

newsletter

AID TO GOVERNMENT - THE PROFESSION - THE PUBLIC - 1904 TO 2000

FPGEE Moves to Computer-based Format

The days of filling in endless tiny circles with a No. 2 pencil are over. On November 1, 2000, NABP converted the Foreign Pharmacy Graduate Equivalency Examination™ (FPGEE®) component of its Foreign Pharmacy Graduate Examination Committee® (FPGEC®) certification program from a paper and pencil to a computer-based examination. The new format is expected to make the FPGEE more accessible to candidates through a national system of testing centers that will offer the examination Monday through Friday all year.

In previous years, the FPGEE was offered on a single test date in one or two locations in the US. The computer-based examination is now available to candidates five to six days per week.

The FPGEE is offered through the LaserGrade Testing Network, of Vancouver, Wash. Candidates who have met eligibility requirements can sit for the examination at any of LaserGrade's testing centers in the United States and its territories.

The computer-based format also reduces the time needed to complete the examination from eight to six hours. In addition

to speed, accuracy is improved because applicants no longer have to properly fill in small circles on paper. Instead, their responses are made directly onto a computer monitor with a mouse or keyboard.

Another advantage of computerizing the test is that the program prompts the applicant at the end of the test for skipped questions.


Of the approximately 1,800 FPGEE applications received by the FPGEC to date, 200 individuals have qualified for the FPGEE. The certification process can take months.

In 1999, 1,350 applicants qualified to take the test and 1,100 sat for it. In 1998, 1,662 applications were received, and 879 sat for the FPGEE. About 70% of test takers pass.

In the process of FPGEC certification, candidates provide documents that verify their educational backgrounds and licensure and/or registration. In addition to the FPGEE, candidates must pass the Test of English as a Foreign Language and the Test of Spoken English. The FPGEC Certificate allows foreign graduates to partially fulfill eligibility

requirements for licensure in the states that consider the Certification.

With the computerization of the FPGEE, all of NABP's current examinations are offered through computer-testing centers. The computer-adaptive Multistate Pharmacy Jurisprudence Examination™ (MPJE™) was introduced in 1998, and the North American Pharmacist Licensure Examination™ (NAPLEX®) was computerized in 1997.

For more information on the FPGEC certification program, call NABP at 847/698-6227, or e-mail fpgec@nabp.net. 



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VIPPS Inspectors Recount Experiences, Highlight Criteria

One year after the first Verified Internet Pharmacy Practice Sites™ (VIPPS™) certifications were awarded, new applications from online pharmacies continue to flow into NABP. VIPPS inspectors are actively working to evaluate applicants against the rigorous criteria of the VIPPS program as part of the certification process.

With more than 50 evaluations completed, VIPPS inspectors noted several common trends in their observations. In many cases, applicants made adjustments to their policies and operations in order to meet the program's criteria and become VIPPS certified.

Steve Hudson, a VIPPS inspector and director of inspections for the North Carolina Board of Pharmacy, says, "VIPPS criteria are patient oriented and represent safe practice standards for the public."

Though the origin of many of the criteria is based in state pharmacy practice acts, the criteria were written to provide a tier of good practice standards in concert with licensure requirements and focused on the unique challenges and demands of long distance patient/prescriber/pharmacist relationships characteristic of the Internet/interstate practice of pharmacy.

The VIPPS 17-point criteria are divided into seven categories

(see pages 156-157 for VIPPS criteria):

- licensure,
- prescription,
- patient,
- communication,
- storage and shipment,
- over-the-counter, and
- QA/QI program.

In the area of prescription processing, addressed in the second category of the VIPPS criteria, VIPPS requires a practical working method for detecting conflicts between state laws when the patient, prescriber, and the pharmacy are in different states.

Generic substitution, prescriber authority, number of refills, and controlled substance prescription requirements are areas of pharmacy practice that most frequently involve a conflict of law between two jurisdictions. In such cases, the VIPPS criteria call for the more stringent law to be followed. Some critics claim that this criterion cannot always be met in interstate commerce and will only become more complex as foreign boards adopt VIPPS programs and apply the criteria to international commerce.

Another prescription matter is the need for a mechanism to prevent hard copy prescriptions from being filled by multiple

online pharmacies. VIPPS inspectors found that, although most pharmacies starting to practice online address the issue of obtaining a valid prescription for their purposes, they sometimes neglect the hard copy in the patient's possession. Additionally, because online pharmacies usually employ many pharmacists and on-the-job trained customer service staff and rarely meet either prescriber or patient face-to-face, a uniform written procedure needs to be in place for detecting, investigating, and resolving cases of questionable prescription orders and personal identity.

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Collaborative Pharmacy Practice Regulation Continues to Advance

States continue in their efforts to allow pharmacists to develop collaborative practice agreements with prescribers. NABP's most recent survey of states on this issue, conducted as part of an update of NABP's *Survey of Pharmacy Law*, revealed that 29 states now allow pharmacists to collaborate with prescribers to initiate, modify, and/or discontinue patient medication therapy.

The number of states that allow collaborative practice agreements has grown since 1995, when an NABP survey showed only seven states granted pharmacists this privilege. The number increased to 17 states in 1997, then to the present 29 states in 2000. The authority granted to pharmacists in this area varies widely from state to state.

In Arkansas, for example, pharmacists may provide drug therapy management services based upon a written protocol from a licensed physician. Drug therapy management may include the selection of drug products if such products are named in the protocol. Pharmacists wishing to participate in such activities must become credentialed in one of four disease state management areas: asthma, anticoagulation therapy, diabetes, or dyslipidemia. Credentialing requirements include:

1. Active state licensure;
2. The passage of a Board-approved disease state management exam; and
3. The passage of a Board-approved practical

disease state management exam.

The Arkansas Board of Pharmacy recognizes the disease state management exams offered by the National Institute for Standards in Pharmacist Credentialing.

In Mississippi, the provision of pharmaceutical care includes the initiation or modification of drug therapy per protocol. Pharmacists wishing to enter into a protocol agreement with a prescriber must meet the following qualifications:

1. Current Mississippi licensure;
2. Successful completion of at least 16 hours of Board-approved continuing education that covers basic pharmaceutical care, development of patient care plans, and the clinical practice of pharmacy; and
3. Successful completion of at least 16 hours of a Board-approved course focusing on a specific disease state, patient

care plans, and protocol management.

Pharmacists must then successfully complete at least six hours of Board-approved continuing education in each disease every two years to continue providing care pursuant to protocol.

"The Mississippi Board is working with primary health care centers throughout the state to incorporate pharmaceutical care into the primary care regimen," adds William L. Stevens, executive director of the Mississippi State Board of Pharmacy. "Protocol arrangements are allowing pharmacists to perform such activities as immunization administration and disease state management. We feel the provision of this type of care by pharmacists is improving the quality of health care given to the state's patients."

The New Mexico Board of Pharmacy has taken a different approach to collaborative

(continued on page 153)

States that Allow Pharmacists to Initiate, Modify, and/or Discontinue Drug Therapy Pursuant to a Collaborative Practice Agreement with a Prescriber

Arizona	Kentucky	Oregon
Arkansas	Michigan	South Dakota
California	Minnesota	Tennessee
Florida	Mississippi	Texas
Georgia	Nebraska	Utah
Hawaii	Nevada	Vermont
Idaho	New Mexico	Virginia
Illinois	North Carolina	Washington
Indiana	North Dakota	Wyoming
Kansas	Ohio	

Too Many Cooks...

By Dale J. Atkinson, JD



It is without question that regulatory boards, including boards of pharmacy, must have the authority to enforce the practice acts and discipline licensees

and other individuals unlawfully practicing a profession. These powers give teeth to a regulatory scheme and must be enforced by a board to fulfill its mission of public protection. Certain regulatory structures within differing jurisdictions create a hierarchy which may or may not be the most efficient means of regulating a profession. In the following case, an administrative disciplinary action procedure involved an administrative law judge (ALJ), the Illinois Board of Pharmacy, the Illinois Department of Professional Regulation, and its director.

A pharmacist with more than 20 years of experience and who also owned the pharmacy in which he worked was having financial difficulties. A long-time vendor from whom the pharmacist had purchased goods over the years offered to sell him some drugs that the vendor claimed came from pharmacies which had closed. In reality, these drugs had been diverted since they had been removed from their packages, the safety seals had been broken, and the manufacturers' labels had been removed. The

pharmacist admitted knowledge that such drugs were diverted and also admitted that he intended and, in fact, did sell the diverted drugs at retail prices to the public.

Based upon a federal investigation known as "Operation Goldpill," the pharmacist pled guilty to a felony charge of the receipt of misbranded drugs through interstate commerce in violation of the Food, Drug, and Cosmetic Act. In the criminal proceeding, he was placed on probation for a period of one year and ordered to perform 200 hours of community service.

As a result of this criminal conviction, the Department of Professional Regulation filed a complaint against the pharmacist and pharmacy pursuant to applicable sections of the Pharmacy Practice Act. The administrative complaint referred to the pharmacist's admissions in his plea agreement that on three different occasions he knowingly purchased up to seven different types of misbranded drugs.

The parties appeared before an ALJ for an evidentiary hearing. The criminal conviction was entered into the record, and the pharmacist admitted knowledge of the acquisition of diverted drugs. He also admitted that he intended to sell the drugs at retail prices. The hearing also revealed that the pharmacist

had never had any legal problems before this incident.

After the hearing, the ALJ issued a report and recommendation to the Board in which he found that the Department proved that the pharmacist was convicted of a felony, and his conviction was the basis for a disciplinary action under the practice act. The pharmacy was also found to have aided and abetted the pharmacist in the felony conduct, which also provided grounds for disciplinary action. Finally, the ALJ found that the pharmacist was a credible witness, had acknowledged his misconduct, and had not previously been disciplined by the Department. Based on these findings, the ALJ recommended that the pharmacy license be revoked and that, among other things, the pharmacist's license be suspended for three months, followed by a probationary period of nine months. Several factors went into the calculations of the sanction by the ALJ. Subsequently, the Board of Pharmacy adopted the findings of the ALJ and recommended the same sanction to the Department.

Thereafter, the Department filed a motion asking for the imposition of a sanction against the pharmacist greater than that recommended by the Board or, alternatively, that the case be remanded to the Board for it to reconsider its

findings of fact, conclusions of law, and recommended sanction period.

On remand, the Board issued a recommendation to the director, which stated that it determined the original recommended sanction was consistent with recommendations made in cases with similar factual patterns. Again, the Department filed a second motion, asking the director to impose a more severe sanction.

Eventually, the director signed an order suspending the pharmacist's license for nine months to be followed by a 27-month period of probation. The pharmacist appealed. The Circuit Court held that the Pharmacy Practice Act did not empower the Department to file post-hearing motions and that the decision of the Department increasing the pharmacist's sanction was against the manifest weight of the evidence. Accordingly, the Circuit Court reversed the decision of the Department and remanded the matter with directions to impose the sanction recommended by the Board. The Department appealed.

The Appellate Court first considered whether the Department was authorized to file a motion seeking a rehearing. Without directly addressing the issue, the court held that the Board did not retreat from its initial recommendation on rehearing, but rather confirmed

it. "Even assuming that the matter never should have been remanded for reconsideration, the fact that it was did not change the Board's initial recommendation and [the pharmacist] cannot, therefore, claim any prejudice."

Next, the Appellate Court noted that the applicable sections of the Pharmacy Practice Act contemplated that a director may take action contrary to the recommendations of the Board. The pharmacist argued that no such statutory authority existed. In disagreeing, the Appellate Court held that "an express grant of power or duty to an agency or one of its officers carries with it the grant of power to do all things that are reasonably necessary to execute that power or duty." That is, administrative agencies are given wide latitude in fulfilling their duties.

Citing the purpose of the Pharmacy Practice Act as protecting the public health, safety, and welfare, the court held that the director, upon request from the Department, may take action contrary to the recommendations of the Board of Pharmacy.

Finally, the court addressed the issue of whether the Department's decision was against the manifest weight of the evidence and whether the sanction imposed upon the pharmacist was an abuse of

discretion. The Appellate Court found that the applicable statutes do not require the director to adopt the findings of the Board. In fact, such statute contemplated that the Director may disagree with the Board and take contrary action. On administrative review, courts are not at liberty to substitute their judgment for that of the agency. Accordingly, the Appellate Court reversed the findings of the Circuit Court and upheld the more harsh sanction issued by the director.

Boards of pharmacy are encouraged to understand the authority vested within those involved in the decision-making process of the regulatory arena. While regulatory boards involved in departmentalized structures may be "overruled" by a reviewing department, decisions must be supported by substantial credible evidence. Furthermore, procedural practice must be understood by the Department, director, and regulatory board when determining how and when to assess sanctions. **NABP**

Wilson v. The Illinois Department of Professional Regulation, 2000 WL 1555190 (IL App 1st Dist. 2000)

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

DEA Issues Letter Clarifying Use of Buprenorphine

A joint letter issued on September 1, 2000, by the US Department of Health and Human Services (HHS), the US Food and Drug Administration, and the US Drug Enforcement Administration (DEA) clarified the status of the partial opioid agonist analgesic, buprenorphine (Buprenex®), and its use in the treatment of opiate addiction. The letter emphasizes that buprenorphine is not currently approved or legally available for the treatment of opiate addiction, except when used under an Investigational New Drug Study. The agencies issued the letter of clarification in response to several inquiries and anecdotal reports that buprenorphine is being used in the treatment of opiate addiction.

“There appears to be a misunderstanding that Buprenex can be used in the treatment of opiate addiction as an ‘off label’ use of an approved drug product,” the letter stated. “Practitioners who dispense Buprenex for the treatment of opiate addiction must comply with the Narcotic Addict Treatment Act (NATA) (21 USC 823(g)). Buprenex may not be used for the treatment of opiate addiction unless and until it is approved for this use and there are standards in

place to permit practitioners to be registered by DEA as required by NATA.”

The letter goes on to state that Congress is considering the issue of new medications for use in the treatment of opiate addiction, and that pending

“There appears to be a misunderstanding that Buprenex can be used in the treatment of opiate addiction as an ‘off label’ use of an approved drug product,” the letter stated.

legislation would provide waivers from NATA requirements for certain narcotic drugs used in the treatment of opiate addiction. In addition, the HHS has published a Notice of Intent to allow for office-based treatment of opiate addiction using certain partial agonist medications. At this time, however, no regulations have been issued.

For further information, please contact Mr Robert Lubran, acting director, Office of Pharmacological and Alternative Therapies, Center for Substance Abuse Treatment, at 301/443-0744.

HHS Issues Final Rule on Electronic Transaction Standards

The US Department of Health and Human Services (HHS) published a final rule in the August 17, 2000 *Federal Register* that describes standards for electronic health information transactions and requirements regarding the use of such standards by health plans, health care clearinghouses, and certain health care providers. Implementing certain segments of the Health Insurance Portability and Accountability Act of 1996, these standards are intended to address the lack of standardization among the approximately 400 electronic data interchange formats currently in use in the United States. Such standardization should improve health programs by simplifying health care system administration and enabling the efficient electronic transmission of health care information. The final rule became effective on October 16, 2000.

HHS intends the implementation of these standards to coincide with the implementation of final regulations addressing the privacy and security of electronic health records and data, which are scheduled to be published before the end of this year. (See November/December 1999 *NABP Newsletter*, vol 27, no 10, pg 160, “Professional Affairs

Update: HHS Proposes Patient Privacy Regulations.”)

USP Revises Packaging Standards

The United States Pharmacopeia (USP) Subcommittee on Packaging, Storage, and Distribution recently revised certain product dating standards relevant to pharmacy practice. For non-sterile solid and liquid pharmaceutical products repackaged into unit-dose or single-unit containers, pharmacists must affix a “beyond-use date” that is “one year or less, unless stability data or the manufacturer’s labeling indicates otherwise.” For all other non-sterile dosage forms, the beyond-use date is

“one year or the time remaining of the expiration date.” Previous standards required the assignment of a beyond-use date that was six months from the date of repackaging or 25% of the time remaining until the expiration date, whichever was less.




Beyond-use dates for multiple-unit containers, such as a typical prescription vial, remain “not later than (a) the expiration

date on the manufacturer’s container or (b) one year from the date the drug is dispensed, whichever is earlier.”

The beyond-use date defines an appropriate period of time


during which a prescription drug may be retained by a patient after it is dispensed and takes into account such factors as the conditions under which the medication may be stored in the patient’s home, the type of packaging, the nature of the drug being dispensed, and the frequency with which the package may be opened.

These revisions appear in the first supplement to *The United States Pharmacopeia, 24th Rev., and The National Formulary, 19th Ed. (USP24/NF19)*. An article detailing the revisions was published in the August 1, 2000 issue of the *American Journal of Health-System Pharmacy*. 


Constitutional Amendment Deadline Set

All proposed amendments to NABP’s Constitution and Bylaws must be submitted in writing to the office of the Executive Director/Secretary between February 5 and March 22, 2001, to be considered during NABP’s 97th Annual Meeting, May 5-9, 2001, at the Sheraton Hotel and Towers in Seattle, Wash.

Submission dates are established by NABP’s Constitution, which specifies that

proposed amendments may be accepted no earlier than 90 days and no later than 45 days before the Annual Meeting’s First Business Session. The First Business Session is scheduled for Sunday, May 6. For more information about the amendment procedure, contact NABP Executive Director/Secretary Carmen A. Catizone at 847/698-6227. 

Name and Address Changes

NABP would like to keep its mailing lists updated. If you have a name or address change for the *NABP Newsletter* or if you do not wish to continue receiving the *NABP Newsletter*, please contact the NABP Publications Desk at 847/698-6227, or e-mail comm@nabp.net. 

Arizona Legislature Passes Bill Allowing the Sale of Drugs in Vending Machines

The Arizona State Board of Pharmacy reported in its October 2000 *Newsletter* the amendment of an administrative rule to include the sale of nonprescription drugs through vending machines.

In July 2000, the Arizona Legislature passed a bill allowing nonprescription drugs to be sold through mechanical vending machines. Due to the passage of House Bill 2046, Administrative Rule R4-23-603.E has been amended to include guidelines for vending machine sales. The sale of nonprescription drugs through vending machines has been a controversial topic in Arizona.

“For many years we had strict rules that stated nonprescription drugs could not be sold in vending machines. Over the course of 15 years, we have had four to five inquiries related to the distribution of nonprescription drugs in vending machines. Through various efforts, we had been able to diffuse these requests,” states Llyn A. Lloyd, RPh, executive director of the Arizona State Board of Pharmacy.

In the fall of 1999, a change in the status of nonprescription drugs for vending machines began to be considered.

A US senator from Arizona and the Chairman of the Arizona Legislature’s House Health Committee, received a letter from an individual in the vending machine industry inquiring why nonprescription drugs were not allowed to be sold in vending machines in Arizona.

The Arizona State Board then discussed the issue with the House Health Committee, stating why it was contrary to public health and in their best interest not to allow the sale of nonprescription drugs through vending machines. In January 2000, the Arizona State Board of Pharmacy received a call from an analyst from the House Health Committee informing it that a bill allowing the sale of nonprescription drugs in vending machines was going to be introduced to the Arizona Legislature.

Lloyd explained that while the Board weighed the issue of vending machines, it conducted some research on the status of vending machine sales in other states. Of the states the Board polled, only six had regulations prohibiting nonprescription drugs in vending machines.

“It’s difficult to argue against the bill when there are only six other states that feel the same way,” adds Lloyd. “Since the chairman of the House Health Committee has been a longtime supporter of the Arizona State Board of Pharmacy, we agreed

not to oppose the bill if we could write the rules to implement this new process.”

The rules were approved by the Governor’s Regulatory Review Council on November 7 and went into effect on November 9.

Some parameters the rule establishes include:

- Vending machines can only be placed in climate-controlled areas;
- Inspectors will have easy access to the products inside the machine;
- A warning notice will be placed on each machine, which will list the permit number and its expiration date, the Board of Pharmacy’s phone number, and the owner’s name and phone number;
- Warning notices like those found on prescription drugs informing consumers about drowsiness; interaction with food, alcohol, or other drugs; and the need to be used by a responsible adult, will be posted on the vending machines; and
- The notice will state if there are any questions or concerns to contact your physician or pharmacist.
- The rule prohibits the sale of precursor chemicals (ephedrine, pseudoephedrine, phenylpropanalanine).

Once the approved rule is published and warning stickers

are available, there will be a minimal waiting period for permits for the vending machines. Ideally, the Board plans to process applications for permits promptly. The actual permits will be issued via mail, usually within 10 days.

The Board expects these machines to be located anywhere there are large numbers of people, such as airports, industrial locations, hotels, restaurants, resorts, large office buildings, and even colleges. Other than being in a climate-controlled environment, there are no location restrictions on these machines, but the Board is hoping these machines will not be located in elementary schools, junior high schools, and high schools.

Massachusetts Board Adds New Position

Following the Institute of Medicine's report "To Err Is Human," the Massachusetts Board of Registration in Pharmacy concluded there was a need to look at the systems in Massachusetts pharmacy practice. As a result, the Board has recently added a part-time quality assurance compliance surveyor for outcomes to its staff.

According to Charles R. Young, executive director of the Massachusetts Board, as a result of an increased number

of adverse drug incidents and national attention to systemic problems, the Board decided to be proactive regarding medical errors and created this new compliance position. "In creating this position," he says "we are trying to create a partnership between the Board and the pharmacists. What makes this position unique is that the compliance surveyor will be reporting directly to the Board instead of the licensing board's investigative unit. This is a whole new perspective toward inspections." (For more information on the newly appointed quality compliance surveyor, see page 159.)

In 1985, the Board had six inspectors who conducted biannual inspections of retail pharmacies and pharmacy departments. Over the course of several administrations, routine structure and process inspections and inspectors have virtually been eliminated in Massachusetts.

"We are looking for a lot of cooperation from pharmacies. We [the Board] have the same intent as the pharmacists, better outcomes for patients. Until we take a good, close look at our systems, we may not get there," Young explains.

Quality assurance compliance inspections differ from typical structure and process inspections in that the new inspections are scheduled, allowing

pharmacy staff advance knowledge of the inspection. Also, an entrance interview is conducted before the inspection, making pharmacists feel more like partners in the system.

According to Young, reaction to the new position has been guarded, but he believes there will be a definite interest in learning more about the program.

In order to provide better education and involve all interested parties, a task force will be developed composed of a certified technician, a representative from the Massachusetts Chain Drug Council, members from professional associations, independent pharmacy members, a representative from the Department of Public Health, and representatives from other patient care settings where pharmaceutical services are provided. The Board hopes this new position will lead to a stronger partnership between pharmacists and the Board and that it will promote collaboration between pharmacists and their patients. Through this process, pharmacists will learn from the results, and eventually, have better control of outcomes.

As part of their long-term plans, the Board hopes to convert this position into a full-time position within a year and develop model regulations. **MAOP**

NAPLEX/MPJE Publications Available

The *2001 North American Pharmacist Licensure Examination™ (NAPLEX®)/Multistate Pharmacy Jurisprudence Examination™ (MPJE™) Registration Bulletin* and the *Operations Manual* are now available. The *NAPLEX Candidate's Review Guide* and the *MPJE Candidate's Review Guide* will be updated in early 2001.


The *2001 NAPLEX/MPJE Registration Bulletin* includes computerized examination registration forms, which candidates must complete in order to sit for the NAPLEX and MPJE. Boards received shipments of the *Bulletin* in November. Printed copies are available through each board of pharmacy and individual schools of

pharmacy. Additional printed copies of the computerized examination registration forms will be available for boards through NABP. The *Bulletin* is available in a printed version as well as online.

The *NAPLEX Candidate's Review Guide* and the *MPJE Candidate's Review Guide*, the companion pieces to the *Bulletin*, are available on NABP's Web site for no charge. The *Guides* will be updated in the beginning of 2001 and will also be available on NABP's Web site. The *Guides* are designed to provide information about each test's structure and format, day-of-test information, on-screen tutorials regarding how to use a mouse,

and a series of sample questions. Both *Guides* include the competency statements used to create the actual MPJE and NAPLEX questions.

Also available to state boards is the *Operations Manual*, which has been sent to the state boards via E-mail. The newly updated manual explains to board staff how the NAPLEX and MPJE examinations work, including test registration, appointment procedures, and score results.

For more information on any of these publications, please contact the NAPLEX/MPJE Manager at 847/698-6227, or visit the NABP Web site at www.nabp.net. 

Fee Increase Reminder for NAPLEX, MPJE, Licensure Transfer


Beginning January 1, 2001, NABP will require candidates for the North American Pharmacist Licensure Examination™ (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination™ (MPJE™) to pay an additional administrative fee. NABP will also increase the processing fee for licensure transfer applications.

The administrative fee for the NAPLEX will be \$110, and the administrative fee for the MPJE will be \$45. The base testing fees for both the NAPLEX and MPJE are

not expected to increase for the next several years. The NAPLEX fee will remain \$250, and the MPJE fee will stay at \$85. This new charge will be implemented to offset higher seating fees charged to NABP by the Chauncey Group International, LTD, the testing vendor of both examinations.

Also effective on January 1, the fee for processing a Preliminary Application for Pharmaceutic Licensure Transfer will increase from \$250 to \$300 per state for the first state to which the

applicant is requesting licensure transfer.

The fee to request licensure transfer to additional states on the same application form as the first state will remain at \$50 per state. In addition, the current \$50 fee for changing the transferring state, referred to as Change of State, and extending the life of an Official Application for Transfer of Pharmaceutic Licensure, known as Extension of Time, will remain unchanged. 

Myths versus Facts: The MPJE

Implemented in 1998, the Multistate Pharmacy Jurisprudence Examination™ (MPJE™) is used by 39 state boards to assess licensure candidates' knowledge of pharmacy jurisprudence. As in the case with anything relatively new, inaccuracies develop due to unfamiliarity with program information. In an effort to dispel some myths associated with the MPJE program, NABP has assembled some common myths and the corresponding facts.

MYTH: NABP determines exam content independently of the state boards.

FACT: NABP coordinates two state-specific, item-pool reviews and an annual review of new questions every year. As part of the State Letter of Agreement, boards must participate in the annual review of new questions and at least one of the state specific item-pool reviews. It is through these reviews that valid, defensible examinations may be provided and compromise of the examinations may be avoided.

MYTH: The ratio of questions that comprise the test are 50% federal law and 50% state law. Boards provide NABP with their current state exam questions and NABP “fills in the blanks” with federal questions.

FACT: There is no specific ratio of federal versus state questions per each state examination. Each state participating

in the MPJE program determines the importance of the state- and federal-related questions. Only board representatives may designate questions that are valid for use in their state and only these

Currently, [the MPJE] is used by 39 state boards to assess licensure candidates' knowledge of pharmacy jurisprudence.

questions will appear on the examination for candidates seeking licensure. NABP administers the examinations through Sylvan Technology Centers.

MYTH: NABP will provide candidates with study materials for the examination.

FACT: It is the boards' responsibility to provide, or direct the candidate towards, the appropriate study materials pertinent to the state's laws and regulations. NABP offers the *MPJE Candidate's Review Guide* at no charge at www.nabp.net. The *Guide* acquaints candidates with the test's computer-adaptive format and the types of questions they will see on the exam. This year, NABP has included in its *NAPLEX Registration Bulletin* the following clause: “Candidates may wish to consult with references such as *Pharmacy Law Digest* or the

USP DI Approved Drug Products and Legal Requirements, which contain federal statutes and regulations applicable to the several states.”

MYTH: The MPJE is a national examination.


FACT: This is a common misconception among state boards. The jurisprudence exam is state-specific. Each state board is responsible for the content of its own examination.

MYTH: The reported score represents a percentage value.

FACT: No. The scaled score reported is not a percentage value. The score is calculated by determining the candidate's ability level on the exam and then comparing it to the predetermined minimum acceptable ability level established for the MPJE.

MYTH: MPJE results may be transferred to other states.

FACT: Because the MPJE is unique to the state or jurisdiction in which a candidate is seeking licensure, it is not possible to transfer an MPJE score to another state. The MPJE is a state-specific examination boards use to assess licensure candidates' knowledge of pharmacy jurisprudence.

For additional information about the MPJE or to discuss other questions, please contact Lisa Nepi, NAPLEX/MPJE manager at 847/698-6227, or visit NABP's Web site at www.nabp.net. 

International Conference Considers Competence, MRAs, Internet Practice

International core competencies, mutual recognition agreements, and Internet pharmacy practice were the primary areas of concern for the regulatory authorities, educators, and governmental officials attending the Fourth International Conference on Pharmaceutical Competence, October 15-18, in Ottawa, Canada. Stately Parliament Hill in its autumn glory provided a scenic backdrop for the Conference, which drew more than 125 representatives from Australia, France, New Zealand, South Africa, the Peoples Republic of China, Canada, and the United States.

Participants were particularly eager to conclude deliberations on the set of international core competencies, which had been developed at the Third International Conference in 1998 and subsequently circulated for comment. While there was prevailing agreement that the competencies were not ready for general adoption by the nations represented, there was consensus that the creation of the competencies fulfilled an objective set by the delegates at the first international conference and provided a foundation for future international collaboration. NABP Executive Director/Secretary Carmen A. Catizone summarized the feelings of the participants during the Conference's final session. "While we acknowledge that, at present,

we are far from our goal of mutual recognition," he said, "we can be proud of the progress that has been made."

Recent inroads by internationally based online pharmacy practice sites were the subject of a half-day Conference program. Moderated by NABP Chairman Dyke F. Anderson and Executive Committee member Paula L. Castor, the session featured a panel comprised of delegates representing Australia, Canada, the European Union, New Zealand, and the United States, who discussed their countries' responses to the new practice model. Andreas Stregachis, director of pharmacy services for drugstore.com, conducted a tour of an online pharmacy, and NABP's Licensure Applications Database Management Director Glenn Detweiler discussed experiences from the Association's Verified Internet Pharmacy Practice Sites™ (VIPPS™) certification program, which is being considered for adoption by Canada's North American Pharmacy Regulatory Authorities (NAPRA) and the Australian Pharmacy Regulatory Authority (APRA). Patrick Mahony, a member of Australia's Pharmacy Board of New South Wales, concluded the discussion of online pharmacy practice by relating APRA's experiences with online pharmacies and their planned participation in the VIPPS certification program.

At the conclusion of the Conference, delegates reviewed the accomplishments of the previous four international conferences on pharmaceutical competence. They agreed that competence continued to be an important objective, but that other factors, such as the Internet, were quickly changing the practice of pharmacy on a global scale and hastening the dawn of the global pharmacist and the eventual need for mutual recognition agreements between nations.

Responding to the group's concerns, Mahony proposed the establishment of an international committee to develop a draft proposal to coordinate international competence efforts and work towards means to discuss and collaborate on legislative issues related to competence, the Internet, and other areas of interest. The group would be composed of a secretary and a delegate from NAPRA, APRA, NABP, and the representatives of other interested countries. Organizations participating would be required to make a financial commitment to the endeavor and agree to consult with all interested bodies as they prepare their final report for distribution and comment by the end of 2001. The committee's report would form the basis for a fifth International Conference to be held in May or September 2002. **NABP**

NABP Releases Survey of Pharmacy Law, NABPLAW


NABP released the 2000-2001 edition of the *Survey of Pharmacy Law* and the fall 2000 update to the NABPLAW® pharmacy law database.

Updated annually, the *Survey* is a compilation of the major state laws and regulations that govern the pharmacy profession. The information is displayed in a chart format with clarifying footnotes for easy reference. Each state board of pharmacy reviews and updates its information yearly to reflect changes in its state's laws and regulations. An educational grant from Wyeth-Ayerst Global Pharmaceuticals enables NABP to provide complimentary copies of the

Survey to the nation's schools and colleges of pharmacy for distribution to all final-year pharmacy students. The purchase price of the *Survey* is \$20.

NABPLAW 3.2 contains all the changes and amendments to state pharmacy laws and board of pharmacy regulations as of September 1, 2000. Updated in the fall and spring, the database's powerful search capability allows users to search for a given topic across one, several, or all 50 states as well as the District of Columbia and Guam. A one-year subscription, which includes the two updates, is available for \$995 for single-site users.

Multiple-site licenses are also available. Contact NABP for information about special rates for educational institutions and boards of pharmacy. NABPLAW is available in a CD-ROM format.

To purchase the *Survey*, send a request with an accompanying check or money order made payable to NABP to the NABP Publications Desk, 700 Busse Highway, Park Ridge, IL 60068. To purchase NABPLAW, please make check or money order payable to the NABP Foundation and send the request to the same address. Refunds are not available for publication orders. 

Collaborative Practice Update *(continued from page 143)*


practice. Only "pharmacist clinicians" may prescribe or modify dangerous drug therapy as authorized by protocol with a prescribing practitioner. To become certified as a pharmacist clinician by the Board, a pharmacist must demonstrate:

1. Satisfactory completion of an academic curriculum that includes a minimum of 60 hours of physical assessment training followed by nine months of supervised clinical experience involving assessment skills; or
2. Satisfactory completion of a 60-hour physical

assessment course approved by the Board and a 150-hour, 300-patient contact, Board-approved, physician-supervised preceptorship and the passage of a Board-approved exam; or

3. If the applicant is certified by the Indian Health Service's Pharmacist Practitioner Program, documentation of 600 patient contacts within the past two years as a pharmacist practitioner; or
4. Achievement of national certification as a physician assistant.

Pharmacist clinicians in New Mexico may also prescribe controlled substances within the parameters of the protocol agreement as long as they possess state and federal controlled substance registrations.

These are only a few examples of how state boards have addressed the issue of collaborative practice between pharmacists and prescribers. Further state-specific information is available from NABP's Professional Affairs Manager Melissa Madigan at 847/698-6227 or via e-mail at mmadigan@nabp.net. 

Season's Greetings from NABP



The Executive Office, Human Resources, and Information Technology



Competency Assessment and Support Programs



Applications/Database, Foreign Pharmacy Graduate Examination Committee Certification Program, and Electronic Licensure Transfer Program



Communications and Customer Service

VIPPS Inspectors Recount Experiences, Highlight Criteria *(continued from page 142)*

The third category of the VIPPS criteria focuses on the patient. VIPPS inspectors verify that sufficient information is collected from patients for drug utilization review (DUR) and consultation. Information about over-the-counter (OTC) medications, prescriptions dispensed by other pharmacies, or relevant medical conditions is also included for review.

Computer-assisted DUR is another area addressed by this

category. VIPPS inspectors examine Internet pharmacies' use of computer-assisted DUR and evaluate systems through functionality testing of computer systems particularly after software updates. The VIPPS review helps to alert pharmacists not to rely solely upon the computer to warn them of improper drug usage because computer software can fail, be improperly programmed, or warning flags can be turned off.

Also of concern are computer systems that have not incorporated into the DUR system reported medical conditions, prescription medications dispensed by other pharmacies, or OTC medication use, and pharmacists who are unaware that the responsibility to detect such issues has been left to him or her.

Communication, addressed in category four of VIPPS criteria,

(continued on page 158)

VIPPS 17-Point Criteria

Licensure

Criteria Number 1:

Qualifying VIPPS Pharmacies will provide NABP with the information necessary to verify that all persons affiliated with the site, including those affiliated through contractual or other responsible arrangements, that are engaging in the practice of pharmacy are appropriately licensed or registered and in good standing in all applicable jurisdictions.

Are all persons affiliated with this site through contractual or other responsible arrangement and who are engaging in the practice of pharmacy (including pharmacists and technicians) appropriately licensed or registered in good stand-

ing in the state in which they practice?

Criteria Number 2:

Agree to comply with all applicable statutes and regulations governing the practice of pharmacy where licensed or registered. When a conflict arises between individual state laws or regulations, or between state and federal laws or regulations, the VIPPS Pharmacy will agree to comply with the more stringent law or regulation that applies as determined by conflict-of-law rules.

Prescription

Criteria Number 3:

Maintain and enforce policies and procedures that assure the integrity, legitimacy, and authenticity of the Prescription Drug Order and seek to prevent

Prescription Drug Orders from being submitted, honored, and filled by multiple pharmacies.

Criteria Number 4:

Maintain and enforce policies and procedures that assure compliance with applicable generic substitution statutes and regulations and prohibit unauthorized therapeutic substitution from occurring without the necessary patient or prescriber authorization and outside of the conditions for participation in state or federal programs, such as Medicaid.

Patient

Criteria Number 5:

Maintain and enforce policies and procedures

VIPPS 17-Point Criteria

ensuring reasonable verification of the identity of the patient, prescriber, and, if appropriate, caregiver, in accordance with applicable state law.

Criteria Number 6:

Obtain and maintain in a readily accessible format, patient medication profiles and other related data in a manner that facilitates consultation with the prescriber, when applicable, and counseling of the patient or caregiver.

Criteria Number 7:

Conduct a prospective drug use review (DUR) prior to the dispensing of a medication or device in accordance with applicable state law.

Criteria Number 8:

Maintain and enforce policies and procedures to assure patient confidentiality and protect patient identity and patient-specific information from inappropriate or non-essential access, use, or distribution. [The *NABP Guidelines for the Confidentiality of Patient Health Care Information as It Relates to Patient Compliance and Patient Intervention Programs* can serve as a useful resource for addressing the confidentiality and security of patient data.]

Communication

Criteria Number 9:

Maintain and enforce policies and procedures requiring pharmacists to offer interactive, meaningful consultation to the patient or caregiver.

Criteria Number 10:

Maintain and enforce policies and procedures establishing a mechanism for patients to report, and the VIPPS Pharmacy to take appropriate action regarding, suspected adverse drug reactions and errors.

Criteria Number 11:

Maintain and enforce policies and procedures that provide a mechanism to contact the patient and, if necessary, the prescriber, if an undue delay is encountered in delivering the prescribed drug or device. Undue delay is defined as an extension of the normal delivery cycle sufficient to jeopardize or alter the patient treatment plan.

Criteria Number 12:

Maintain and enforce policies and procedures establishing mechanisms to inform patients or caregivers about drug recalls and to educate patients and caregivers about the appropriate means to dispose of expired, damaged, and unusable medications.

Storage and Shipment

Criteria Number 13:

Ship controlled substances to patients via a secure and traceable means.

Criteria Number 14:

Assure that medications and devices are maintained within appropriate temperature, light, and humidity standards, as established by the United States Pharmacopoeia (USP), during storage and shipment.

Over-the-Counter

Criteria Number 15:

Comply with all applicable federal and state laws regarding the sale of Over-the-Counter Products identified as precursors to the manufacture or compounding of illegal drugs.


QA/QI Program

Criteria Number 16:

Maintain a Quality Assurance/Quality Improvement Program.

Criteria Number 17:

Notify NABP within 30 days of any change of information provided as part of the verification process or involving data displayed on the VIPPS Web site.

Notify NABP of any change of the Pharmacist-in-Charge. 

VIPPS Inspectors Recount Experiences, Highlight Criteria *(continued from page 156)*

is a critical area of the VIPPS program. VIPPS inspectors have found that online pharmacies are able to provide a great deal of information to patients. Direct communication between patients and pharmacists, however, tends to be challenging. Phone contact is an option, as is e-mail, a method preferred by online pharmacies. The VIPPS review works to ensure that online pharmacies are explicit when it comes to instructing online users how to reach a pharmacist, and hours of pharmacist availability, along with expected response time to an e-mail report of a suspected medication reaction.

Another key area of observation is in the shipping stage, when medications and their packaging are challenged by a wide range of ambient conditions. Temperature control is much more of a concern today because of the new biological products which are costly, labile, and in great demand from Internet and mail-order pharmacies.

“VIPPS requirements for storage, handling, and shipping of drugs are closely examined because of the impact on patient care,” notes Richard Morrison, VIPPS inspector and chief investigator for the Washington State Board of Pharmacy.

NABP believes quality control (QC), quality assessment (QA),

and quality improvement (QI) are important ingredients in safe patient care and these three points are incorporated into the fifth category of VIPPS criteria.

“QA/QI plans are the cornerstone of NABP’s regulating for outcomes initiative, a regulatory approach that shifts the focus of pharmacy regulation from rules related to structure and process to a system that considers the quality of care and therapeutic outcomes,”

*– Jerry Moore,
NABP president*


“Because of pharmacy’s scope of practice, quality assessment and improvement plans are a necessity. The VIPPS QA/QI requirement is beneficial not only for VIPPS pharmacies, but for non-VIPPS pharmacies, too,” states Tim Benedict, VIPPS inspector and assistant executive director of the Ohio State Board of Pharmacy.

“QA/QI plans are the cornerstone of NABP’s regulating for outcomes initiative, a regula-

tory approach that shifts the focus of pharmacy regulation from rules related to structure and process to a system that considers the quality of care and therapeutic outcomes,” adds Jerry Moore, NABP president.

VIPPS inspectors agree that online pharmacies should not be dismissed as doing a lesser job than traditional brick and mortar pharmacies.

“A pharmacy that is able to comply with VIPPS standards is more likely to be at the pinnacle of meeting regulatory requirements than any other pharmacy out there,” explains Morrison. “VIPPS requirements support licensing standards. State boards of pharmacy license pharmacies and establish standards of practice, which are for the most part consistent across the United States, and provide minimum safe practice standards. VIPPS standards improve the system and ultimately patient care.”

Inspectors have found that VIPPS-certified online pharmacies not only meet licensure and practice standards in their online businesses but incorporate VIPPS principles in all areas of their pharmacy practice. 

Around the Association

Ohio Address Change

The Ohio State Board of Pharmacy has a new address. The Board now has a room number and a new zip code. The new address is 77 S High St, Room 1702, Columbus, OH 43215-6126.

Frankhauser New Compliance Surveyor

Frederick Frankhauser, RPh, has been named quality assurance compliance surveyor for outcomes at the Massachusetts Board of Registration in Pharmacy. This new position is responsible for drafting a model plan for outcomes-based regulation.

"I am very excited about the role he will play in ensuring positive outcomes in Massachusetts pharmacy practice settings. The number of compliance inspections has been virtually eliminated because of resource cutbacks,

so this is a new approach to conducting a pharmacy survey. Fred Frankhauser will be learning how the systems work in retail pharmacies and other pharmacy practice settings. This [new position] should present a new twist and challenge," Charles R. Young, executive director, explains.

Frankhauser received his degree in pharmacy from the Massachusetts College of Pharmacy in 1994. A third-year law student at Western New England College of Law, he will be working at the Massachusetts Board of Registration in Pharmacy part time while finishing his degree.


Members Named to College of Apothecaries

The American College of Apothecaries (ACA) has installed two state board of pharmacy members as officers. Gerald G. Ritt, member of the

Arizona State Board of Pharmacy, has been named president-elect, and Don Coody, member of the Oklahoma State Board of Pharmacy, has been named vice president. The two men were installed at the ACA Annual Conference.

High Named Independent Pharmacist of the Year

Doyle High, RPh, was named the 2000 Willard B. Simmons Independent Pharmacist of the Year by the National Community Pharmacists Association in October. High, a member of the Texas State Board of Pharmacy, is the owner of The Drug Store in Haskell, Tex.

The award recognizes an independent pharmacist for exemplary leadership and commitment to independent pharmacy and the community. 

NABP Awards VIPPS Certification to Clickpharmacy.com


Clickpharmacy.com, located at www.clickpharmacy.com, is the most recent online pharmacy to receive Verified Internet Pharmacy Practice Sites™ (VIPPS™) certification.

"The VIPPS certification confirms our commitment to excellence and supports our dedication to setting high standards for our independent

pharmacy network to effectively participate in e-commerce," says Gloria Rodriguez, chief executive officer of Clickpharmacy.com.

Clickpharmacy.com, based in Miami, Fla, was launched December 1998. The site offers a range of services including online prescription filling and electronic communications with

independent community pharmacists. Consumers can also purchase over-the-counter medications, first aid supplies, and pet medications.

For more information about the VIPPS program, please call NABP at 847/698-6227, or log on to NABP's Web site at www.nabp.net. 

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NABP Meeting Dates

Thursday-Friday, December 14-15, 2000
Task Force on Model Guidelines for Formulary Development and Task Force on Drug Diversion through Institutional Outlets Meetings, Marriott Suites O'Hare, Rosemont, Ill

Sunday-Monday, January 21-22, 2001
Advisory Committee on Examinations Meeting, Location to be Announced

Thursday-Friday, January 25-26, 2001
Committee on Law Enforcement/Legislation Meeting, Location to be Announced

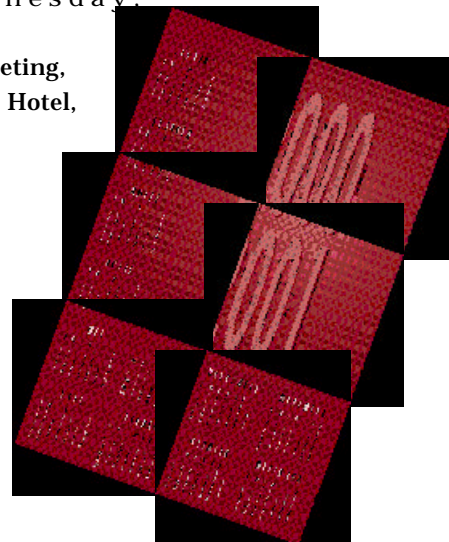
Friday-Saturday, February 2-4, 2001
Executive Committee Meeting, Amelia Island Plantation, Amelia Island, Fla

Thursday-Friday, February 22-23, 2001
New Executive Officers Orientation Program, Location to be Announced

Friday, March 30, 2001
Committee on Constitution and Bylaws Meeting, Location to be Announced

Friday, May 4, 2001
Pre-convention Executive Committee Meeting, The Sheraton Seattle Hotel, Seattle, Wash

Saturday - Wednesday,
May 5-9, 2001
NABP 97th Annual Meeting,
The Sheraton Seattle Hotel,
Seattle, Wash



newsletter

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