, should be generated. The CQI report should list those persons in attendance at the quarterly meeting, the list of incident reports reviewed, and a description of the steps taken or to be taken to prevent a recurrence of each incident that was reviewed. All reports generated by the CQI program are available for inspection by the Kansas Board.

AR Board Adopts Changes to Pharmacy and Wholesale Distributor Regulations

As a result of a public meeting held during the Arkansas State Board of

Pharmacy's October 2008 meeting, the Board adopted changes to two of its regulations, Regulation 4 and Regulation 8.

Regulation 4 – Pharmacy, was amended to clarify equipment requirements. In addition, to be consistent with Food and Drug Administration guidelines and Department of Health regulations, the regulation now specifies that food is not to be stored in the refrigerator with prescription medications.

To better organize the pharmacy regulations, a major restructuring took place around 2000. During this restructuring, several sections were placed under the retail pharmacy heading when they should have

been placed in the initial section of Regulation 4 under "General Regulations Regarding Pharmacies." Since these areas of the regulation were always intended to apply to all types of pharmacies, they have been rearranged so that they are now located under "General Regulations Regarding Pharmacies."

In addition, there has been an update for areas of the regulation to reflect previous changes in the statutes and regulations including changing references of "annual" to "biennial" renewal of permits to be consistent with the Board's biennial permits that are currently issued.


The last change in Regulation 4 is to section

04-05-0001 – Hospital Pharmaceutical Services Permit. This section is being reworded to further specify the role of a PIC and the time requirements for the PIC in hospital settings. This change was made because the language "one (1) pharmacist" was intended to mean the PIC as it had been interpreted by most hospitals but was not stated specifically so. This change will correct this oversight and speak directly to the intent of the regulation.

Regulation 8 – Wholesale Distribution, was amended to clarify language regarding the requirements for a wholesale distributor in Arkansas to report thefts or losses of

controlled substances in a timely manner, consistent with the requirements for pharmacies to report losses.

Changes also delete the term "annually" in reference to registration with the Board of Pharmacy and replace "annual license renewal" with "biennial license renewal" to be consistent with the fact that all permits issued by the Board of Pharmacy are issued on a biennial basis.

The above summaries briefly explain the overall changes to the regulations. These regulations can be viewed in their entirety on the Board Web site in the Pharmacy Lawbook section at www.arkansas.gov/asbp. 

Around the Association

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experience in Missouri state government. Prior to her current position, she served as an assistant attorney general, senior legal counsel for the Missouri Department of Insurance, and as legal counsel for the Division of Professional Registration where she provided general counsel services to a wide variety of autonomous and

administrative licensing boards/commissions.

Board Member Appointments

- **Kenny Sanders, RPh**, has been appointed a member of the Alabama State Board of Pharmacy. Sanders' appointment will expire on December 31, 2013.
- **Ryan Brooks** has been appointed a public member to the California State Board of Pharmacy. Brooks' appointment will expire on June 1, 2012.

- **Nenad Milenkovich, PharmD, JD**, has been appointed a member to the Illinois Division of Professional Regulation – State Board of Pharmacy. Milenkovich's appointment will expire on April 1, 2012.


Board Officer Changes

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

- **Tammy H. Rogers, RPh**, President

- **Mike Mikell, RPh**, Vice President
- **Robert J. Nelson, PharmD**, Treasurer

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

- **Kenneth H. Schell, PharmD**, President
- **D. Timothy Daze**, Vice President
- **Stanley C. Weisser, RPh**, Treasurer 

Legal Briefs

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amount of \$250,000. The defendants filed a motion for summary judgment, which admits there are no issues of material fact in dispute and allows a court, without a trial, to rule on a complaint as a matter of law.

The defendants first argue that the Eleventh Amendment to the United States Constitution bars claims for damages against them in their official capacities. The Eleventh Amendment prohibits federal courts from entertaining suits by private parties against states and their agencies unless the state unequivocally waives its Eleventh Amendment protections or Congress abrogates the state's Eleventh Amendment immunity. However, plaintiffs may seek prospective equitable relief for ongoing violations of federal law against a state official under the Ex Parte Young doctrine. But, state agencies and state officials in their official capacities are immune from lawsuits seeking money damages. The court held that the Board was a state agency for purposes of the Eleventh Amendment. Thus, the court granted the defendants motion for summary judgment as to that portion of her complaint seeking \$250,000, but upheld her right to pursue equitable relief.

The applicant also alleged that the defendants deprived her of her liberty interests without due process of law under the Fourteenth Amendment of the United States Constitution. The Fourteenth Amendment provides that no one may be "deprived of life, liberty, or property, without due process of law." Due process generally means notice and an opportunity for a hearing. The first inquiry under a due process analysis is whether the applicant was deprived of life, liberty, or property. If she establishes a protected interest, the next inquiry is what process is therefore due.

The applicant argued that the state deprived her of her liberty interest to pursue her chosen profession of teaching. Citing other judicial opinions, the court stated that certain professions, including teachers, must meet certain criteria related to education, age, and passage of an examination(s) as part of the application and licensure process. Further, the court noted that the protected interest does not vest until the applicant satisfies the statutorily mandated requirements for a professional license.

Relating to the facts of the case, the court noted that the applicant did not have an initial or standard certificate to teach in Illinois schools, but instead possessed a substitute teaching certificate. As argued by the defendants,

there are no state imposed testing requirements to obtain or maintain a substitute teaching certificate. Thus, the court concluded

Boards of pharmacy are encouraged to understand and meaningfully participate in the programs and processes related to licensure decisions, including the use of NABP programs, to ensure compliance with the public protection, statutory mandates of the practice acts.


that the applicant has "no claim of entitlement and consequently has no protected interest."

The applicant also argued that the conduct of the defendants damaged her reputation and her ability to pursue her chosen career. While judicial opinions have clearly held that individuals do not have a cognizable liberty interest in their reputations subjecting due process protections, the government may be found to infringe upon an individual's liberty interest to pursue the occupation of choice where a state actor casts doubt upon an individual's good name in such a manner that makes it virtually impossible to

pursue employment. To establish such a claim, the applicant must show that the defendant's actions stigmatized her, that such stigmatizing information was publicly disclosed, and that the impacted party has suffered a tangible loss.

The court held that the applicant did not address any of these necessary elements which would or might create a disputed issue of material fact and, thus, granted the defendants' motion for summary judgment dismissing the matter.

Several important issues are addressed in this case, including the potential for imposters to sit for the licensing examination, the need for forensic evidence in the event of allegations of wrongdoing in the examination process, the differentiation of legal rights between applicants for licensure and licensees, and the potential liability of a state board in the event of publication of certain information about applicants and/or licensees. Boards of pharmacy are encouraged to understand and meaningfully participate in the programs and processes related to licensure decisions, including the use of NABP programs, to ensure compliance with the public protection, statutory mandates of the practice acts.

Bates v Dunn, 2008 WL 554243 (ND Ill 2008) 

Medication Collection Program Task Force Calls for Multifaceted Approach to Solution for Safe Drug Disposal

Medication collection programs, patient education, and reductions in unused drugs are all important strategies for curbing the effect of drug disposal on the environment, the members of the Task Force on Medication Collection Programs concluded at their December 6, 2008 meeting in Tucson, AZ.

Established in response to Resolution 104-5-08, Task Force on Medication Collection Programs, which was approved by the NABP membership at the Association's 104th Annual Meeting in May 2008, the task force met to consider the following charges:

1. Evaluate the status of medication collection programs throughout the country.
2. Review state and federal laws and regulations, including those administered by the United States Drug Enforcement Administration (DEA), applicable to medication collection programs.
3. Suggest possible medication collection program protocols compliant with current, applicable state and federal laws and regulations.
4. Recommend revisions, if necessary, to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* addressing this issue.

One of the first issues the task force members discussed was the current inability to collect controlled substances due to the closed distribution system. Noting that DEA planned to release an Advance Notice of Rulemaking in early 2009 pertaining to this issue, the task force members' first recommendation was that NABP monitor the situation and provide comment at the appropriate time to advocate for DEA to allow licensed pharmacies to be repositories for unused controlled substances.

As part of their discussions, the task force members reviewed the strengths and weaknesses of several existing medication collection programs. They agreed that, although the reviewed medication collection programs are advantageous in that they achieve the collection of some unused medications, challenges still exist, particularly with the collection of controlled substances. Many of the programs reviewed were organized, efficient, convenient, low in cost, secure, Health Insurance Portability and Accountability Act-compliant, and ecological through the use of high temperature destruction. Disadvantages found in some of the programs included infrequent or sporadic collections, expensive public notice, no assurance of proper disposal, lack of accountability, quantity/

volume restrictions, need for continuous public education, disposal in landfills, and no patient feedback. As such, the task force members

Reducing the amount of unused medications may be a crucial factor in reducing the impact of medications on the environment because it would lessen the amount of drugs that are carried "down-stream".

recommended that NABP provide general guidelines to assist the state boards of pharmacy in the development of medication collection programs to ensure compliance with applicable state and federal laws and regulations. In regard to suggesting possible medication collection program protocols that comply with current, applicable state and federal laws and regulations, the members agreed that boards of pharmacy should focus on the following factors:

1. Involved entities
2. Regulating authority to ensure compliance with applicable state and federal rules and regulations
3. Responsibility for program implementation
4. Program funding
5. Program components
 - a. Method of collection

- b. Record keeping
- c. Storage/security
- d. Transportation
- e. Disposition
 - i. High-temperature incineration preferable; or
 - ii. Disposal in landfills

In addition to the development of medication disposal programs, the task force recognized the importance of reducing the amount of unused medications, and therefore recommended that NABP work with the appropriate stakeholders to research the feasibility of establishing methods that will reduce the amount of unused prescription medications that require disposal. Reducing the amount of unused medications may be a crucial factor in reducing the impact of medications on the environment because it would lessen the amount of drugs that are carried "down-stream" to a point where they may need to be disposed of through such programs. Members discussed how the culture for "super-sizing" in the US may also be at work in the purchasing of prescription medications, with patients purchasing the largest amount available and potentially resulting in increased amounts of unused medications that require disposal. Additionally, many third-party payers encourage three-month supplies of medication even when a pa-

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nabp newsletter

Technician Certification

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by the Board of Pharmacy.” The revisions also incorporate provisions for grandfathering.


The discussion, however, is not over yet. Members agreed that standardization of pharmacy technician education and training is an ongoing issue and

should be addressed on a regular basis until at least such time that all states license or register pharmacy technicians and that a national licensure transfer program is operational.

To achieve that goal, the task force recommends that NABP develop an interactive educational session at the 105th Annual Meeting to address issues

related to the standardization of pharmacy technician education and training. Furthermore, the task force recommends that NABP request a second meeting of the task force and/or create a standing committee on pharmacy technicians to review existing state requirements for educational and training programs and national

accrediting organizations’ core competencies. This group would be charged with recommending national standards for the educational and training requirements for pharmacy technician certification.

The full report of the task force is available on the NABP Web site at www.nabp.net under News/Press. 

Medication Collection Program

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tient has not been stabilized on a particular drug or dose. To curb this behavior, the task force members agreed that a two-prong approach that includes an educational component and an incentive program is necessary to achieve this goal. However, realizing the effect on stake-

holders, members concluded that further research is necessary to assess the feasibility of this approach.

The task force also discussed medication reuse programs, and recommended that NABP work with the boards of pharmacy and appropriate state and federal agencies, such as Food and Drug Administration, to research programs for the reuse of

previously dispensed prescription medications and whether safe and legally compliant methods can be utilized. The task force members recognized the societal value of reusing medications rather than having them destroyed; however, they agreed that any medication collection programs for reuse must be compliant with all state and federal regulations

including standards of the United States Pharmacopeia to ensure public safety.

The recommendations of the task force were approved by the NABP Executive Committee during its February 2009 meeting. The full report of the task force is available on the NABP Web site at www.nabp.net under News/Press. 

New Day In Health Care

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Lander, PhD, as co-chairs of the President’s Council of Advisors on Science and Technology. Varmus, who received the Nobel Prize for his work in cancer research, is the former director of the National Institutes of Health and current president of the Memorial Sloan-Kettering Cancer Center. Lander is the founding director of the Broad Institute and a


Massachusetts Institute of Technology biologist who was instrumental in the human genome project.

Questions of Conscience Remain

One of President Bush’s 11th hour actions was to establish federal protection for health care workers’ rights of conscience, allowing those in certain settings receiving federal funds to opt out of providing any services or information they might

find morally objectionable. This topic has arisen repeatedly since emergency contraception, commonly referred to as “Plan B,” became available over the counter for adults. Several pharmacists have refused to dispense the drug, citing moral objections, raising legal questions over the patients’ right to obtain the medication vs the pharmacists’ right to refuse to dispense it, or to impede the patients’ ability to obtain it elsewhere.

It is yet to be seen as to whether or not this rule nullifies board of pharmacy regulations in states that require pharmacists to dispense all valid prescription drug orders.

The US Department of Health and Human Services (HHS) issued a proposal to rescind the rule in the March 10, 2009 *Federal Register*. HHS will accept comments on the proposal through April 9. 

TOEFL iBT Passing Standards

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As a **fourth** recommendation, the task force proposed that NABP close its investigation into petitioners' complaints and allegations pertaining to the TOEFL iBT. The task force carefully considered all concerns voiced by the petitioners and found that their allegations bore no merit for NABP to lower the TOEFL iBT standards for the speaking portion or to utilize other English language proficiency examinations for FPGEC Certification. The negative assertions pertaining to the TOEFL iBT were found to have stemmed from a small group of petitioners and were not thought to be the view of the majority of TOEFL iBT test takers.

After reviewing the petitioners' allegations in depth, the task force concluded that:

- of those requesting an alternative English proficiency test, none had provided proof of successful passage of either the MELAB or IELTS;
- of those alleging grading discrepancies, none had indicated that they requested an independent rating;
- of those alleging unfair and illogical scoring process, none stated that they utilized the TOEFL iBT practice test to prepare;
- of those lodging complaints about the allotted time, none had conceded that the time frame was consistent and realistic as compared to the North American Pharmacist Licensure Examination®; and
- of those presenting complaints about environmental issues, none provided compelling evidence that real-life work situations are less stressful, and without noise or disruptions of any kind.


The task force also viewed a demonstration of the TOEFL iBT practice test during its deliberation. This official guide, which is meant to provide applicants with a more transparent view of the scoring process, assists applicants in preparing for the TOEFL iBT by including real examples of high, medium, and low scoring responses.

After careful review, it was agreed that despite the petitioners' allegations, the TOEFL iBT is an objective and transparent examination and, with proper preparation, applicants should be capable of obtaining a passing score.

The **fifth** and final recommendation of the task force was that NABP establish a dialogue to the extent possible with the TOEFL iBT provider, Educational Testing Services (ETS), regarding future complaints pertaining to test center conditions. Though

the current allegations of the petitioners appeared to hold no merit, the task force believes that NABP should work closely with ETS to exchange information regarding future complaints to ensure that all allegations are adequately addressed.


Overall the members agreed that the importance of English proficiency and the ability to successfully communicate is an essential component of the practice of pharmacy. Requiring a high standard is not meant to create a barrier for foreign graduates but, rather, a means of continuing to promote patient safety.

The recommendations of the task force were approved by the NABP Executive Committee during its February 2009 meeting. The full report of the task force is available on the NABP Web site at www.nabp.net under News/Press. 

Why was the Task Force to Review TOEFL iBT Score Requirements Convened?

Developed at the direction of the NABP Executive Committee, the Task Force to Review TOEFL iBT Score Requirements convened following the NABP Advisory Committee on Examinations (ACE) TOEFL iBT review in late 2007. During this review, ACE assessed the use of the TOEFL iBT as the sole English proficiency examination required for FPGEC Certification as a response to some concerns raised by graduates of foreign pharmacy schools.

ACE conducted extensive research on the use of alternative examinations to measure students' English proficiency to determine if three main objectives could be preserved: (1) uniformity throughout the FPGEC program must be maintained; (2) the examination must remain highly accessible to applicants; and (3) any changes to the requirements must minimally impact the state boards of pharmacy and any existing regulations. From its

research, ACE recommended to the NABP Executive Committee that it forego the adoption of a new examination and continue to require the TOEFL iBT since the examination reaches the greatest number of FPGEC applicants and provides continuity and uniformity in testing from location to location. In turn, the Executive Committee called for the development of the task force to further examine the current TOEFL iBT passing standard required. 



Register now for the NABP 105th Annual Meeting.
See page 60 for details.



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