NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

newsletter

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

NABP Begins Transmitting Disciplinary Information to HIPDB

Reporting to the Healthcare Integrity and Protection Data Bank (HIPDB) is now an easy, seamless process for those state boards that choose to use NABP as an authorized reporting agent. NABP recently completed the Disciplinary Clearinghouse Data Entry Module, and has successfully transmitted data to HIPDB.

As part of the advanced clearinghouse program, NABP created the Disciplinary Clearinghouse Data Entry Module, an Access-based software program, for participating member boards. Simple to use, the data entry module was given to the boards pre-loaded with disciplinary information dating back to 1982. As state boards receive disciplinary action information, it is entered into the Data Entry Module. Pop-up windows and pick lists help users navigate the program, and each month the board e-mails the file to NABP. From this file, NABP updates the Disciplinary Clearinghouse records, converts the data into the required format and sends the information to the HIPDB. Each participating state board receives a report of its previous month's activities, as well as a comprehensive summary of activity from all reporting states.

"To avoid hardship on the state boards of pharmacy, NABP developed the Data Entry Module to be user friendly and to accommodate reporting of disciplinary action to the NABP Clearinghouse and HIPDB," says Jerry Moore, NABP president.

NABP began working on the software program for reporting disciplinary actions last summer. Participating state

(continued on page 82)

NABP Completes Build-out

The remodeling of NABP's first level, including the addition of three managerial offices, 15 staff cubicles, and a file room, was completed in mid-June. See story on page 90.

83 International VIPPS Program to be Launched by NABP

87 NABP's VIPPS Elected to ASAE "Honor Role"

88 The Prescription Drug Marketing Act: Final Regulations

90 NABP Completes Headquarters Remodeling Project

in this issue

VOLUME 29 - NUMBER 6 - JUNE/JULY 2000

NABP Begins Transmitting Disciplinary Information to HIPDB (continued from page 81)

boards received and installed the Data Entry Module (the software program for reporting) in January and February 2000, and NABP began routine transmissions of data to HIPDB in March 2000.

The Data Entry Module does not require the boards to have the full Access software program on their computer system. Though some functions are limited, the run-time version (Access Light) accepts all information required by HIPDB and the NABP Clearinghouse. NABP staff works with each state to create a version that meets all the state's needs.

Currently, 24 states have received, and are using, the software, which is provided at no charge. Most of those states who are not using NABP's data module are umbrella boards. In these cases, disciplinary action reporting is usually done by an agency other than the board of pharmacy.

"We try very hard to accommodate the boards regarding what information they give us and how they are able to provide it to us," notes Moore. "If a state board is required to submit information directly to the HIPDB, we will accept a hard copy of disciplinary information as a submission to NABP's clearinghouse; and the data will be entered manually by NABP staff."

HIPDB was developed by the US Department of Health and Human Services to create a comprehensive data collection program for the reporting and disclosing of most final adverse actions taken against health care providers, suppliers, and practitioners. Federal and state agencies and health plans are required to report to the data bank, and are permitted access to the system for a fee. Health care suppliers, providers, and practitioners are only allowed to "self-query" (see "HHS Proposes Mandatory Disciplinary Reporting to National Data Bank" in the January 1999 *NABP Newsletter*).

For more information or to make NABP your board's reporting agent, contact Glenn Detweiler, Licensure Application Database Programs Director, by telephone at 847/698-6227, or by e-mail, gdetweiler@nabp.net. NABP

Renewal and Application Process Update

NABP's Information Technology team continues to work with eGovNet.com, a provider of Web-based solutions for online transactions, to customize the Renewal and Application Process (RAP) system for each participating state board. Since each board's database systems are unique, their link to the RAP system must be refined to produce an effective end result. The analysis and creation of each link is going smoothly, and the project is moving along as planned.

Representatives of eGovNet presented the RAP system to the executive officers and members of the state boards of pharmacy at a special session during NABP's Annual Meeting in May 2000. Once completed, the system will allow pharmacists and pharmacies to submit their initial licensure application and renewal via the Internet. When fully operational, NABP's RAP system will feature credit and debit card payment for fees, and provide licensees with easy access to their professional information on file with participating boards of pharmacy. NABP

The NABP Newsletter
(ISSN 0027-5700) is published ten times a year by the National Association of Boards of Pharmacy (NABP) to educate, to inform, and to communicate the objectives and programs of the Association and its 68 member boards of pharmacy to the profession and the public. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABP or any board unless expressly so stated. The subscription rate is $35 per year.
National Association of Boards of Pharmacy
700 Busse Highway
Park Ridge, Illinois 60068
847/698-6227
www.nabp.net
comm@nabp.net

Carmen A. Catizone
Executive Director/Secretary

Mark E. Paulson
Editorial Manager

© 2000 National Association of Boards of Pharmacy. All rights reserved. No part of this publication may be reproduced in any manner without the written permission of the Executive Director/Secretary of the National Association of Boards of Pharmacy.

International VIPPS Program to be Launched by NABP

In order to help meet the growing threat posed by rogue Internet pharmacy sites operating from outside the United States, the Association's Executive Committee has endorsed a plan to work with the licensing authorities in participating foreign countries to certify online pharmacies located within their jurisdictions.

Based on NABP's successful Verified Internet Pharmacy Practice Sites™ (VIPPS™) program, the new International VIPPS program will utilize the same core criteria and policies to certify candidate Web sites. However, the review of relevant licensure, site inspections, and other criteria verification performed by NABP in the US will be conducted by the participating foreign licensing authority.

(continued on page 95)

Fee Increase for NAPLEX, MPJE, Licensure Transfer Effective January 1

In 1999, the NABP Executive Committee approved fee increases for the NAPLEX® (North American Pharmacist Licensure Examination™), the Multistate Pharmacy Jurisprudence Examination™ (MPJE™), and transfer of pharmaceutic licensure.

Effective January 1, 2001, candidates sitting for the NAPLEX and MPJE will be required to pay an additional administrative fee. The administrative fee for the NAPLEX will be $110, and the administrative fee for the MPJE will be $45. This new charge will be implemented to offset higher seating fees charged to NABP by the Chauncey Group International, LTD, testing vendor of both examinations.

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.

Also effective January 2001, 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. This increase is the first since 1996, when the Electronic Licensure Transfer Program™ (ELTP™) was implemented, and is set to absorb the average annual cost of living between 1996 and 2003.

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 fees 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. NABP

NAPLEX Score Transfer Fee Increase

Beginning September 1, 2000, NABP will increase the score transfer fee for the NAPLEX® (North American Pharmacist Licensure Examination™) from $50 to $75. Although the Executive Committee approved this increase for the Fiscal Year beginning January 1, 2000, NABP will not implement the change until the beginning of September 2000. Those requests received from candidates postmarked after September 1, 2000, without the appropriate fee adjustment included, will be returned. NABP will be notifying appropriate schools of pharmacy.

For additional information about the NAPLEX, please call NABP at 847/698-6227, or visit the Association's Web site at www.nabp.net. NABP

Legal Briefs

How Do You Stop a Charging Pharmacist?

By Dale Atkinson, JD

Perhaps one of the most effective tools for a board of pharmacy in carrying out its mission of public protection is the ability to enter an administrative order that prohibits or limits the rights of a licensee to practice. Whether the board has the authority to "limit" the practice privileges of a licensee must be interpreted through the practice act, which legislatively creates and empowers the regulatory entity. Many practice acts do not specifically provide for the authority of the board to limit the license of a practitioner as part of an administrative disciplinary proceeding. The following case provides an interesting judicial analysis of board orders under disciplinary proceedings, including the limitation placed upon the license of a pharmacist-in-charge. Additional interesting issues involving administrative searches are also discussed.

A pharmacist duly licensed in New Hampshire purchased a pharmacy. Thereafter, he became the pharmacist-in-charge under the applicable statute. While visiting the pharmacy in the course of an unrelated matter, a New Hampshire Board investigator observed that a number of the pharmacy's records were inaccurate and disorganized. The investigator recommended continuing the investigation to the Board, and eventually conducted an audit on the pharmacy. Based upon this audit, the Board commenced disciplinary proceedings against the pharmacist.

The pharmacist was charged with 10 counts of failing to maintain accurate and complete controlled drug records, four counts of dispensing controlled drugs in unlawful quantities, and one count of dispensing incorrect medication. The Board also questioned the pharmacist's competence, both generally and as a pharmacist-in-charge. After a formal hearing and upon rehearing the matter due to a petition by the pharmacist, the board restricted the practice privileges of the pharmacist's license by precluding him from serving as a pharmacist-in-charge for an indefinite period of time and imposing a $1,000 fine. The pharmacist, however, was not precluded from practicing pharmacy in a capacity other than as a pharmacist-in-charge.

The pharmacist appealed the ruling of the Board on numerous grounds. First, the pharmacist contended that the statutes governing the Board's authority and procedures to inspect pharmacy were impermissibly vague because they did not adequately notify him of the standard for evaluating compliance with the law. In rejecting this argument, the Supreme Court of New Hampshire cited numerous statutes that authorized the Board to enforce the practice act and provide for the protection of the public. Such authorization also provided for the authority of the Board, or its designated representatives, to enter pharmacies and investigate possible violations of applicable laws.

Incredibly, the pharmacist argued that since perfect compliance with the laws is impossible, express standards are necessary to inform him as to what degree of noncompliance will subject him to penalties under applicable law. The court quickly disposed of this argument, stating that pharmacists and pharmacies have an unequivocal duty to comply with pharmacy and drug laws. Therefore, any noncompliance with such laws will potentially subject a licensee to investigation and prosecution. The court continued, stating that while perfect compliance may not be possible, decisions to investigate and prosecute are committed to the sound discretion of the Board. By virtue of its specialized knowledge and authority, the Board alone is empowered to develop enforcement policies best calculated to achieve the

ends contemplated by the Legislature and must allocate available funds and personnel in a way to execute these policies effectively and efficiently.

The pharmacist next argued that the audit conducted by the Board constituted an illegal administrative search under the federal and state constitutions. In addressing these arguments, the court first stated the general rule that absent a recognized exception, a warrantless search by a government body is, per se, unreasonable and invalid. However, New Hampshire has explicitly recognized an administrative search exception. In order to satisfy this exception, three criteria must be met:

1. There must be a substantial government interest that informs the regulatory scheme pursuant to which the inspection is made;
2. The warrantless inspection must be necessary to further the regulatory scheme; and
3. The implementation of the statutory inspection program must provide a constitutionally adequate substitute for a warrant.

Regarding the first requirement, New Hampshire has long required pharmacists to keep accurate records of sales of certain drugs. Thus, the state clearly has a recognized substantial interest in regulating the sale and distribution of drugs to deter their illicit use whenever possible and trace their movement through the channels of commerce.

> ***Incredibly, the pharmacist argued that since perfect compliance with the laws is impossible, express standards are necessary to inform him as to what degree of noncompliance will subject him to penalties under applicable law.***

Addressing the second requirement, requiring a warrant before inspection would impede the abilities of the inspectors to deter faulty records and illegal dispensation of drugs. Requiring a warrant would also inhibit the ability of the Board to quickly investigate wrongdoing that may pose a threat to public safety. Accordingly, warrantless access to records is necessary to ensure that the mere prospect of inspections will prompt otherwise questionable licensees to comply with the law.

Finally, and because access is limited to normal business hours and to original records or prescriptions, the statutory scheme is sufficiently limited in time, place, and scope as to constitute an adequate substitute for a warrant. Based upon the foregoing, the court held that the audit was lawfully conducted, and the information uncovered was admissible in the administrative proceedings.

Next, the licensee argued that the Board disclosed the contents of prescriptions during the proceedings in violation of applicable confidentiality statutes. Such statutes prohibit Board officials or representatives from divulging prescription orders and records inspected in the course of their duties "except in connection with a prosecution or administrative proceeding before a licensing board to which prosecution or proceeding of the person to whom such prescriptions, orders or records relate is a party." The pharmacist argued that the person to whom such prescriptions "relate" refers to the customer, and therefore the customer's consent must be obtained before the prescriptions can be disclosed during the disciplinary hearings. The court declined to accept this argument based upon the unreasonable result that could occur when the pharmacist and customer act in concert and refuse to authorize disclosure.

(continued on page 86)

NABP Awards VIPPS Certification to Tel-Drug Rx

Tel-Drug Rx®, of Sioux Falls, SD, a wholly-owned subsidiary of CIGNA HealthCare and located at www.teldrug.com, has become the most recent online pharmacy to receive the Verified Internet Pharmacy Practice Sites™ (VIPPS™) certification from NABP.

Tel-Drug Rx is a mail order pharmacy program offered by Tel-Drug, Inc, especially for maintenance medications prescribed for long-term treatment of chronic conditions. Tel-Drug Rx also provides toll-free customer service and 24-hour refill ordering and emergency pharmacy services.

Participation in the VIPPS certification program is voluntary. The program was developed to provide consumers with reliable means to identify those online pharmacies that have proven their ability and authorization to dispense pharmaceuticals to the public in the jurisdictions listed on the VIPPS Web site.

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

Legal Briefs *(continued from page 85)*

Finally, the licensee argued that there was no evidence presented that he personally failed to enter data which gave rise to the current charges. In effect, the pharmacist argued that he could not be personally responsible for the alleged wrongdoings. The court rejected this argument, stating that the licensee was the pharmacist-in-charge and responsible for the practice of pharmacy in and by that pharmacy, including, but not limited to, compliance with all local, state, and federal pharmacy and drug laws. Hence, the licensee's status as a pharmacist-in-charge imposed upon him heightened responsibilities under the law compared to those imposed on a pharmacist. Related to this argument, the licensee argued that indefinitely prohibiting him from serving as a pharmacist-in-charge unfairly and disproportionately imposed a sanction in violation of the state constitution.

Recognizing that the licensee was able to continue practicing pharmacy and was also able to petition the Board anytime to lift the restriction upon a showing that he is capable of assuming the duties of a pharmacist-in-charge, the court rejected the arguments of the pharmacist. Applying appropriate deference to the decision of the Board, the court recognized that sanctions are necessarily tailored to the facts of each case and, thus, the court would not substitute its judgment for that of the Board under these circumstances. Based upon the foregoing, the court upheld the sanction imposed upon the licensee.

Boards of pharmacy must be aware of the legislative authority that empowers the regulatory agency to investigate and discipline licensees. Understanding the relationship of the investigative process to the eventual sanction should wrongdoing be substantiated is essential in avoiding appeals and ultimately protecting the public. Board members and inspectors must understand the necessity of and process for obtaining a warrant prior to performing inspections. Boards must also understand their authority in crafting an appropriate sanction under certain circumstances. Interestingly, this opinion did not address the authority of the board to "limit" a license, and in this case, prohibit a practitioner from acting as a pharmacist-in-charge while allowing the authority to continue the practice generally. From a practical standpoint, boards which limit the practice privileges of a licensee must also be prepared to monitor and enforce such limitations.

Appeal of William H. Morgan, RPh 742 A.2d 101 (NH 1999).

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

HRSA Announces Clinical Pharmacy Initiative

The US Health Resources and Services Administration's (HRSA) Bureau of Primary Health Care (BPHC) recently announced its Clinical Pharmacy Initiative, a program that emphasizes clinical pharmacy services as a necessary part of the delivery of primary health care. HRSA is the agency within the US Department of Health and Human Services responsible for improving access to health care. Through the Clinical Pharmacy Initiative, the BPHC's Office of Pharmacy Affairs (OPA) will develop working relationships with BPHC programs to help them implement and maintain clinical pharmacy services.

"The Initiative's emphasis on comprehensive pharmacy services is consistent with HRSA's strategy for achieving 100% access to health care and zero health disparities among ethnic and racial groups," states Dr Marilyn Gaston, HRSA's Associate Administrator for Primary Health Care. "A clinical pharmacist is a key member of a health delivery team. In addition to dispensing drugs, the pharmacist consults with patients, monitors their use of prescribed drugs, and checks for potential drug interactions. A clinical pharmacist prevents problems caused by drug interactions, inappropriate doses, and failure to adhere to the prescribed therapy."

For more information on OPA activities, visit their web site at www.hrsa.gov/odpp.

ISMP Calls for Elimination of Handwritten Rxs

The Institute for Safe Medication Practices (ISMP) has published a discussion paper that calls for the elimination of handwritten prescriptions and advocates the widespread use of handheld prescribing technology tools by 2003 to help prevent medication errors resulting from poorly handwritten prescriptions. The paper, entitled "A Call to Action:

Eliminate Handwritten Prescriptions Within 3 Years," is the first in a series of "White Papers" planned by ISMP to address the topic of medication errors. It describes the benefits, drawbacks, costs, and technological considerations of using this kind of technology to address medication errors.

"Technology can't solve all the medication error problems in the world," states ISMP President Michael R. Cohen, MS. "In fact, we often see that technology can actually introduce a whole new set of problems if we don't use it appropriately. Still with proper systems design, implementation, and maintenance, the benefits of handheld prescribing far outweigh the drawbacks. There's simply no good reason why we can't begin using this technology now to make prescribing a lot safer."

The document is available on ISMP's Web site at www.ismp.org. NABP

NABP's VIPPS Elected to ASAE "Honor Roll"

NABP has been elected to the Associations Advance America Honor Roll, a national awards competition sponsored by the American Society of Association Executives (ASAE), Washington, DC, in recognition of its Verified Internet Pharmacy Practice Sites™ (VIPPS™) program.

Specifically, ASAE recognized NABP's VIPPS program for its efforts to inform consumers about those online pharmacies that have met the rigorous 17-point VIPPS criteria, and are in compliance with the licensure laws of the jurisdictions in which they practice pharmacy. By clicking on the VIPPS seal found on the home pages of program-certified online pharmacies, consumers are instantly hyperlinked to

(continued on page 92)

The Prescription Drug Marketing Act: Final Regulations

Editor's Note: Following is a special column, submitted by the US Food and Drug Administration, to further explain final regulations concerning the Prescription Drug Marketing Act (PDMA).

The final regulations implementing the Prescription Drug Marketing Act (PDMA) amendments to the Federal Food, Drug, and Cosmetic Act were published in the December 3, 1999 *Federal Register* (Docket Nos. 92N-0297 and 88N-0258). The regulations become final December 4, 2000.

The final rule covers:

(1) the reimportation and wholesale distribution of prescription (Rx) drugs;

(2) the distribution of Rx drugs purchased by hospitals or other health care entities;

(3) drugs donated to charitable organizations;

(4) the distribution of Rx drug samples; and

(5) certain sections of the "Guidelines for State Licensing of Wholesale Prescription Drug Distributors" (21 CFR Part 205).

Reimportation

The reimportation section of the PDMA was amended by the US Food and Drug Administration (FDA) Modernization Act to include drugs composed wholly or partially of insulin. Therefore, drug products composed wholly or partially of insulin, whether prescription or over-the-counter (OTC), are subject to the reimportation restrictions of section 801(d) of the Federal Food, Drug, and Cosmetic Act (the Act). Section 801(d) of the Act prohibits the reimportation of any prescription drug that was originally manufactured in the United States back into the US unless the importation is by the manufacturer of the drug or, in the case of a medical emergency, with the permission of the FDA.

Drug Donation of Samples

Prescription drug samples may be donated provided there is accountability and oversight of such donations that will serve to minimize the potential for diversion of the samples. Even though no comments were received on this section in the proposed rule (F.R. Vol. 59, No. 49, March 14, 1994), several of the proposed requirements have been eliminated as too burdensome. Prescription drug samples may be donated provided the following rules are observed:

(1) Donated drug samples are packaged in their original, unopened packaging with intact labeling.

(2) Donated drug samples may be delivered by mail or common carrier to the recipient charitable organization, collected by an authorized agent or employee of the charity, or by personal delivery by the donor. Samples must be placed in a sealed carton by the donor for delivery to or collection by the recipient charity.

(3) A donated sample cannot be dispensed to a patient or be distributed to another charitable institution until it has been examined by a licensed practitioner or registered pharmacist at the recipient charity to confirm that the donation record accurately describes the drug sample delivered, and that the drug sample is not adulterated or misbranded for any reason.

(4) The recipient charity must dispose of any drug sample found to be unsuitable by destroying it or returning it to the manufacturer for destruction. The charity shall maintain complete records of the disposition of all destroyed or returned samples.

(5) The recipient must prepare a complete and accurate donation record at the time of the collection or delivery of the drug samples. A copy of this donation record must be kept for at least three years.

(6) Each recipient must keep complete and accurate records of drug sample donation sufficient for complete accountability and auditing of drug sample stocks.

(7) Each recipient must conduct, at least annually, an inventory of prescription drug sample stocks and prepare a report reconciling the results of each inventory with the most recent prior inventory.

(8) Drug samples must be stored under appropriate conditions.

(9) A recipient shall notify the FDA within five working days of discovering a significant loss or known theft of prescription drug samples.

Drug Donation of Non-Samples

Although no specific controls are established in this regulation for the donation of non-sample prescription drugs, the Agency (FDA) recommends that:

(1) the donor verify that the charity is legitimate;

(2) all donated drugs are screened by a physician or pharmacist to eliminate drugs that are recalled, outdated, or otherwise unsuitable for human use;

(3) unsuitable drugs are destroyed or returned to the supplier for destruction; and

(4) there are adequate inventory, accountability, and security systems to prevent loss, theft, or diversion of the donated drugs. For the FDA, the bottom line on donations is that **if a drug cannot be sold in the United States, it cannot be donated.** The Agency advises that previously dispensed prescription drugs may **not** be donated. In addition, since such donation is distribution of a prescription drug to a party other than a consumer or patient, the Agency considers this to be wholesale distribution.

Electronic Records and Electronic Signatures

21 CFR Part 11, Electronic Records; Electronic Signatures (F.R. March 20, 1997) supersedes the requirements concerning electronic systems and records in the proposed PDMA regulations.

Part 11 applies to any records created, modified, archived, retrieved, or transmitted to the agency under all laws and regulations administered by the FDA. Provided the requirements of Part 11 are met, electronic records, electronic signatures, handwritten signatures executed to electronic records may be used in place of paper records to comply with PDMA.

Paper Records

Part 11 does **not** apply to paper records that are transmitted by electronic means, such as faxing. Since Part 11 does not apply to paper documents that are photocopied, microfiched, or faxed, the final regulations contain revised security and authentication requirements for paper records.

Mid-Level Practitioners

When there is a question concerning whether a mid-level practitioner may request, receive, or dispense prescription drug samples, one must look to the laws of the state where the practitioner practices. It is state law that determines the practices and authorities granted to such practitioners. If a mid-level practitioner is permitted to prescribe prescription drugs but is prohibited by state law from receiving samples, that mid-level practitioner may not be sampled.

Drug Returns

All drug shipments sent back to the manufacturer or supplier by hospitals and other health care entities are categorized as **returns**. A credit memo containing information specified in the regulation must be prepared by the hospital, health care entity, or charitable organization, and a copy must be sent to the manufacturer. Any drugs returned to a manufacturer or wholesale

(continued on page 93)

NABP Completes Headquarters Remodeling Project

Construction of the remodeling of the first level at NABP's headquarters in Park Ridge, Ill, was completed in early June. Construction began on April 17, 2000.

Consruction workers near completion of the final phase of the build-out. This main row of cubicles is now the home of the Foreign Pharmacy department and Office Services.

"This build-out will help NABP provide more efficient service to the boards by centralizing customer service and application data processing," says Jerry Moore, JD, RPh, NABP president. "In the long run, this will help NABP control costs by using the current space available to its maximum capability. As the Association continues to expand its programs and services, this project will also allow NABP to plan for its future needs."

In order to provide expanded member services, NABP began to explore its options to accommodate additional staff early this year. After much consideration, remodeling the first level of its Park Ridge headquarters was determined to be the most cost-effective choice.

"The general idea was to create a suite of offices on the first level that was as pleasant a working atmosphere as the existing second level," says Margaret Gould, NABP office services manager, who has overseen the entire remodeling project. "After seven weeks of construction, we are pleased with the results and looking forward to moving in."

The newly transformed first level includes three managerial offices, 15 staff cubicles, and an updated file room. Also part of the expansion, NABP has installed a new phone system. Staff moved into the first level in late June. NABP

NABP Accepting Inspector DSA Nominations

NABP is currently accepting nominations for the Association's 2000 Lester E. Hosto Distinguished Service Award (DSA) for Inspectors. The award honors those board compliance officers who have been acknowledged by NABP's Executive Committee for their efforts in furthering NABP's objectives to protect the public health and welfare. A special luncheon will be held to honor the recipient of NABP's 2000 DSA for Inspectors on Monday, November 13, 2000 during NABP's Health Law Officers Conference in Biloxi, Miss.

All letters of nomination for the award must be received at NABP headquarters no later than Friday, September 1, 2000. Letters should be addressed to Executive Director/Secretary Carmen A. Catizone, and should include a written narrative that explains why the nominee should be considered. The list of nominees will be reviewed by the Executive Committee.

Nomination letters should be sent to NABP headquarters at 700 Busse Highway, Park Ridge, IL 60068, or faxed to 847/698-0124. NABP

Washington Board Expands the Legal Use of Needles and Syringes

The Washington State Board of Pharmacy is expanding its definition of the legal use of needles and syringes to include the prevention of blood borne diseases. Although the state of Washington does not require a prescription to sell syringes, they can only be sold for legal use.

Currently, the law in Washington states "the retailer shall satisfy himself or herself that the device will be used for the legal use intended." By redefining legal use, pharmacists would have more legal discretion to sell syringes to intravenous drug users, thus helping to slow the spread of HIV and hepatitis.

After reviewing the evidence presented at a program sponsored by NABP, the Centers for Disease Control and Prevention (CDC), and the American Pharmaceutical Association (APhA) in the Spring of 1999, Washington State Board of Pharmacy Executive Director **Donald H. Williams** drafted a resolution for the Board to consider, which is now moving through the rulemaking process. "I believe that if the Board could reinterpret the syringe law, we might find a way for our pharmacists to participate in another public health program," says Williams.

"I find it interesting that the boards of pharmacy, medicine, nursing, etc, are very interested in the rehabilitation of the licensed health professionals that get into trouble with drugs or alcohol. We send these individuals to treatment . . . and allow them to return to the practice of their respective profession. However, we take a different, less kindly, view of other drug abusers, particularly intravenous drug users. By increasing the availability of syringes, we have an opportunity to help these unfortunate individuals while preventing the overall spread of disease at the same time."

Many pharmacies stopped selling needles and syringes after passage of the 1998 State Drug Paraphernalia Law, which made the distribution of needles and syringes a civil offense when they are used to inject illegal controlled substances. An exception exists, however, when injection syringe equipment is distributed through public health and community-based HIV prevention programs. While the exception was placed in the law to allow needle exchange programs to continue to operate, the Board recommends that pharmacists use the exception to sell needles and syringes after establishing a relationship with their local public health agency. Such a relationship could be created by contract or by obtaining a letter of support from the health agency. NABP

NABP Seeks Item Writers for Testing Programs

Pharmacy practitioners, educators, and regulators who are interested in serving as an item writer for the North American Pharmacist Licensure Examination™ (NAPLEX®), Multistate Pharmacy Jurisprudence Examination™ (MPJE™), or the Disease State Management (DSM) examinations should send or fax a letter of interest and a current resume or curriculum vitae to NABP's Executive Director/Secretary Carmen A. Catizone at 700 Busse Highway, Park Ridge, IL 60068; fax 847/698-0124.

Item writers will receive training materials describing the skills necessary for their designated examination, and may be asked to attend a weekend workshop at NABP headquarters or an area hotel, with applicable expenses paid by NABP. Item writers will receive periodic requests to develop new test items that will be considered for inclusion in NABP's assessment programs.

State board of pharmacy members and staff are particularly encouraged to participate in the item writing process. Questions about item writing should also be directed to Carmen A. Catizone at NABP headquarters. NABP

Expanded ELTP Training Session Offered to Boards of Pharmacy Staff

A more extensive Electronic Licensure Transfer Program (ELTP) training session for boards of pharmacy staff members will be held late this summer at the NABP headquarters in Park Ridge, Ill. This year's training is delayed because more time is needed to prepare the program training.

The training session will focus on features of the latest version of Lotus Notes board offices will use to communicate with NABP. According to NABP President Jerry Moore, JD, RPh, "This year's training session will also include the new Clearinghouse/HIPDB program and some new areas suggested by last year's participants. It is applicable to both new and established board staff members."

Along with the expanded training, NABP is providing hardware and software for the ELTP system to those board offices that require it. The hardware is a Pentium III 500 MHz, or faster, personal computer. Some state board offices already have the appropriate hardware and will only receive the new software.

"The upgrades will allow state boards to use more features of our system," says Information Technology Manager Andrew Duda, "and to use the current communications channels to contact our server and use the World Wide Web in the future. We will be processing data over the Internet instead of through dial-up connections."

ELTP is a rapid and accurate method for licensure transfer. Within 24 to 48 hours from the time NABP recives a preliminary application, a Requests for Verification is e-mailed to the state boards, and their response to NABP can be returned almost instantaneously. The program also verifies disciplinary information, competency assessment scores, and Foreign Pharmacy Graduate Equivalency Certification. "NABP's disciplinary clearinghouse has the most up-to-date information available from all the boards," says Moore. "We frequently find disciplinary information in the database that an applicant has not disclosed in the application."

Besides showcasing the quick and effective methods to obtain that necessary information, training has other pluses. "Training provides the opportunity to discuss what NABP can do for boards in very specific terms," says Moore. "Past attendees said it was beneficial to gain an overview of NABP and how the data they submit is used to benefit the boards."

The Licensure and Application Database Programs department will issue notices when training dates are finalized. Board staff members interested in attending will fill out a simple registration form. Questions can be directed to Licensure and Application Database Programs Director Glenn Detweiler at 847/698-6227, or e-mailed to eltp@nabp.net. NABP

NABP's VIPPS Elected to ASAE "Honor Roll" *(continued from page 87)*

NABP's VIPPS Web site, where they may access specific information that will assist them in choosing an online pharmacy they can trust with their family's health care needs.

"We are pleased that the ASAE has recognized NABP and the VIPPS certification program," comments Jerry Moore, JD, RPh, NABP president. "To have been included on ASAE's Associations Advance America Honor Roll is, indeed, an honor for NABP."

Now in its 10th year, the Associations Advance America awards program recognizes associations that propel America forward with innovative projects in education, skills training, standards-setting, business and social innovation, knowledge creation, citizenship, and community service.

"Your program is a perfect example of how associations play a vital role in helping the nation adapt to complex and changing times," says Michael S. Olson, CAE, ASAE president and CEO, in regards to the VIPPS program. "Contributions such as yours are vital, and add real value to society." NABP

PDMA: Final Regulations *(continued from page 89)*

distributor must be kept under proper conditions for storage, handling, and shipping, and written documentation showing the proper conditions were maintained must be provided to the manufacturer or wholesale distributor with the returned drug products.

Starter Packs

Since the Agency does not regard **starter packs** as drug samples under the Act, use of the term "starter" on drug sample labeling is inappropriate and should not be used.

Indigent Patient Programs

The Agency has determined that drug products distributed to indigent patients programs are not samples under the PDMA when distributed through manufacturer-sponsored indigent patient programs. Such programs generally include appropriate controls, documentation, and verification of the distribution and use of these products.

Samples in Retail Pharmacies

The proposal to consider the presence of a drug sample in a retail pharmacy as a violation of the Act has been withdrawn. However, the agency continues to interpret the presence of samples in a retail pharmacy as probative that samples are being distributed in violation of the Act and would consider opening an investigation if prescription drug samples are found in a retail pharmacy.

Bulk Drugs/Pharmacy Compounding

Under PDMA, the term "bulk drugs" refers to Bulk Drug Substances (BDS), which is defined as drugs or drug components, furnished in forms other than finished

dosage form, that are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to effect the structure or any function of the body of humans. Because the statute makes all drugs subject to section 503(b)(1) of the Act subject to PDMA, a bulk drug that is intended to furnish pharmacological activity or other direct effect when it becomes a finished dosage form that is a prescription drug is subject to the PDMA. Requirements concerning the wholesale distribution of prescription drugs also apply to bulk drugs because similar concerns exist, as with finished dosage form products, involving personnel and facilities through which bulk drugs are distributed and how they are stored and handled. For imported bulk drugs, including those imported for pharmacy compounding, the importer of record is engaged in wholesale distribution and must be state licensed. Any agent that subsequently distributes the BDS must also be state licensed.

Controlled Room Temperature/21 CFR Part 205

The proposed regulations modified section 205.50(c) of the wholesaler licensing regulations to require, in the absence of labeled storage conditions on a prescription drug, that the drug would have to be stored according to the definition of Controlled Room Temperature (CRT) as stated in the revised edition of the *US Pharmacopeia* (USP). The Agency agreed that this proposal is substantive rather than technical since the definition of CRT changed significantly from the edition of the *USP* in effect at the time of the original drafting of the proposed regulations and the current *USP* edition. Therefore, this proposal has been withdrawn.

Questions about the Prescription Drug Marketing Act (PDMA) and the final regulations may be directed to: Margaret O'Rourke, senior regulatory expert, Division of Prescription Drug Compliance and Surveillance (HFD-330), Center for Drug Evaluation and Research, US Food and Drug Administration. Phone: 301/827-7296; e-mail: orourke@cder.fda.gov. NABP

Survey Shows State Boards Gain Autonomy

More state boards of pharmacy are working independently of central agencies than in years past, according to NABP's biennial Resources and Responsibilities Survey. In 1999, 47 boards of pharmacy responded to the Survey, which covers such topics as board organization, responsibilities, procedures, budget processes, and computer capabilities.

Since the 1997 Survey, three boards have begun functioning as autonomous agencies, bringing the total members of boards that function independently of other state agencies to 27. Seventeen boards function as part of a central agency, and the remaining three fall into both categories, depending on the task involved.

Regardless of whether they function independently or not, every state board of pharmacy has the power to license and discipline pharmacists. Nearly all of the boards, 43, perform pharmacy inspections. Only 27 boards are responsible for enforcing the Federal Food, Drug, and Cosmetic Act, while 31 have responsibility for the Controlled Substances Act.

In terms of fines, only seven of the boards do not impose fines, which is down by two from the 1997 Survey. Of the 40 boards that can impose fines, 12 boards did not collect any fines, while New York and New Jersey collected more than $200,000 each. The average annual revenue from fines was $36,410.

Permit and licensing fees bring in the most revenue for the boards. Of the states that responded, five boards each awarded more than 15,000 registered pharmacist licenses. California granted the greatest number, with 29,423 licenses. Alaska granted the fewest, awarding only 478 pharmacist licenses.

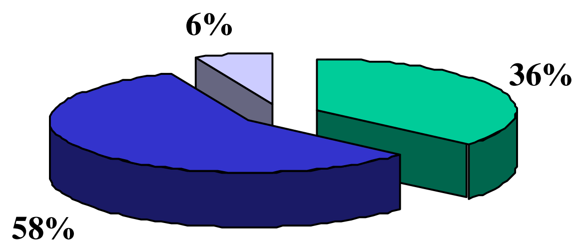
California, with its $5 million budget, reported the largest annual budget. Three states have a budget of $2.5 million or more, and 10 states have a yearly budget of $1 million.

As the number of autonomous boards has increased, so has the state boards' power to set budgets. Currently, 56.5% of the boards of pharmacy develop budgets, while 30.4% report that a central agency controls budget development. This is down from the 35% recorded in the 1997 Survey. The responding state boards also showed gains in responsibility for setting and collecting fees, at 69.5% and 67.4%, respectively.

Almost all of the boards have made use of NABP's Electronic Licensure Transfer Program™ (ELTP™) computer system. Only two states use a central computer system in conjunction with another state department, while 43 of the boards make use of the ELTP computer system. The ELTP system is also used by the boards for word processing (44%), financial/budgeting (7%), and database management (30%).

Copies of the 1999 Resources and Responsibilities Survey may be obtained by contacting the office of NABP's executive director/secretary at 847/698-6227. NABP

Central Agency vs. Autonomous Board Operations



Central Agency ■ Autonomous ■ Both

Warren New Executive of Colorado Board

Susan L. Warren, MS, JD, assumed the position of program administrator of the Colorado State Board of Pharmacy effective April 10, 2000. She replaces **Kent Mount**, who retired in March.

Most recently, Ms Warren was manager of medical services delivery for the Colorado Department of Labor and Employment and was responsible for three medical service programs. She has also held positions with the Colorado Department of Public Health and Environment, the Colorado Department of Regulatory Agencies, and the Colorado Attorney General's Office.

Warren has a masters of public health from Harvard School of Public Health, a juris doctorate from the University of Nebraska Law School, and a degree from the University of Nebraska.

New Board Members

The North Carolina Board of Pharmacy announces two new members, **Stan Haywood, RPh**, and **Wallace E. Nelson, RPh**. Both Haywood and Nelson began their five-year terms in May.

Haywood is the owner and chief pharmacist of Prevo Drugs in Asheboro, NC. A graduate of the University of North Carolina School of Pharmacy, he serves on the Mutual Drugs Legislative Affairs, and is a member of the Asheboro City Board of Education.

Nelson is the director of Chowan Hospital Pharmacy in Edenton, and is a graduate of the University of North Carolina – Chapel Hill. He was chosen by the governor to serve

on the Governor's Council on Alcohol and Other Drug Abuse and the Institute on Alcohol and Other Drug Studies board of directors. Also involved in education, Mr Nelson is the chairman of the Perquimans County Board of Education.

Moné Serves on APhA Board of Trustees

Kentucky Board of Pharmacy Executive Director **Michael Moné, JD, RPh,** was elected to the American Pharmaceutical Association (APhA) Board of Trustees as the 2000 – 2001 speaker-elect for the house of delegates. Moné is currently a member of NABP's Multistate Pharmacy Jurisprudence Examination™ Review Committee. NABP

International VIPPS Program to be Launched *(continued from page 83)*

The new program will also offer a separate interface to foreign Internet users from the existing VIPPS pages, located at http://vipps.nabp.net. Users wishing to verify an international certified Web site will click on the VIPPS "Click To Verify" seal, and be instantly linked to a series of VIPPS Web site pages that list information about that country's specific requirements, and about online pharmacies certified in that particular nation. International VIPPS Web pages are currently under development by NABP.

So far, licensing authorities from Australia, Canada, and New Zealand have expressed interest in participating in the VIPPS program. It is expected the new VIPPS program will go live on the Internet during the fourth quarter of this year. For more information regarding VIPPS, please call NABP's Licensure Programs Department at 847/698-6227, or e-mail via vipps@nabp.net. NABP

NABP Meeting Dates

Saturday-Sunday, July 29-30, 2000
Executive Committee Meeting,
NABP Headquarters, Park Ridge, Ill

Sunday-Tuesday, August 6-8, 2000
District III Meeting,
Grove Park Inn, Asheville, NC

Thursday-Saturday, August 10-12, 2000
District V Meeting,
Sheraton Hotel, Winnipeg, Manitoba, Canada

Thursday-Sunday, September 21-24, 2000
District VII & VIII Meeting,
Hilton Tucson East, Tucson, Ariz

Thursday-Sunday, October 5-8, 2000
District VI Meeting,
Arkansas Excelsior Hotel, Little Rock, Ark

Thursday-Saturday, October 12-14, 2000
District I Meeting,
Sheraton Hotel, Burlington, Vt

Sunday-Wednesday, October 15-18, 2000
Fourth International Conference of
Pharmaceutical Competencies,
Ottawa, Ontario, Canada

Thursday-Saturday, October 19-21, 2000
District II Meeting,
Hilton Shorts Hotel, Short Hills, NJ

Friday-Sunday, November 10-12, 2000
District IV Meeting,
Radisson Hotel & Suites, Chicago, Ill

Saturday-Sunday, November 11-12, 2000
Executive Committee Meeting,
Beau Rivage Casino-Hotel,
Biloxi, Miss

**Sunday-Tuesday,
November 12-14, 2000**
Health Law Officers Conference,
Beau Rivage Casino-Hotel,
Biloxi, Miss

newsletter
National Association of Boards of Pharmacy
700 Busse Highway
Park Ridge, Illinois 60068