newsletter

National Association of Boards of Pharmacy®

September 2006 / Volume 35 Number 8

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1904 to 2006

This Month on www.nabp.net:

Special Items
Report of the Second Meeting of the 2005-2006 Task Force on Telepharmacy

Proceedings of NABP's 102nd Annual Meeting

Headlines
NABP Launches Pharmacy Authenticated Licensure Service Program

Upcoming Meetings

Friday, September 29, 2006
NABP's Annual Program Review and Training Sessions
NABP Headquarters
Mount Prospect, IL

Wednesday-Saturday, October 4-7, 2006
NABP/AACP District VII & VIII Meeting
Disneyland Hotel
Anaheim, CA

Thursday-Saturday, October 12-14, 2006
NABP/AACP District I & II Meeting
Renaissance Harborplace Hotel,
Baltimore, MD

Wednesday-Saturday, October 25-28, 2006
NABP/AACP District VI Meeting
The Peabody Little Rock
Little Rock, AR

Friday-Saturday November 3-4, 2006
NABP Fall Educational Conference
Hyatt Regency Savannah
Savannah, GA

NABP Collaborates with AACP, ACPE on Curriculum Assessment Tool

NABP is working closely with the American Association of Colleges of Pharmacy (AACP) and the Accreditation Council for Pharmacy Education (ACPE) on the development of the Pharmacy Curriculum Outcomes Assessment™ (PCOA™), a curriculum assessment tool intended for use by schools and colleges of pharmacy. Based upon the upcoming revision of the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) blueprint that is being derived from ACPE's recently updated standards and guidelines for the professional curriculum, the collaborative effort between AACP, ACPE, and NABP will position the PCOA as a valuable and integral component of the process schools use to assess their curriculum. The data obtained from the PCOA will provide to the individual colleges and schools detailed feedback related to the subject matters covered throughout the professional curriculum.

In 2005, a member college of AACP approached NABP requesting help to assess the pharmacy curriculum. A pilot study of the assessment mechanism was administered in the fall of 2005 to determine the feasibility of this project. In this first pilot study, NABP provided an assessment tool to the college for administration to 176 P1 to P4 students. The results showed that second year students performed better than first year students, and third year students performed better than second year students. The results of the pilot test were very encouraging and served as the basis for a serious consideration of making an assessment available for use by all colleges and schools of pharmacy. As conceived, the PCOA will provide data that can be directly mapped to a school's curriculum and offers more detailed information than the North American Pharmacist Licensure Examination™ (NAPLEX®) results. Although NAPLEX performance is an important measure, the applicability of this data in directly assessing curriculum is limited because the intent of the NAPLEX is assessment of the application of the

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The NABP Newsletter (ISSN 8756-4483) 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 65 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.

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NABP Task Force on Telepharmacy Issues Final Report

Two separate meetings of the 2005-2006 Task Force on Telepharmacy and the Implementation of the Medicare Drug Benefit Medication Therapy Management Provisions have resulted in an eight-recommendation final report that encompasses the work product of both meetings. This report, approved by the NABP Executive Committee at its July 14, 2006 meeting, is available on NABP's Web site at www.nabp.net.

The appointment of this Task Force came at the direction of NABP's Executive Committee in response to Resolution 101-8-05, Implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and in response to a recommendation from the 2004-2005 Committee on Law Enforcement/Legislation to examine the evolving practice of telepharmacy.

Guest speakers, Kim A. Caldwell, a member of the Texas State Board of Pharmacy and past director of division of Clinical and Economic Performance in the Centers for Beneficiary Choices for the Centers for Medicare and Medicaid Services, and Stanley Wm. Goldenberg, member of the California State Board of Pharmacy, provided needed background on these issues for the Task Force. Mr Caldwell reviewed the federal regulatory provisions of medication therapy management (MTM) services that arose from the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, while Mr Goldenberg addressed the efforts of the California State Board of Pharmacy intended to allow pharmacists to provide the multitude of MTM services through a new regulatory framework that would allow for the licensing of entities that strictly provide cognitive services (not in conjunction with a pharmacy that dispenses drugs) and the licensure or registration of nonresident entities that provide such services.

The Task Force's charge was to review existing state regulations relating to the practice of telepharmacy and, if necessary, develop model legislation/regulations to address the provision of pharmacist care across state borders considering the MTM provisions of the Medicare Drug Benefit.

The vast majority of the Task Force's recommendations involved amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*. These amendments address four primary areas: 1) the provision of MTM services and pharmacist care; 2) the use of remote pharmacy technologies and services for telepharmacy practice; 3) the independent provision of pharmacist care services using telepharmacy technologies outside of a licensed pharmacy setting; and 4) the use of these technologies and provision of these services across state lines.

The first change to the *Model Act* was the incorporation of "medication therapy management" services as defined by the majority of the pharmacy profession, and a change from the term "pharmaceutical care" to "pharmacist care" along with an expansion in this term's definition. These changes were made to reflect pharmacy practice activities as they have evolved and are anticipated to evolve, and to recognize that the term "pharmaceutical care" has a currently accepted definition within the profession.

The second area of change to the *Model Act* involved adding language allowing for the use of "automated dispensing systems" in "remote pharmacies" or at "remote dispensing sites" that are electronically linked to a "coordinating pharmacy" responsible for the practices performed at the remote sites. Recognizing the national pharmacist shortage and the potential to provide pharmacist care services using electronic technologies to patients at a distance,

the Task Force developed a framework for the provision of remote services while considering current regulatory and patient safety standards, allowable scope of practice, the use of pharmacy support personnel, and maintenance of quality assurance procedures.

The third area of change involved adding language that allows and provides guidelines for the practice of pharmacy by pharmacists outside of a pharmacy setting. Recognizing that such activities are on the rise as a result of MTM services now being offered as a benefit to some Medicare recipients, members felt regulation of these activities was necessary, and focused on the protection of patient information.

The final area of change to the *Model Act*, closely related to the previous change, involved the incorporation of a nonresident pharmacist registration requirement for pharmacists who work outside a pharmacy setting and who are practicing telepharmacy across state lines. Prior to this change, the *Model Act* required full pharmacist licensure in the state where the patient was located if the pharmacist was practicing telepharmacy across state lines. The Task Force agreed that the objective of this requirement, which is for each jurisdiction to have a record of who is providing services to their citizens, was a good one, but felt it was overly burdensome and did not necessarily provide protection to the public above and beyond single state licensure. Task Force members agreed that the current method by which the majority of states regulate nonresident pharmacists, through nonresident pharmacy registration (as opposed to nonresident pharmacist licensure) is effective and provides the boards with the needed authority over pharmacists via their employers, which is why the model language only impacts pharmacists practicing outside a licensed pharmacy.

With an eye towards the future, Task Force members also made a related recommendation, asking the NABP Executive Committee to explore the implementation of a centralized, multi-state pharmacist licensure compact model, perhaps administered by NABP, which encompasses mutual licensure recognition and the current nonresident pharmacy license structure. The Task Force reviewed the multistate licensure models implemented by the nursing and medical professions and found that the nurse licensure compact model, with some modification, could be a workable solution. The Task Force felt NABP should evaluate a model that allows independently practicing pharmacists to use the one license obtained in their state of residency for traditional pharmacy practice in that state, and electronic, but not physical, practice, in any other state that enters into the compact.

Members of the first Task Force included Task Force Chair Karen M. Ryle, member, Massachusetts Board of Registration in Pharmacy; Monica K. Franklin, member, Tennessee Board of Pharmacy; Susan Ksiazek, member, New York State Board of Pharmacy; Michael A. Podgurski, member, Pennsylvania State Board of Pharmacy; Stephen R. Statz, member, South Dakota State Board of Pharmacy; Woodrow E. "Woody" Storey, member, New Mexico Board of Pharmacy; Hal Wand, executive director, Arizona State Board of Pharmacy. Gary A. Schnabel, executive director, Oregon State Board of Pharmacy, served as Executive Committee liaison. The second meeting of the Task Force was chaired by Susan Ksiazek and was attended by members, Monica K. Franklin, Michael A. Podgurski, and Hal Wand, who were joined by new members, Mary Ryan, Medco Health Solutions, Inc, and Dan Luce, Walgreen Co. Gary A. Schnabel again served as the Executive Committee liaison and was joined by fellow Executive Committee representative, Oren M. Peacock, Jr. Karen Ryle stepped down from serving as the chair of the Task Force due to her election to the NABP Executive Committee.

Executive Committee

Dennis K. McAllister
Chairperson, District VIII
One-year term

Lawrence H. Mokhiber
President, District II
One-year term

Oren M. Peacock, Jr
President-elect, District VI
One-year term

John R. Dorvee, Jr
Treasurer, District I
One-year term

Malcolm J. Broussard
Member, District VI
Serving first year of a three-year term

Reginald B. "Reggie" Dilliard
Member, District III
Serving second year of a three-year term

Patricia F. Harris
Member, District VIII
Serving second year of a three-year term

Lloyd K. Jessen
Member, District V
Serving a one-year term

Richard A. "Rich" Palombo
Member, District II
Serving third year of a three-year term

Karen M. Ryle
Member, District I
Serving a one-year term

Gary A. Schnabel
Member, District VII
Serving first year of a three-year term

William T. "Bill" Winsley
Member, District IV
Serving second year of a three-year term

NABP's Executive Committee is elected each year at the Association's Annual Meeting. The 103rd Annual Meeting is May 19-22, 2007, at the Hilton Portland & Executive Tower, Portland, OR.

Who's Alford?

By Dale J. Atkinson, JD

The grounds for discipline section of the pharmacy practice act empower the board to "discipline" pharmacists for various acts or omissions that endanger or injure patients. These grounds must be carefully crafted as they not only set the parameters for determining disciplinary issues to be rendered by the board, but also provide notice to pharmacists and the public as to what constitutes conduct that may subject licensees to administrative discipline. As licenses are considered property rights bestowed upon qualified applicants, certain due process rights are afforded to license holders before adverse actions can be taken by a board of pharmacy. That is, licensees must be reasonably placed on notice as to what may constitute prohibited acts or omissions for which the board may, after notice and an opportunity for a hearing, discipline the license.

The grounds for the discipline section of the practice act are generally contained in the statutes enacted by the legislature. Boards of pharmacy, using their expertise, thereafter promulgate rules to more definitively identify conduct that may subject licensees to administrative discipline. Again, these rules/regulations are a vital component to fulfillment by the boards of their public protection mission through the regulation of the profession.

Article IV §402 of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* contains the grounds for discipline bestowed upon pharmacy boards. As pharmacy practice acts are reviewed and, under the appropriate political climate, amended to better provide the board with the authority to protect the public, NABP member boards are encouraged to consult the *Model Act* for guidance and suggested language. Not only are the common grounds contained in the *Model Act* (ie, unprofessional conduct, fraud, misrepresentation, discipline in another jurisdiction), but also included is a prohibition of conduct that subverts or attempts to subvert any licensing examination or the administration of any licensing examination (§402(13)).

While seemingly obvious, the reference to a criminal conviction as grounds for discipline section can be a source of legal debate and argument as related to subsequent administrative discipline by the board. Section 402(3) of the *Model Act* addresses criminal conduct and references being guilty of a felony, any act involving moral turpitude or gross immorality, or violations of pharmacy or drug laws. Determinations of "guilt" in a subsequent administrative proceeding following a criminal disposition of a matter may be creatively argued by licensees. It is important to understand and define guilt as part

of a criminal matter. Consider the following.

Kentucky law empowers the Board of Dentistry (Board) to discipline dentists who are convicted of any misdemeanor involving moral turpitude. A licensed dentist (licensee) was a pediatric practitioner for over twenty years. Based upon a lengthy investigation by law enforcement authorities and the potential for numerous charges, the licensee agreed to an "Alford plea" to a single charge misdemeanor of knowingly making a false statement to receive medical assistance under Medicaid. The criminal court sentenced the licensee to 12 months in jail, probated for two years or until he paid $143,632.79 as restitution to the Kentucky Medical Assistance Program, and an additional restitution of $25,000 to the Kentucky Attorney General's office.

Following the criminal plea, the Board issued a formal complaint against the licensee for purposes of taking administrative action against his license. The Board conducted an administrative hearing on the complaint and allowed the licensee to explain the circumstances giving rise to the criminal conviction. Over the objection of the licensee, the Board placed his license to practice dentistry in Kentucky on probationary status until he paid the restitution ordered by the sentencing court. The sole reason for the administrative findings and sanction by the Board was the licensee's criminal conviction of an offense involving moral turpitude. The matter was upheld by the circuit court. Thereafter, the licensee appealed the administrative matter to the appellate court.

On appeal, many of the contentions of the licensee were determined by the court to be collateral attacks on his criminal conviction. Because only the Board order containing the sanction was under appeal regarding the administrative matter, the court disregarded these collateral attacks. It noted that any irregularities that existed in relation to the criminal conviction may be raised only in a separate post-conviction petition for relief of the criminal matter. Thus, the appellate court confined its analyses to the administrative matter and alleged grounds on appeal.

First, the licensee argued that the Alford plea was not an acceptable method of adjudicating a criminal case under Kentucky law. That is, the plea does not actually amount to a conviction necessary to trigger an ancillary administrative action. He argued that Kentucky law only authorizes a criminal court to accept a guilty or not guilty plea and does not recognize a plea of nolo contendere. Thus, the Alford plea is not able to be entered in Kentucky, thus rendering the conviction upon which the Board based its administrative action a nullity.

In rejecting this argument, the court held that the licensee failed to recognize that an Alford plea is a specialized type of guilty plea. Specifically, the court identified an Alford plea as a "guilty plea by an accused who refuses to acknowledge guilt, but waives trial and accepts all consequences of a conviction." The court cited several cases finding that an Alford plea "clearly constitutes a conviction." Thus, the court held that the Alford plea constituted a conviction for purposes of triggering an administrative sanction under the grounds for discipline section of the practice act.

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

FDA Removes Stay of Pedigree Requirements; Issues CPG

On June 14, 2006, the United States Food and Drug Administration (FDA) published in the *Federal Register* an announcement that there will no longer be a delay in the effective date of certain pedigree provisions of a final rule, published on December 3, 1999, implementing the Prescription Drug Marketing Act of 1987 (PDMA). These provisions, which were to have originally taken effect in December 2000, had been delayed for several years due to objections raised by various stakeholders and efforts by FDA to assess whether or not the industry could implement compliant electronic pedigree technology by 2007. The effective date is December 1, 2006. In addition, FDA also published a notice of availability of a draft Compliance Policy Guide (CPG) detailing FDA's enforcement strategy with regards to the pedigree requirements and a request for comments on the CPG.

PDMA and Rules Background

The PDMA established a pedigree requirement for the wholesale distribution of prescription drugs, This requirement, found at 21 USC 353(e)(1)(A), mandates those engaged in wholesale drug distribution who are not manufacturers or "authorized distributors of record" to pass a pedigree. Although the PDMA defines an "authorized distributor of record"[1], it does not define "ongoing relationship," thus it was unclear as to which entities needed to comply. The 1999 rule addressed this issue by defining "ongoing relationship" (21 CFR 203.3(u)) and outlined specific pedigree requirements (21 CFR 203.50). In effect, 21 CFR §§203.3(u) and 203.50 require "unauthorized distributors" of prescription drugs to provide a pedigree to the purchaser of such drugs, identifying each prior sale, purchase, or trade. These sections, however, were objected to by secondary wholesalers, who claimed they would prevent them from selling prescription drugs, as they would not be able to comply. As a result, FDA delayed the effective date of these provisions on several occasions, most recently in 2004, when members of the drug supply chain informed FDA that they would voluntarily implement electronic track and trace technology by 2007. As it is now apparent that industry will not be able to implement electronic track and trace technology by that time, FDA announced its intention to no longer delay the December 1, 2006 effective date for 21 CFR §§ 203.3(u) and 203.50.

Compliance Policy Guide

The draft CPG, entitled "Prescription Drug Marketing Act Pedigree Requirements Under 21 CFR Part 203," is intended to aid in the implementation of the new pedigree requirements. The CPG serves to clarify how FDA intends to

[1] An "authorized distributor of record" is defined as a wholesaler that has an ongoing relationship with the manufacturer to distribute the drug.

prioritize its pedigree-related enforcement resources, and describes a phased-in type approach for the enforcement of the pedigree law, with the hope of providing wholesale distributors with an idea of where to focus their energies in implementing an effective pedigree system.

The CPG has been published in draft form to receive comment for final publishing prior to the December 1, 2006 effective date.

With regards to enforcement, FDA intends to take a risk-based approach that will focus on those prescription drugs that are the most vulnerable to counterfeiting and diversion. The CPG includes four factors (listed below) that should help wholesale distributors determine how to focus their initial efforts. Each factor includes basic questions intended to assist wholesalers in determining whether or not a particular prescription drug may be subject to pedigree requirements. The factors also provide specific examples of drug products that meet the criteria listed in the factor. FDA was careful not to limit the scope of the factor to the drug products listed.

Factor 1: High Value in the US Market

- Does the drug product have a high sales volume or price in the US? Examples: Lipitor®, Nexium®, Risperdal®, Plavix®
- Is the drug product a "high priced/specialty" product used for a serious or life-threatening disease? Examples: Procrit®, Epivir®, Combivir®, immune globulin (IGIV), Gamimune®, Gammagard®, Epogen®, Serostim®
- Is the drug in high demand? Example: Oxycontin®
- Is there a shortage of the drug? Examples: Certain metered dose inhalers, reserpine tablets

Factor 2: Prior Indicators

- Are there prior cases of the drug being counterfeited or diverted in the US? Is there a history of false pedigrees associated with the product? Examples: Viagra®, Procrit, Zyprexa®, Serostim, Tamiflu®, Combivir, Epivir, Sustiva®, Trizivir®, Zerit®, Diflucan®, Lamisil®

Factor 3: Reasonable Probability (for newly approved drug with insufficient marketing history to determine if the drug would be in Factors 1 or 2)

- Is there a reasonable probability that the drug may be counterfeited or diverted based on Factors 1 or 2?
- Does the drug have priority review status?
- Based on drug products that are in a similar drug class, is the drug predicted to have a high potential market size and value?

Factor 4: Other Violations of Law

- FDA intends to enforce relevant law against wholesale distributors or other entities that are engaged in conduct related to the manufacture and distribution of counterfeit drugs, or engaged in the manufacture or distribution of prescription drugs that otherwise violate the PDMA or other laws – regardless of the type of drug or whether or not it falls into Factors 1-3.

The CPG will expire one year from the date of issuance in its final form. It is anticipated that the CPG will be issued on or

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Pedigree

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around December 1, 2006. FDA has stopped short of making a specific list of products that are vulnerable to counterfeiting, but did specifically request comments on the utility of such a list in the phased-in implementation of pedigree systems.

FDA Task Force Report

This *Federal Register* announcement was issued on the heels of the June 9, 2006 publication of FDA's 2006 Update to its Counterfeit Drug Task Force Report, which recommended not only expiration of the stay of 21 CFR §§203.3(u) and 203.50, but also discussed the extent to which electronic track and trace technology is being used across the supply chain for electronic pedigrees and the use of radio-frequency identification (RFID) for drug products in the drug supply chain. In addition, the report details technical issues related to the implementation of electronic track and trace technology, such as mass serialization, universal and uniform pedigrees, data management, and privacy issues.

NABP Efforts

Since 2003, NABP has advocated for three tiers of change to state wholesale drug distributor laws:

1. Increasing the criminal penalties to reduce the incentives for counterfeiting;
2. Increasing the licensing requirements and implementing accreditation to promote uniformity amongst states; and
3. Implementing an effective pedigree system – initially by utilizing the list of susceptible products, and more recently moving to the concept of the normal distribution channel, that will eventually evolve into an electronic track and trace system for all drug products. As states have adopted pedigree legislation, they have not embraced the list of susceptible products concept but have instead advocated for the "normal distribution channel" definition. NABP has embraced this concept with certain parameters, as an ***interim*** pedigree model until a full fledged electronic track and trace system for all drugs can be implemented.

Implications for the State Boards of Pharmacy

The FDA Task Force Report and this *Federal Register* announcement seem to provide only minimal guidance to the state boards of pharmacy for implementation of electronic track and trace technology. Although, the Task Force Report recommended that FDA "remain committed to facilitating RFID implementation," it, unfortunately, did not set a mandated date, timetable, or provide timing expectations for implementation. While the stay on the PDMA's pedigree requirements will be lifted, the existing language in the PDMA may not adequately address the security of the drug supply chain.

From a regulatory and enforcement perspective, many state boards of pharmacy have already started to implement their own pedigree systems, primarily by utilizing the normal distribution channel, while others are moving toward an electronic track and trace system. No state has moved forward with implementing the pedigree concept in the PDMA, nor has any state recently considered legislation or regulations similar to that concept. NABP believes that the interim "normal distribution channel" model is an effective model of wholesale drug distribution that recognizes current distribution practices not implemented at the time the PDMA was enacted.

Preemption of State Law

Since the PDMA does not address preemption of state law, and 21 CFR §205, "Guidelines for State Licensing of Wholesale Prescription Drug Distributors," sets the "*minimum* standards, terms, conditions" (emphasis added) for state licensing, if a state has more stringent standards for the issuance and maintenance of a license than what is required in the minimum standards in the PDMA, the state law will take precedence. NABP has already started to review the state laws that have been implemented to determine whether or not the PDMA would preempt state law, as being more stringent. In most cases, the existing state laws are more stringent than the PDMA pedigree system. NABP believes, however, that in each case, the more stringent law should prevail, regardless of whether it is the state pedigree system or the PDMA. NABP is prepared to assist the state boards of pharmacy in determining which pedigree system takes precedence.

Both NABP and FDA share the overall common goal of achieving a transparent and secure drug supply chain in an effort to protect the public health. Although achieving this goal is still a few years away, NABP will continue to provide educational and regulatory

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DEA Holds Public Meeting on E-Prescribing for Controlled Substances

On July 11-12, 2006, Drug Enforcement Administration (DEA), in conjunction with the Department of Health and Human Services (HHS), conducted a public meeting to discuss electronic prescribing (e-prescribing) of controlled substances (CS). The meeting was intended to allow interested stakeholders – prescribers, pharmacies, software and hardware vendors, and other interested third parties – to address how e-prescribing systems can meet DEA's prescription requirements under the Controlled Substances Act, ensuring security and accountability, while mitigating costs and burdens associated with the adoption of the new technology.

Adoption of e-prescribing is encouraged among the health care industry since such prescriptions allow for the improvement of patient safety by helping to eliminate medical errors arising from misread and/or misunderstood handwritten prescriptions. However, as NABP concluded in its testimony submitted to the National Committee on Vital and Health Statistics (NCVHS) on February 1, 2005, "While many arguments can be made to support the rapid adoption of electronic prescribing, consideration should be given to the development of a national standard that is focused on patient safety, public protection, and the provision of quality health care."

> While many arguments can be made to support the rapid adoption of electronic prescribing, consideration should be given to the development of a national standard that is focused on patient safety, public protection, and the provision of quality health care.
>
> NABP Testimony to NCVHS, February 2005

DEA is gathering information in preparation of drafting regulations pertaining to e-prescribing of CS, which makes up approximately 11% of all drugs dispensed. Responsible for enforcing the Controlled Substances Act, which includes the prescribing and dispensing of CS, DEA must also enforce signature requirements as well as those related to the retention of prescription records, whether they are handwritten or electronic.

HHS shares DEA's interest in e-prescribing. In November 2005 HHS published a Final Rule that became effective January 1, 2006. This Rule, which adopts foundation standards regarding transmission of electronic prescriptions specifically pertaining to covered Medicare Part D drugs prescribed for Part D eligible individuals, resulted from HHS's responsibility to promulgate the transmission standards for the Medicare electronic prescription drug program.

In order to gather the valuable information necessary to determine the best process for the e-prescribing of CS, DEA assigned several panels to present during the meeting, focusing on specific perspectives of the states, practitioners, pharmacists, vendor, and law enforcement.

As part of the state perspectives panel, NABP, along with representatives from the Alliance of States with Prescription Monitoring Programs, the National Association of State Controlled Substances Authorities, and the Federation of State Medical Boards, took a closer look at the states' requirements for the e-prescribing of CS. It was during this panel that NABP provided meeting attendees with additional information including:

- Various initiatives taken by NABP such as the passing of Resolution No. 92-4-96: Electronic Transmission of Prescriptions for Schedule II CS at NABP's 92nd Annual Meeting and Resolution No. 97-2-01: Task Force to study the Electronic Transmission of Prescriptions and Prescription Information via Electronic Devices, during NABP's 97th Annual Meeting, as well as the Association's "Testimony on State Issues Related to the E-Prescribing of CS" submitted to NCVHS;
- The *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* and e-prescriptions;
- State laws/regulations regarding e-prescriptions; and
- Considerations that NABP believes safeguard patient safety for e-prescriptions.

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Fall Educational Conference Offers Up to 10 Hours of Continuing Education Credit

This year, NABP's Fall Educational Conference (FEC) has been condensed to two days without reducing the number of available continuing education (CE) hours. Held November 3-4, 2006, at the Hyatt Regency Savannah in Savannah, GA, the FEC offers members the opportunity to earn up to 10 CE contact hours on topics such as patient safety and quality of care; the state and federal regulation of pharmacy compounding; non-pharmacists providing medication therapy management (MTM) services; regulation of the destruction and/or disposal of medications; and the electronic prescribing of controlled substances.

Friday, November 3

A National Agenda to Improve Patient Safety and Quality of Care: Implications for the Boards of Pharmacy

With the federal government expected to have expenditures in excess of $558 billion over the next nine years for the new Medicare drug benefit, evaluating quality of care is particularly important. Defining and measuring robust outcomes, however, is a significant challenge for the professional and regulatory pharmacy community. Equally, continued concerns regarding the current state of patient safety highlights that there is still much work needed in reducing medication errors across all health care settings. During this session, participants will review the major recommendations of the Institute of Medicine's "Preventing Medication Errors: Quality Chasm Series," as well explore provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that require plan sponsors to develop quality assurance measures to reduce medication errors, adverse drug reactions, and drug interactions.

Regulatory Roundtable

This roundtable session will provide participants with an opportunity to discuss in small group settings various topics of interest and hear reports of each group's findings. Topics will include board mission, board member conflict of interest, ethical considerations for board members, and more.

Saturday, November 4

A Legal Analysis: State vs Federal Regulation of Pharmacy Compounding

While the United States Food and Drug Administration (FDA) usually defers to the state boards of pharmacy with respect to regulating the practice of pharmacy, FDA has initiated enforcement proceedings against pharmacies that have manufactured under the guise of compounding preparations presenting quality, safety, or purity concerns for patients. In June 2006, US District Judge Robert Junell ruled in the case of *Medical Center Pharmacy, et al v Gonzales, et al*, that the practice of pharmacy compounding pursuant to a valid prescription does not create a "new drug" as claimed by FDA. The issuance of this ruling has sparked continuing debate over FDA's authority to conduct inspections of pharmacies and collect pharmacy records. The session will provide participants with an overview of this decision and examine how this

ruling could potentially impact the state and federal oversight of compounding and pharmacy practice.

The Delivery of Pharmacist Care by the Non-Pharmacist: Legal, Regulatory, and Professional Implications

Developed to encourage the optimization of therapeutic outcomes by improving medication use and reducing adverse events among Medicare beneficiaries, the MTM provisions of the MMA have been hailed by many in the pharmacy professional community as an important step in realizing the impact of pharmacists as medication experts and not merely as medication dispensers. MTM services include those activities that enhance the understanding, adherence, and utilization of medication by targeted beneficiaries.

In addition to pharmacists being able to provide such services, MMA also allows "other qualified providers" such as physician assistants and nurses to provide MTM services. To allow non-pharmacist practitioners to provide services that have been legally categorized as the practice of pharmacy has resulted in a legal, regulatory, and patient safety quandary. During this session, participants will explore these issues in consideration of state versus federal oversight, including future implications particularly for state boards of pharmacy. Also, determinants that qualify non-pharmacist practitioners to provide MTM services will also be discussed.

Regulatory Approaches to Managing Pharmaceutical Waste

A number of states have regulations addressing the destruction and/or disposal of medications that are dispensed to patients in institutional facilities; however, fewer states cite regulations on the destruction and/or disposal of medications dispensed to outpatients. Currently, federal controlled substance regulations prohibit patients from returning such medications to pharmacies for destruction. During the 102nd Annual Meeting, the NABP Delegation passed Resolution 102-2-06, Safe and Environmentally Friendly Medication Destruction Programs, directing NABP to develop guidance for the boards of pharmacy and the pharmacy community addressing the environmentally safe and legal collection and destruction of unwanted, unused, or expired medications from patients.

In light of the scarcity and ambiguity of specific regulatory guidance pertaining to the medication destruction and disposal, this session will provide an overview of federal and state initiatives to address the collection of pharmaceutical waste with particular emphasis on prescription medication collection programs.

Electronic Transmission of Controlled Substance Prescriptions: Opportunities and Challenges

On January 1, 2006, the "foundation standards" for an electronic prescription drug program as mandated by Title I of the MMA became enforceable, representing an incremental approach to adopting final foundation standards consistent with the MMA objectives of patient safety, efficiency, quality, and cost savings associated in the delivery of care. In line with these efforts, DEA has been working to implement a system to permit the electronic transmission of controlled substance prescriptions, which is currently prohibited according to the federal Controlled Substance Act.

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Fall Educational Conference Program*

*Program subject to change.

November 3-4, 2006 **Hyatt Regency Savannah** **Savannah, GA**

Friday, November 3

10 AM - 5:15 PM
Registration/Information Desk Open

1 - 1:15 PM
Welcome Remarks

1:15 - 3:15 PM
A National Agenda to Improve Patient Safety and Quality of Care: Implications for the Boards of Pharmacy
Program #: 205-000-06-007-L04
(0.2 CEUs – 2 contact hours)

3:15 - 3:30 PM
Refreshment Break

3:30 - 5 PM
Regulatory Roundtable
Program #: 205-000-06-008-L04
(1.5 CEUs – 1.5 contact hours)

6:30 - 8:30 PM
Welcome Reception
(Buffet dinner will be served.)

Saturday, November 4

7 - 8 AM
Registration/Information Desk Open

7 - 8 AM
Continental Breakfast

8 - 9:30 AM
A Legal Analysis: State vs Federal Regulation of Pharmacy Compounding
Program #: 205-000-06-009-L03
(0.15 CEUs – 1.5 contact hours)

9:30 - 9:45 AM
Refreshment Break

9:45 - 11:45 AM
The Delivery of Pharmacist Care by the Non-Pharmacist: Legal, Regulatory, and Professional Implications
Program #: 205-000-06-010-L03
(0.2 CEUs – 2 contact hours)

Noon - 1 PM
Luncheon

1:15 - 2:45 PM
Regulatory Approaches to Managing Pharmaceutical Waste
Program #: 205-000-06-011-L04
(0.15 CEUs – 1.5 contact hours)

2:45 - 3 PM
Refreshment Break

3 - 4:30 PM
Electronic Transmission of Controlled Substance Prescriptions: Opportunities and Challenges
Program #: 205-000-06-012-L03
(0.15 CEUs – 1.5 contact hours)

4:30 - 4:45 PM
Closing Remarks

NABP and the NABP Foundation are approved by the Accreditation Council for Pharmacy Education (ACPE) as providers of continuing pharmacy education. ACPE Provider Number: 205. Participants may earn up to 10 contact hours (1 CEU) of ACPE-approved continuing education credit from NABP. Participants in continuing pharmacy education programs will receive credit by completing a "Statement of Continuing Pharmacy Education Participation" and submitting it to NABP. A validated "Statement of Continuing Pharmacy Education Credit" will be sent as proof of participation within approximately six weeks. Full attendance and completion of a program evaluation form for each session are required to receive continuing pharmacy education credit and a "Statement of Continuing Pharmacy Education Credit."

FEC

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During this session, participants will examine some of the evidentiary challenges of electronic prescribing systems and the needs of law enforcement in the enforcement of state and federal laws pertaining to electronic prescribing for controlled substances. Additionally, the role of various electronic prescribing technologies in potentially meeting the regulatory and legal expectations set forth for both the federal and various state controlled substance acts will be provided.

For more information on the Fall Educational Conference, or to register online, visit NABP's Web site at www.nabp.net.

Explore "Haunted" Savannah, Site of NABP's Fall Educational Conference

Savannah, GA, site of NABP's 2006 Fall Educational Conference, is known for its beautiful scenery, enticing atmosphere – and as "America's Most Haunted City?" Yes, the American Institute of Parapsychology graced Savannah with such an honor in 2002. According to legend and the popular local ghost tours, Savannah deserves such a title. So when you attend the Fall Educational Conference to be held November 3-4, 2006, at the Hyatt Regency Savannah, you can decide for yourself whether or not you believe in spirits and the tales Savannah tells.

Savannah may in fact be haunted; it was built over old cemeteries. Many locals insist that Savannah rests above 9,000 or more plots. Visit the corner of Oglethorpe Avenue and Bull Street to see for yourself; there lies a cemetery beneath the roads, marked with only a small sign dedicated to the 16 plots that lie below.

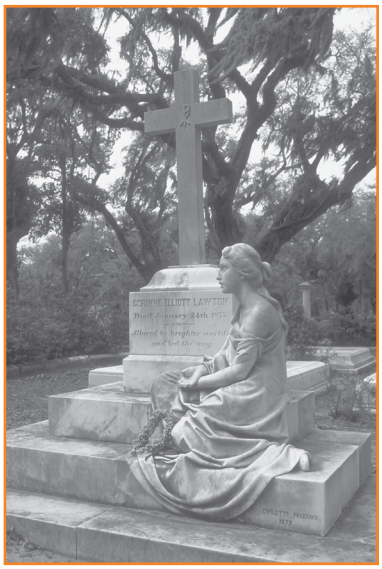
Although the city may be built over haunted graves, some believe the cemeteries that were not covered with asphalt are haunted as well. The city's central cemetery, Colonial Park, is home to one of Savannah's most popular ghosts, Rene Asche Rondolier. Rondolier was an orphan in the 1800s and feared by many of the townspeople because he was said to be a striking seven feet tall. According to legend, Rondolier was suspected of murdering two girls; the townspeople took matters into their own hands and lynched him near a swamp. When two more children and a woman were found murdered after Rondolier's death, the townspeople blamed Rondolier's ghost (instead of realizing that a murderer was still on the loose).

Another alleged ghost of Savannah is Captain John Flint, a member of Robert Louis Stevenson's *Treasure Island*. The notorious captain reportedly buried an enormous treasure on the imaginary Skeleton Island with the help of his six-member crew. Once the treasure was buried, he murdered all the men and left one pointing towards the buried treasure. According to legend, he died screaming for rum in Savannah's old Pirate House Inn, which is still standing and operating as a restaurant.

If you too find yourself screaming for rum, visit the 17 Hundred 90 house, a restaurant, bar, and inn. All three are currently open and available for booking and dining, if you dare. Apparently, the 17 Hundred 90 house is home to three ghosts: a sailor in the restaurant, a servant in the kitchen, and a lady in the inn.

With all these stories and ghosts looming about the city, Shannon Scott, a parapsychologist and creator of Sixth Sense Savannah Ghost Tours, looks for answers. In fact, he has found one reason as to why these spirits stay in Savannah, an electromagnetic charge. The magnetic energy is believed to come from Savannah's sand, creating a "geomagnetic anomaly" according to Scott. The magnetic energy is said to pull spirits towards it and keep spirits from leaving.

If all this sounds quite preposterous, try a tour yourself. Many tourists and tour guides boast of seeing a ghost themselves.



Rumored to be haunted, Bonaventure Cemetery was made famous in the book Midnight in the Garden of Good and Evil. *Whether or not spirits are seen, this cemetery is still worth the trip as it is beautifully carved and the final resting place of Savannah's founders, as well as other famous people.*

Ghost Talk Ghost Walk
912/233-3896
www.savannahgeorgia.com/ghosttalk/

Old Town Trolley Tours® of Savannah's "Frightseeing"
912/233-0083
www.gotobus.com/historictours/savannah/ghosts_gravestones_savannah.html

Sixth Sense Savannah Ghost Tours
1-866/666-DEAD
(or 3323)
www.sixthsensesavannah.com

If you do not have time for a tour (averaging about 90 minutes), but want to check out pieces of the tales visit any of the following:

17 Hundred 90
307 E President St
Savannah, GA 31401
912/236-7122
www.17Hundred90.com

Colonial Park Cemetery
E Oglethorpe St at
Abercorn St
Savannah, GA 31401
912/651-6843

The Pirate's House
20 E Broad St
Savannah, GA 31401
912/233-5757
www.thepirateshouse.com

Bonaventure Cemetery
330 Bonaventure Rd
Savannah, GA 31404

Pedigree

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support to the boards of pharmacy on this important patient safety issue by promoting uniformity through the use of the Verified-Accredited Wholesale Distributors™ (VAWD®) program and the Model Rules for Licensure of Wholesale Distributors. NABP, with the support of the state boards, will continue to advocate for an electronic track and trace system that will be standardized and can be implemented across the drug supply chain by working with industry stakeholders and other interested parties.

Further Information

FDA's final rule can be accessed at: http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/06-5362.htm. The draft CPG can be accessed at: www.fda.gov/oc/initiatives/counterfeit/cpg.html. FDA's Update to the Counterfeit Drug Task Force Report can be accessed at: www.fda.gov/oc/initiatives/counterfeit/report6_06.html. For more information on NABP's Model Rules for Licensure of Wholesale Distributors or the VAWD program, please visit NABP's Web site at www.nabp.net.

Legal Briefs

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The licensee also argued that the Board was not required to discipline him under these circumstances as the language in the statute was permissive, not mandatory. Thus, the licensee argued that the Board "may" discipline a licensee convicted of a misdemeanor, rather than "must" discipline. The court rejected this argument stating that the permissive language did not mean that the Board lacked the authority to discipline the licensee. In fact, the court held that such an interpretation would run afoul of the clear statutory grant of authority contained in the legislation.

Finally, the licensee argued that he should not be disciplined because he was unaware of the consequences of the Alford plea and the fact that he would be subject to collateral administrative sanctions. The court stated that clearly, a defendant does not need to be told of all potential consequences of a guilty plea in order for that plea to be legally enforceable, proper, and binding.

Finding that the Board's decision was neither arbitrary nor erroneous, the court affirmed the sanction of the licensee and upheld the findings of the Board and lower court.

Criminal convictions generally constitute grounds for discipline of a professional license. Distinguishing between felony and misdemeanor convictions may be necessary to apply such conviction to a subsequent administrative prosecution. Sometimes, the issue of whether a "conviction" has been established may be argued. Finally, the definitions of felonies may differ from jurisdiction to jurisdiction. Thus, it is important for the practice acts to be broadly drafted to empower the board of pharmacy to adequately protect the public.

Caudill v Kentucky Board of Dentistry, 2006 WL 357879 (App. Ct. KY 2006)

DEA Meeting

(continued from page 167)

Representatives from other interested stakeholder organizations provided testimony addressing needs and vulnerabilities of practitioners and pharmacies, the evolution of technologies for e-prescribing as it relates to electronic health records, the authentication of prescriptions, signature requirements, record keeping requirements for CS prescriptions, and the mitigation of risks within the framework of DEA's laws and regulations.

Lastly, the law enforcement panel focused on the needs of law enforcement regarding state and federal laws pertaining to electronic CS prescriptions. Representatives from the Broward County Sheriff's Office and the Executive Office, Office for United States Attorneys as well as NABP Executive Committee member and Executive Director of the Ohio State Board of Pharmacy, William T. "Bill" Winsley, served on the panel.

Other NABP members attending the meeting included William T. Douglass, Jr, executive director and general counsel for the West Virginia Board of Pharmacy and Jack William "Jay" Campbell IV, executive director for the North Carolina Board of Pharmacy.

At press time, DEA was unable to give any information about its next steps. Testimony and presentations from the meeting are available on DEA's Web site at www.deadiversion.usdoj.gov. For additional information on e-prescribing please refer to the February 2005 *NABP Newsletter* on page 30, and the March 2005 *NABP Newsletter* on page 49.

FDA Celebrates 100 Years of Regulation

Food and Drug Administration (FDA) recently celebrated the 100th Anniversary of the Pure Food and Drugs Act of 1906, which marks the beginning of the modern FDA. From daily rituals to rare medical advances, FDA has made regulations and standards that many of us take for granted, all stemming from this first legislation.

In June 1906, the Bureau of Chemistry (which later became FDA) was entrusted with the implementation of the Pure Food and Drugs Act, signed by President Theodore Roosevelt. The first federal law to regulate food and drugs in interstate commerce, the Act allowed for meat inspections and prohibited adulterated and misbranded drugs from interstate commerce. Only the beginning, FDA would later regulate cosmetics, over-the-counter and prescription drugs, biologics, animal feed and drugs, radiation-emitting products, and medical devices. Today, these products make up more than 20% of all United States consumer spending.

In the beginning of the 20th century, drug manufacturers had very few limitations, permitting them to make a profit through unsafe and ineffective drugs. The 1906 Pure Food and Drug Act allowed for FDA to stop some of these drugs from being sold; however, the Act had limited powers.

A consequence of limited powers can be traced to the 1937 Elixir Sulfanilamide (an anti-infective) tragedy that caused 107 deaths due to the presence of diethylene glycol, which is chemically related to antifreeze as a solvent. At that time, FDA could not penalize the company for marketing a deadly medication; however, FDA was able to remove the drug from the market because of misbranding – "elixirs" were to contain alcohol as a solvent, which this product did not contain.

This disaster spurred Congress to refine the Food, Drug, and Cosmetic Act (FD&C Act), which was signed into law by President Roosevelt in 1938. One provision of the law required that firms had to prove to FDA that any new drug was safe before it could be marketed. This marked one of the first steps FDA was able to take towards further protection of the public health. In addition, the FD&C Act stated that some drugs could not be labeled for safe use and needed a physician or dentist prescription; thus the creation of prescription drugs, which included such drugs as barbiturates, amphetamines, and levothyroxine-based products.

Prescription drugs created more obstacles for FDA, but resulted in more legislation being passed, such as the Kefauver-Harris Amendments in 1962. The Kefauver-Harris Amendments stated that in addition to being proven safe, drugs must be proven effective before being placed on the US market. The company would then turn over its research for a particular drug to FDA, consequently the drug review program commenced.

Presently, the drug review program is much more in-depth and is recognized worldwide. Each approved drug undergoes vigorous testing that includes safety, efficacy, and quality, along with drug interactions, how the body metabolizes the drug, and potential differences in safety and effectiveness for people of different ages, gender, and races.

Of course drug safety and efficacy is only one component of FDA's many responsibilities. FDA is made up of eight centers and offices: Drug Evaluation and Research; Food Safety and Applied Nutrition; Devices and Radiological Health; Biologics Evaluation and Research; Veterinary Medicine; Regulatory Affairs; Toxicological Research; and the Office of the Commissioner. Employing more than 9,000 people, FDA is trusted by the American public and many countries to ensure safety and efficacy in more than $1 trillion worth of products.

In the future, FDA plans to continue overseeing safety in America's food supply; safety and efficacy in drugs, vaccines, and medical devices; protection from health and safety threats including bioterrorism and AIDS, while also approving new products and technology.

Congratulations on 100 years of progress and we look forward to FDA's future success!

Pharmacy Boards Participate in USP Webinar

More than 46 state board of pharmacy members from 20 states benefited from participating in an online training session, referred to as a "Webinar," facilitated by United States Pharmacopeia (USP). This Webinar provided NABP members with an opportunity to learn firsthand of the USP 797 proposed revision highlights as well as a chance to ask questions regarding the proposed revisions. Our thanks to USP for providing this service free of charge to our member boards.

FDA Launches Consumer Educational Program on the Safe Use of OTCs

The United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cooperation with the National Council on Patient Information and Education and Maryland's Montgomery County Public Schools, has launched "Medicines in My Home," an interactive educational program aimed at informing middle school students about the safe and effective use of over-the-counter (OTC) medicines. Key concepts students will learn from the program are:

- the Drug Facts label tells you what a medicine treats, if it is right for you and your problem, and how to use the medicine;
- read the label and follow the directions carefully and correctly;
- two medicines with the same active ingredient should not be used at the same time; and
- measure medicines correctly with measuring tools made for medicines.

The program emphasizes that medicines should be used only with permission from an adult and that if there are questions about medicine use, ask a pharmacist or doctor. Materials are provided to encourage students to share what they learn with their families so that all family members can learn to use OTC medicines more safely. Program information can be found at www.fda.gov/medsinmyhome.

FDA/ISMP National Campaign to Help Eliminate Ambiguous Medical Abbreviations

FDA and the Institute for Safe Medication Practices have launched a national education campaign that focuses on eliminating the use of potentially harmful abbreviations by health care professionals, medical students, medical writers, and the pharmaceutical industry. The campaign addresses the use of error-prone abbreviations in all forms of medical communication, including written medication orders, computer-generated labels, medication administration records, pharmacy or prescriber computer order entry screens, and commercial medication labeling, packaging, and advertising. For more information visit www.fda.gov/cder/drug/MedErrors.

FDA Advances E-Health Efforts

In mid-2006, FDA announced that it was adopting the Systematized Nomenclature of Medicine (SNOMED) as the standard computerized medical vocabulary system to be used to electronically code important terms in the "Highlights" section of prescription drug labeling. According to FDA, this will allow health care professionals nationwide to electronically access and share critical health and treatment information more easily and efficiently, paving the way to realizing electronic health records for all Americans within the next decade.

> In mid-2006, FDA announced that it was adopting the Systematized Nomenclature of Medicine (SNOMED) as the standard computerized medical vocabulary system to be used to electronically code important terms in the "Highlights" section of prescription drug labeling.

SNOMED, developed by the College of American Pathologists (CAP), is one of the terminologies chosen by the US government as part of the health information technology infrastructure for clinical language. Specifically, FDA is adopting the "Problem List" subset of SNOMED, which can electronically code certain terms in the "Highlights" data elements of the new format for prescription drug information. This format will be required beginning June 30, 2006, for recently approved (within the last five years) and newly approved drug products.

FDA's adoption of SNOMED is consistent with the May 2005 US Department of Health and Human Services (HHS) announcement that SNOMED will be used by federal agencies for the exchange of clinical information across the federal government for laboratory result contents, non-laboratory interventions and procedures, anatomy, diagnoses and problems, and nursing, and FDA will be working with the federal Health IT Standards Panel as SNOMED is implemented. A licensing agreement with CAP, administered through the National Library of Medicine, and a component of the National Institutes of Health, is making it possible for US health care professionals, hospitals, insurance companies, public health departments, medical research facilities, and others to easily incorporate this uniform terminology system into their information systems. The Problem List Subset

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Washington Bans Prescriptions Written in Cursive

Under a recently enacted state law, Washington health care providers can no longer write prescriptions in cursive. The law, passed by the legislature this year, is intended to protect patients from receiving the wrong medication because of illegible prescriptions.

The legislation expanded the definition of a "legible prescription" in Revised Code of Washington 69.41.010, which now requires all prescriptions to be hand printed, typewritten, or electronically generated. Prescriptions issued in cursive writing are considered illegible, effective June 7, 2006. Prescriptions written in cursive should be handled like any other illegible prescriptions. The Washington State Board of Pharmacy is working with other professions on this issue.

For more information contact the Washington State Board of Pharmacy or visit their Web site at https://fortress.wa.gov/doh/hpqa1/hps4/pharmacy/default.htm.

Source: Washington State Board of Pharmacy News, *Volume 28, No. 1 July 2006*

Missouri Releases Results of Compounding Study

In a 2001 study of online pharmacies conducted by Food and Drug Administration, 10 out of 29 compounded products failed to meet quality standards. The Missouri Board of Pharmacy responded to the study by implementing stricter regulations on compounding. Such regulations ensure pharmacists have and maintain the skill and education necessary to compound. Also, the regulations mandate that the pharmacist cannot compound any commercially available products unless it is during a rare instance when the product is temporarily unavailable or is made without an offending agent for a specific patient (but maintains original product efficacy). The Board also conducted random drug tests of sterile drugs for quality, sterility, and/or pyrogenicity, and non-sterile drugs for quality and potency.

Between July 2003 and December 2005, the Board tested more than 400 different compounded drugs finding a 19.8% failure rate for potency (all products passed the tests for sterility and pyrogenicity) according to then Executive Director, Kevin E. Kinkade, RPh. Compounded drugs that failed to meet standards were reported back to the pharmacist-in-charge. These reports have resulted in pharmacists being more aware of the special care and expertise that goes along with compounding, resulting in higher quality products being dispensed to patients.

The Board intends to expand testing into the inpatient hospital setting through an agreement with the State Department of Health, which regulates hospitals in Missouri.

Changes in Louisiana Pharmacy Technician Regulation

. . . The [Louisiana] Board [of Pharmacy] published the Final Rule in the June 2006 *Louisiana Register*, amending certain provisions in §907 of the Board's rules.

Some highlights of the new rule for pharmacy technicians:

- A supervising pharmacist may allow a technician to accept an original verbal prescription. When a technician accepts an original verbal prescription, the order must be reduced to written form immediately. Before releasing that prescription for processing, both the receiving technician and the supervising pharmacist shall initial the hard copy of the prescription.
- A supervising pharmacist may allow a technician to give or receive verbal transfers of prescriptions. However, please remember that with respect to the transfer of prescriptions for controlled substances (CS), federal rules require such transfers to be accomplished between two licensed pharmacists.
- The new rule also provides some flexibility in the pharmacist-to-technician ratio. When there are no pharmacy technician candidates present, then one pharmacist on duty may supervise as many as three pharmacy technicians on duty.
- The new rule makes **no** changes relative to scope of practice or ratio for pharmacy technician candidates.
- Finally, the new rule also clarifies the restriction on the "interpretation" of a prescription. A supervising pharmacist may allow technicians and technician candidates to translate abbreviations and other phrases into

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Around the Association

New Program Director

Wendy L. Anderson, RPh, is the new program director for the Colorado Board of Pharmacy. She practiced pharmacy in various settings until 1996, when she became an inspector for the Board. She was then promoted to chief pharmacy inspector in 2002. Anderson attended University of Colorado where she received her bachelor of science degree. She replaces **Susan L. Warren.**

Louisiana Board Executive Director, Members Receive Awards

Malcolm J. Broussard, RPh, Louisiana Board of Pharmacy Executive Director and a member of the NABP Executive Committee, received the Pharmacist of the Year Award from the Louisiana Pharmacists Association (LPhA) at its 124th Annual Meeting. Two members of the Board also received awards from the LPhA. **J. Douglas Boudreaux, RPh,** was presented with the Compounding Pharmacist of the Year Award and **Allen W. Cassidy, Jr, RPh,** received the Independent Pharmacist of the Year Award.

Patient Safety

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of codes will be made available free of charge through the National Cancer Institute Web site.

Source: www.fda.gov/bbs/topics/NEWS/2006/NEW01361.html

HHS Warns Public of Heroin and Fentanyl Deadly Combo

In efforts to warn the public and health care professional communities regarding a recent rash of drug-related deaths due to an illicit street drug combination consisting of the prescription medication fentanyl and either heroin or cocaine, HHS released a fact sheet containing specific information with the goal of saving lives.

A letter from H. Westley Clark, director of the HHS Center for Substance Abuse Treatment, to health care professionals warned that in "just one week, an estimated 33 individuals in the Detroit, MI area are reported to have died after using this fatal mix of drugs; the same drug combination may have been responsible for more than 100 deaths in the same region last September [2005]." Philadelphia, PA; Chicago, IL; St Louis, MO; and Camden, NJ have also recently experienced similar clusters of drug-related deaths.

Fentanyl, an injectable Schedule II prescription opioid analgesic, is roughly 50 to 80 times more potent than morphine but can also be produced in clandestine laboratories in powder form and then mixed with or substituted for heroin. Fentanyl-related overdoses can result in sudden death through respiratory arrest, cardiac arrest, severe respiratory depression, cardiovascular collapse, or severe anaphylactic reaction. In some cases, heroin or cocaine users are aware they are purchasing this dangerous combination of drugs and in other cases, they are not. Because the potency of street-sold heroin or cocaine is amplified markedly by fentanyl and because the inclusion of fentanyl may not be disclosed, any use, even a reduced dose, can result in overdose or death. The fact sheet advises that suspected overdoses should be treated rapidly with naloxone injection, 0.4 to 2 mg intravenously, subcutaneously, or intramuscularly every two to three minutes, which should rapidly reverse symptoms related to a narcotic overdose; if there is no response after 10 minutes, then a different diagnosis should be considered.

For additional information, contact Kenneth Hoffman at the Substance Abuse and Mental Health Services Administration at 240/276-2701 or via e-mail at Kenneth.Hoffman@samhsa.hhs.gov.

Board News

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patient-oriented language as they enter prescriptions into a dispensing software system. However, the "interpretation" of a prescription, which includes the analysis of a new prescription order, its integration into the patient's existing medication regimen, as well as drug utilization review procedures, is a professional activity restricted to pharmacists and pharmacy interns under the supervision of a pharmacist.

The Board is currently compiling a *Louisiana Pharmacy Law Book* update that will include the new laws passed during the just completed legislative session. When that compilation is complete, we [the Board] will forward updates to all subscribers. Until then, the new language for §907 can be found on the Board's Web site www.labp.com.

Reprinted from the Louisiana Board of Pharmacy News, *Volume 28, No. 1 July 2006.*

"Survey Says" Pre-NAPLEX is Most Representative of Actual Licensure Examination

In a recent survey of 217 pharmacy students, the Pre-NAPLEX®, the only practice examination developed by NABP for the North American Pharmacist Licensure Examination™ (NAPLEX®), ranked No. 1 out of 12 when comparing preparation tools that were most representative of the actual licensure examinations.

In the online survey conducted by Drs Peak and Arnett (Butler University) and Dr Sheehan (Purdue University), pharmacy graduates who attended Butler or Purdue Universities and completed the NAPLEX (whether or not they passed) were asked to rank different preparation tools that are used for the NAPLEX and the Multistate Pharmacy Jurisprudence Examination®.

The Pre-NAPLEX was ranked highly among the students who had attended the universities, taken the NAPLEX, and responded to the survey. Specifically, when comparing NAPLEX preparation tools used by 10% or more of the respondents, the Pre-NAPLEX ranked second among the most commonly used NAPLEX preparation tool, only preceded by the American Pharmaceutical Association's *Complete Review for Pharmacy*.

"NABP developed the Pre-NAPLEX in order to help students familiarize themselves with the NAPLEX experience while also giving students a score estimate, which students can use to predict how well they may do on the NAPLEX," says NABP President Lawrence H. Mokhiber, "We are proud the Pre-NAPLEX provides students with a useful, cost-effective review method and we will continue to strive for such excellence."

At a cost of $50 per attempt, students can take the Pre-NAPLEX up to two times. The Pre-NAPLEX consists of 50 multiple choice questions posed in similar format as the NAPLEX. NABP anticipated that this would provide students with exactly what they needed to judge their preparedness for the examination.

The survey, titled "Perceived Utility of Pharmacy Licensure Examination Preparation Tools" is located on the American Journal of Pharmaceutical Education Web site at www.ajpe.org. For more information on the Pre-NAPLEX, visit www.prenaplex.com.

FPGEE Blueprint Update

Responses from a survey of all Accreditation Council for Pharmacy Education (ACPE)-accredited schools and colleges of pharmacy, conducted in the spring of 2006, are currently being analyzed by NABP to aid in the revision of the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) blueprint. The blueprint provides important information about the topics covered on the examination and the knowledge applicants are expected to demonstrate while taking the FPGEE.

Development of the survey stemmed from the FPGEE Blueprint Committee's first meeting, held January 9, 2006, at NABP Headquarters in Mount Prospect, IL. The Committee, which is comprised of representatives from ACPE, the American Association of Colleges of Pharmacy, and NABP's FPGEE Review Committee, developed the survey in order to ascertain the credit hours devoted to the various areas of the schools' and colleges' pharmacy curricula. The Committee will use the survey results to review and revise the examination standards and distribution of the examination item pool.

Once updated, the blueprint will be reviewed by NABP's Advisory Committee on Examinations who will either recommend approval to the NABP Executive Committee or oppose it. When a blueprint is approved by the Executive Committee, the item pool is reclassified and any gaps in coverage are filled with additional items developed by practitioners and educators from across the country during NABP's fall item-writing workshop.

The revised FPGEE blueprint will be posted on www.nabp.net after it has been approved. The first examination based on the revised blueprint is scheduled to be administered in June 2007.

PCOA

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knowledge and skills necessary for entry-level practice and is not intended for use in the assessment of curricula.

NABP, assisted by a group of educator and practitioner advisors, continues to work closely with AACP and ACPE on the development of the PCOA. It is NABP's hope that, together with AACP and ACPE, the details of the PCOA will soon be finalized and that the PCOA will become a valuable resource in institutional assessment programs.

NEWLY ACCREDITED VAWD FACILITIES

The following facilities were recently accredited through NABP's Verified-Accredited Wholesale Distributors™ program:

Henry Schein, Inc
Jacksonville, FL
Accredited July 27, 2006

Henry Schein, Inc
Indianapolis, IN
Accredited July 27, 2006

Parmed Pharmaceuticals, Inc.
Niagara Falls, NY
Accredited July 28, 2006

Reminder

Register online for the NABP's Fall Educational Conference to be held November 3-4, 2006, at the Hyatt Regency Savannah in Savannah, GA.

nabp newsletter

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