NABP to Administer Pharmacy Practice Analysis Survey, Revise NAPLEX Blueprint

In an effort to ensure that the North American Pharmacist Licensure Examination® (NAPLEX®) maintains its position as a valid and relevant licensing and credentialing examination, NABP is conducting a practice analysis survey during the second quarter of 2009.

Periodically, the competency statements, which comprise the blueprint for the NAPLEX, are reviewed and revised by a subcommittee of practice and content experts. These periodic reviews allow NABP to ensure that the NAPLEX continues to provide the state boards of pharmacy with a means of maintaining safe and effective pharmacy practice. During late 2008, the NAPLEX Review Committee recommended that some revisions be made to the NAPLEX blueprint competency statements for clarification and specification purposes. The recommended changes were subsequently approved by the NABP Advisory Committee on Examinations (ACE) and the NABP Executive Committee, and in February 2009 the NAPLEX blueprint was updated to reflect the revisions. These minor revisions were made to clarify the competency statements for students and did not include any additions or deletions of competencies or substantive changes.

In addition to the periodic blueprint reviews, NABP performs a full pharmacy practice analysis at least every five years in accordance with standard testing industry examination development and revision guidelines. It ensures that the competencies are in line with existing pharmacy practice standards and that they accurately reflect the current knowledge, skills, and abilities of entry-level pharmacists seeking licensure. As part of this analysis, NABP is conducting a survey among a random sampling of pharmacists in all areas of pharmacy practice in order to obtain the research data necessary for updating and validating the current North American Pharmacist Licensure Examination® competency statements. Questions may be directed to custserv@nabp.net or 847/391-4406.

NABP Seeks Pharmacists’ Assistance

Pharmacists in all areas of pharmacy practice are invited to participate in the pharmacy practice analysis survey available from April 1 to June 30, 2009, at http://www.zoomerang.com/Survey/?p=WEB228YSFHUR9UR. Expertise provided through this survey will assist NABP in updating and validating the current North American Pharmacist Licensure Examination® competency statements. Questions may be directed to custserv@nabp.net or 847/391-4406.

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NABP Introduces 2009-2010 NAPLEX Review Committee Members

NABP is pleased to introduce the North American Pharmacist Licensure Examination® (NAPLEX®) Review Committee members for 2009-2010. Composed of faculty and pharmacists who are representative of the diversity of pharmacy practice, the NAPLEX Review Committee is responsible for reviewing the examination questions, attending and participating in meetings, and writing new test questions. These dedicated volunteers, acting under the policy and planning guidance of the Advisory Committee on Examinations and the NABP Executive Committee, share the task of safeguarding the integrity and validity of the Association’s examination.

NABP appreciates the assistance of these committee members as they evaluate examination content and ensure that it meets the specified competency assessment statements, which, in essence, determine the question pool. The NAPLEX Review Committee members begin their term each year on February 1.

NAPLEX Review Committee Members

- Marie A. Abate, West Virginia University
- Loyd V. Allen, Jr, Edmond, OK
- Jennifer Beall, Samford University
- Christi Capers, Hermitage, TN
- Michael Cockerham, University of Louisiana at Monroe
- Andrea Collaro, Deerfield, IL
- Betty Dong, University of California, San Francisco
- Thomas S. Foster, University of Kentucky
- Darla Gallo, Elkins Park, PA
- W. Franklin Gilmore, Montana Tech of the University of Montana
- Robert P. Henderson, Samford University
- William A. Hopkins, Jr, Big Canoe, GA
- Tom M. Houchens, London, KY
- Arthur I. Jacknowitz, West Virginia University
- William Kehoe, University of the Pacific
- Susan C. Lutz, Altoona, IA
- David W. Newton, Shenandoah University
- Stephen M. Ouellette, Oakland, ME
- Roy Parish, University of Louisiana
- David B. Roll, Granbury, TX
- Theresa Salazar, Butler University
- Eric F. Schneider, University of Arkansas
- James A. Seaboldt, Thornton, CO
- Cynthia Sieck, Vancouver, WA
- John L. Szarek, A.T. Still University
- Neal F. Walker, Hibbing, MN
- Siu-Fun Wong, Western University of Health Sciences

Revised NAPLEX Blueprint

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to update and validate the current NAPLEX competency statements. Entry-level and experienced pharmacists as well as pharmacy academicians and experiential preceptors are asked to participate.

Upon receipt, the survey responses will be carefully analyzed and weighted. The results of the analysis will then be translated into the new version of the NAPLEX blueprint and presented to the NAPLEX Review Committee, ACE, and NABP Executive Committee for final approval. Once the blueprint is approved, the NAPLEX Review Committee will recode the NAPLEX questions to follow the new blueprint. Revisions to the blueprint are expected to be implemented in 2010, and all schools and colleges of pharmacy as well as the state boards of pharmacy will be notified of these revisions.

The current version of the NAPLEX blueprint is located in the Examination Programs section of the NABP Web site at www.nabp.net.
European Union Seizes 34 Million Fake Drugs in Two Months with Medi-Fake; NABP’s Not Recommended List Increases

While NABP continues to list Internet drug outlets on the NABP Web site that do and do not meet state and federal laws and NABP patient safety and pharmacy practice standards, increased efforts and awareness to protect patients from illegitimate drugs have surfaced across international borders.

Over a two-month period, European Union (EU) custom officials seized approximately 34 million counterfeit drugs – originating mostly from India, Pakistan, and China – through operation Medi-Fake, Medi-Fake, which began in mid-October 2008, is the first coordinated action undertaken by custom controls through the 27 EU member states in an effort to protect citizens and legitimate business from new and increasing security and safety threats.

Since its launch, Medi-Fake seized 2.2 million fake pills at the Brussels airport, consisting of 1.6 million painkillers and 600,000 anti-malaria treatments, the largest seizure of illegal medications ever recorded in Europe. Also, Le Havre customs in France prevented 400,000 counterfeit medicine pills and 11 million pseudoephedrine pills from entering the drug distribution system.

These results of Medi-Fake’s seizures demonstrate that counterfeit medications continue to threaten public safety, both in and through surrounding international borders. And these counterfeit products are often sold via the Internet.

As part of its mission to educate patients about the potential dangers of purchasing medication online, NABP continues to identify and list Not Recommended Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards on the NABP Web site.

As of April 10, 2009:
- 2,084 sites were reported as Not Recommended. Of these:
  - 1,983 sites do not require a valid prescription
  - 1,088 sites offer foreign or non-FDA-approved drugs
  - 768 sites are located outside the United States and selling drugs illegally to patients in the US
- Sixteen sites are listed as Recommended Internet pharmacies. These sites are accredited through the NABP Verified Internet Pharmacy Practice Sites™ program (VIPPS®). Celebrating its 10th anniversary this year, the VIPPS program enables consumers to confidently access important information regarding the licensure and practices of legitimate Internet pharmacies in the nation.

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

VIPPS Celebrates 10 Years as a Trusted Source for Patient Safety

The NABP Verified Internet Pharmacy Practice Sites™ (VIPPS®) program celebrates its 10th anniversary this year. See the March 2009 NABP Newsletter article “VIPPS: 10 Years of Guiding Consumers to Legitimate Internet Pharmacies,” for more details.
Reinstraightment
By Dale J. Atkinson, JD

Boards of pharmacy are entrusted with the important mission of enforcing the practice act in the interest of public protection. As such and among other things, boards license, renew, and discipline individuals found to have violated the act, the rules, or other regulatory interests. In an administrative disciplinary action, such a mission does not preclude the board from considering, as part of its deliberations, the interests of the licensed pharmacist in fashioning an appropriate sanction.

In a disciplinary setting, boards of pharmacy consider mitigating circumstances presented on behalf of licensees and structure a particular sanction in the interest of enforcing the practice act, protecting the public, and attempting to provide the licensee with an opportunity to continue to practice or, if the circumstances dictate, eventually be reinstated upon the completion of certain prerequisites to re-licensure. Crafting creative disciplinary orders may provide flexibility to the board, while affording the disciplined individual with reasonable opportunities to return to practice. Consider the following:

A pharmacist (licensee) was originally licensed by the Ohio State Board of Pharmacy in 1979. In 1999, the Board issued a citation against the licensee alleging numerous statutory violations regarding his practice of pharmacy. After an administrative hearing, the Board, in June 2000, issued an order suspending the licensee from the practice of pharmacy indefinitely. The Board suspension order required the licensee to obtain, within 90 days of the effective date of the order, a full psychiatric evaluation that includes a plan of treatment for anger control. In addition, the order required the licensee to submit, before two years from the effective date of the order, the final report of the treating psychiatrist or psychologist indicating compliance with the plan of treatment. Finally, the order required that, upon completion of the two conditions, the licensee successfully complete the jurisprudence examination offered by the Board.

The licensee appealed the matter to the trial court which, on June 19, 2000, stayed the enforcement of the Board order pending the appeal. In March 2001, the trial court affirmed the Board order. On September 11, 2002, the Supreme Court of Ohio declined to grant the licensee’s petition to hear the matter. The licensee immediately filed a motion with the Ohio Supreme Court for reconsideration, which was denied on October 23, 2002.

In January 2004, the licensee contacted the Board regarding his licensure reinstatement process. The Board responded by letter indicating that taking the jurisprudence examination would be “futile because [licensee] failed to comply with the conditions [requiring an evaluation and report of compliance] of its June 14, 2000 order.” The licensee disputed the Board’s position and, on October 5, 2004, filed with the Board a final psychological report completed by the psychologist who conducted the evaluation.

The final psychological report noted the commencement of the professional relationship, indicating an initial visit in November 2001. The report outlined the interview process and visits, and concluded that the licensee had no diagnosable condition and did not require treatment for anger control.
The evaluating psychologist indicated his inability to comprehend the requirements of the Board order as it appeared to require treatment for a disorder that the licensee did not possess.

Through counsel and at a Board meeting, the licensee presented his arguments regarding his recent request for reinstatement. Thereafter, in June 2005, the Board denied the licensee’s request for reinstatement. The licensee appealed the matter to the trial court based upon his belief that the Board’s order was illegal. Specifically, the trial court held that the licensee failed to undergo a full psychiatric evaluation within 90 days of the effective date of the order and, further, did not submit a final report within two years of such effective date. The licensee appealed the matter to the appellate court.

On appeal, the licensee argued that certain features of the conditions imposed by the Board in its original order were legally or practically improper. Applying the doctrine of “claim preclusion,” the court held that “[a] valid judgment rendered upon the merits bars all subsequent actions based upon any claim arising out of the transaction or occurrence that was the subject matter of the previous action.” It continued that such preclusion applies to administrative actions of a judicial nature and where the parties have had an ample opportunity to litigate the issues involved in the proceeding.

Nevertheless, the appellate court reviewed the foundation for the lower court’s determination for error. It noted the limited review of the appellate court to determine only if the trial court abused its discretion, defined not merely as an error in law or judgment, but determinations that are unreasonable, arbitrary, or unconscionable.

The appellate court held that the trial court premised its affirmation of the Board order on the failure to obtain an evaluation within 90 days of the effective date of the order and the failure to submit a final report within two years of such date. The appellate court noted that the trial court used the September 11, 2002 date (the date the Ohio Supreme Court refused to hear the appeal) as the effective date of the order.

Noting that the licensee filed a motion for reconsideration with the Ohio Supreme Court, the appellate court held that the actual effective date of the order was October 23, 2002, the date of denial of reconsideration, rather than the September 11, 2002 date. Thus, the court held that the two-year period for filing the psychological report expired on October 23, 2004. Because the report was filed on October 5, 2004, the appellate court held such report to be timely filed and that the trial court erred in determining otherwise.

Regarding the requirement of a full evaluation within 90 days of the effective date of the Board order, the court noted that the licensee failed to strictly comply with such a condition. But, the court continued, based upon the information within the report, the licensee complied with the “substance of the condition” by visiting with the psychologist well before the effective date of the order with numerous subsequent visits thereafter.

Further, the court held that the psychologist concluded that the licensee had no diagnosable condition in need of treatment. Indeed, given the psychologist’s conclusion, it would have been impossible for the licensee to comply with the requirement of a treatment plan with no condition to treat. The court held that it would be “unfair and unreasonable to preclude [licensee’s] reinstatement and deny him the opportunity to take a professional examination because the psychological evaluation he obtained from a licensed mental health professional did not cor-
Internet Prescribing: Finding the Line

For more than a decade, regulators in the pharmacy and medicine fields have struggled to balance the promise and pitfalls of the Internet. On the one hand, technology has the potential to bring badly needed medical care to underserved populations and reduce costs. On the other, it allows the ethically challenged to illegally peddle dangerous and counterfeit medications anonymously and on a mass scale.

Some Internet interactions are easy to classify as acceptable or not. Prescribing sites that feature leading questionnaires allowing customers to enter and re-enter information until they “qualify” for the medication they are seeking, the doctors that sign off on such prescriptions for a fee per prescription, and the pharmacies that fill thousands of controlled substance or frequently abused lifestyle drug prescriptions without question clearly violate ethics – and often, state and federal laws. On the other end of the spectrum, those legitimate sites that allow consumers increased access to medications, prescribers who use technology to communicate outside of office hours, and the pharmacists who accept e-prescriptions safely advance convenience, access, and (at times) cost savings. While there will always be gray areas, focusing on the traditional elements of the patient-practitioner relationship – particularly the in-person examination and access to medical records – can clarify whether a given practice is acceptable.

Valid Telemedicine

Telepharmacy has expanded pharmacy services to previously underserved areas, for example, North Dakota’s pioneering telepharmacy system, established in 2001, is credited with restoring, retaining, or establishing pharmacy services for about 40,000 rural citizens; adding approximately $12 million in economic development to the local rural economy; and adding up to 50 new jobs. Telemedicine also holds great potential to increase needed access to health care. However, it also holds potential for abuse, and both lawmakers and regulators are working to facilitate its adoption while minimizing negative outcomes.

Some Internet prescribing sites may argue that they are practicing “telemedicine,” and allowing patients access to treatment that they might otherwise find difficult to obtain. Regulators do not always agree that the access is appropriate, or that the purported brand of telemedicine is acceptable. Which begs the question: What does valid telemedicine look like?

The Federation of State Medical Boards (FSMB) has proposed a definition of telemedicine as “the practice of medicine using electronic communication, information technology or other means between a physician in one location and a patient in another location with or without an intervening health care provider.” With expanding technological innovation, this encompasses myriad possibilities. But just because technology allows a new approach to medical care does not mean that the standards of what constitutes “good medical practice” have changed. Physicians “still must be able to provide the same level of service as face-to-face,” says Lisa Robin, MLA, FSMB’s senior vice president for member services.

Among the most common of telemedicine’s many applications is allowing patients, as well as their primary care physicians or other health care providers, access to specialists whose physical practices are miles (if not states) away. A consulting specialist may review test results, ultrasound scans, X-rays or CAT scans...
(as just a few examples) received electronically, and talk directly with patients and their health care providers via interactive video. Or networked databases may allow a doctor to seek an e-mail opinion from a specialist in a connected hospital, based on a review of the patient’s records. Whatever the scenario, however, just as North Dakota’s telepharmacy system protects patients’ health by staffing telepharmacy locations with trained technicians and using video links for visual contact between pharmacist and patient, these scenarios all involve an in-person component with a qualified health care professional.

The Patient-Practitioner Relationship

Central to acceptable telemedicine in general, and Internet prescribing in specific, is the question: What constitutes a valid patient-practitioner relationship?

FSMB, in its “Model Guidelines for the Appropriate Use of the Internet in Medical Practice,” states, “[a]lthough the Board recognizes that it may be difficult in some circumstances, particularly in an online setting, to define precisely the beginning of the physician-patient relationship, it tends to begin when an individual seeks assistance from a physician with a health-related matter for which the physician may provide assistance.

However, the relationship is clearly established when the physician agrees to undertake diagnosis and treatment of the patient and the patient agrees.”

Technology has, at times, made it difficult to define, as FSMB’s model guidelines above indicate, at what precise moment a patient-practitioner relationship begins. It is, however, universally recognized in statutes, regulations, and standards that a patient-prescriber relationship must include, at some point, in the words of the American Medical Association (AMA), “a reliable medical history and . . . a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided . . .”

As the NABP Newsletter has discussed at various times in the past, Drug Enforcement Administration (DEA) has included an in-person examination as a necessary element of a valid patient-practitioner relationship, and several states now specify a similar requirement in their laws or regulations.

Federal requirements have become clearer in terms of controlled substances, following passage of the Ryan Haight Online Pharmacy Consumer Protection Act, signed into law in 2008. Among other stipulations, it mandates a face-to-face consultation with a health care provider as part of the patient-prescriber relationship required for a controlled-substance prescription to be filled via the Internet. The act does not address non-controlled substances. (At press time, DEA was in the process of drafting regulations pertinent to telemedicine, in response to the Ryan Haight Act, and was therefore unable to comment on any potential changes in its guidance.)

Telemedicine has changed some of the expected standards of the patient-physician relationship, notes FSMB’s Robin. Nonetheless, an Internet questionnaire by itself, she notes, “is not an acceptable standard of care.” Regardless of other considerations, a physician merely reviewing the answers “would have no way to verify the data on an online questionnaire.” Potentially acceptable alternatives to a traditional in-person examination with the prescriber do not eliminate all face-to-face contact with a health care worker, even in the case of a video link: A physician at a remote location might, for example, work in conjunction with a nurse on the spot who could provide necessary physical findings.

At press time, a FSMB working group had released for comment a draft model policy on telemedicine; the draft was scheduled to be

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2009 NABP Award Recipients to be Honored for their Dedication at 105th Annual Meeting

NABP will honor leaders whose support and initiative have furthered NABP’s mission of protecting the public health during the NABP 105th Annual Meeting to be held May 16-19, 2009, at the Hyatt Regency Miami Hotel in Miami, FL. The 2009 awards to be presented include the NABP Honorary President Award, the Fred T. Mahaffey Award, the Henry Cade Memorial Award, the John F. Atkinson Service Award, and the Lester E. Hosto Distinguished Service Award.

**Honorary President**

Receiving the 2009 NABP Honorary President Award is **Lydia D. Main, RPh**, in recognition for her strong and active commitment to supporting the NABP mission and to the practice of pharmacy. Currently, Main is serving her third term as the vice president of the West Virginia Board of Pharmacy.

As an active member of NABP, Main has served on numerous committees and task forces, including the Committee on Resolutions, the Task Force on Expanded Use of Internet in Pharmacy Practice and Regulation, the Committee on Law Enforcement/Legislation, the Task Force on Electronic Transmission of Prescriptions, and the Committee on Constitution and Bylaws.

In addition to her services with NABP and the Board of Pharmacy, Main supports the practice of pharmacy through other services throughout the state. Main is the past president of the West Virginia University School of Pharmacy Alumni Association, and a member of the West Virginia Pharmacist Association. She has also served on the Executive Committee and Board of Directors for Valley Mental Health of Monongalia, Preston, and Harrison counties in West Virginia. For 35 years, Main has been mayor for Masontown, where she also has co-owned and operated Main Pharmacy for the past 47 years.

Main graduated from West Virginia University School of Pharmacy.

**Fred T. Mahaffey Award**

The **Oregon State Board of Pharmacy** will be honored with the Fred T. Mahaffey Award in recognition of its exemplary service and dedication to NABP’s mission of protecting the public health. In July 2006, Oregon became the first state to adopt a rule requiring prescriptions for all pseudoephedrine products in an attempt to reduce the manufacture and abuse of methamphetamine across the state. From July 2006 to December 2008, the Oregon State Board of Pharmacy has seen a 95% reduction in methamphetamine laboratories throughout the state.

**Henry Cade Memorial Award**

In recognition of their support of the goals and objectives of NABP and the state boards of pharmacy and for advancing the safety and integrity of the medication distribution system through the generous support of the Internet Drug Outlet Identification program in 2008, **David Searle, RPh, and Walt Slijepcevich, RPh**, will receive the 2009 Henry Cade Memorial Award.

Searle began his pharmacy career in 1970. He purchased his first pharmacy in 1979 and eventually owned and operated three independent community pharmacies for 20 years. In 1998 Searle joined Pfizer Inc as a clinical education consultant where he worked with community pharmacies to assist in the implementation of patient-focused
programs. Searle currently is director of pharmacy development for Pfizer’s US Trade Group working as a liaison between Pfizer’s medical teams and the database providers to manage drug-drug interactions and pricing data. Searle also works with national and state pharmacy associations to enhance relationships and engage in policy dialog. He graduated from the University of the Pacific.

Slijepcevich serves as director of team leader pharmacy development at Pfizer. His responsibilities include maintaining and enhancing the relationships with the national and state retail pharmacy associations. Slijepcevich is also the primary contact to the pharmacy clinical database providers. Before beginning his career at Pfizer, Slijepcevich worked for Caremark from 1984 to 1993. In 1991 he was named general manager of Caremark’s pharmacy benefits management (PBM) operation. In 1993 Slijepcevich served as director of clinical services and brand pharmaceutical purchasing at Eckerd Drug where he was responsible for building Eckerd’s PBM operation.

Slijepcevich obtained his bachelor of science degree in pharmacy from the University of Illinois at Chicago, College of Pharmacy.

John F. Atkinson Service Award

In recognition of her efforts in protecting the public health through her work as a drug agent for the Florida Board of Pharmacy, Tram Vu, PharmD, will receive the first ever John F. Atkinson Service Award. Since May 1997, Vu has assisted the Florida Board of Pharmacy in protecting the public health throughout her inspections of 22 counties. In addition to her inspection responsibilities, Vu continues to serve on the Florida Board of Pharmacy’s Drugs, Devices and Cosmetics Certified Designated Representatives for Prescription Drug Wholesaler Exam Development and Review Committee.

Vu’s vast knowledge of inspection and investigative techniques has made her an important resource to her colleagues. She has helped train new drug agents based on her understanding of the Florida Drug and Cosmetic Act and other state and federal regulations. Vu has also provided hands-on training and presentations to other drug agents and pharmacy inspectors on Chapter 499 issues including pedigree papers and authentication.

Vu obtained her doctor of pharmacy degree from the University of Florida.

Lester E. Hosto Distinguished Service Award

Receiving the 2009 Lester E. Hosto Distinguished Service Award is Edith G. Goodmaster, for her exemplary service in protecting the public health and her significant involvement with NABP. This award is the highest honor bestowed by NABP.

Goodmaster was first appointed public member of the Connecticut Commission of Pharmacy in 1988, and has served for 20 consecutive years. During this time she has been an active member of the Commission of Pharmacy, attending every meeting, as well as compliance hearings, examination sessions, and on occasion has filled the position of chair. She currently is serving her third term as treasurer. Goodmaster is also an active member of NABP, serving on numerous NABP committees and task forces, including the Committee on Constitution and Bylaws, the Task Force on Model Guidelines for Formulary Development, Committee on Law Enforcement/Legislation, task forces on Recycling Safety Closure Prescription Containers and Prescription Drug Diversion from Common Carriers, and most recently, the Task Force on Medication Collection Programs.

She is also a member of the Advisory Committee for the Technician Program at Briarwood College and is Commission liaison for the Unwanted Medication Disposal Program. Goodmaster obtained her associate of (continued on page 95)
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revised and presented to the FSMB House of Delegates in May, for potential adoption as official policy. The unrevised draft reads as follows.

Issues medical boards should consider when determining whether the physician has formed a valid physician-patient relationship include:
- verifying that the person requesting the medication or treatment is in fact who he or she claim [sic] to be;
- conducting an appropriate examination of the patient that meets the applicable standard of care;
- establishing a diagnosis through the use of accepted medical practices, i.e., a patient history, mental status examination, physical examination and appropriate diagnostic and laboratory testing;
- discussing with the patient the diagnosis, risks and benefits of various treatment options to obtain informed consent;
- insuring the availability for appropriate follow-up care; and
- maintaining a complete medical record available to the patient and other treating health care providers.

AMA provides similar guidance for physicians in regard to Internet prescribing.

NABP makes clear its position on valid Internet prescribing on the Criteria page of the Internet Pharmacies section of its Web site: For a prescription to be valid, it must be issued pursuant to a legitimate patient-prescriber relationship. That relationship must have established that the patient has a legitimate medical complaint, and must have included a face-to-face physical examination sufficient to establish the legitimacy of the medical complaint (or, have been established through a telemedicine practice approved by the relevant practitioner board). Moreover, there must exist a logical connection between the medical complaint, the medical history, the physical examination, and the drug prescribed.

Access to Medical Records

The other important piece relevant to valid Internet prescribing (and telemedicine) is access to a patient’s medical records. Indeed, it is access to this history that most differentiates cross-coverage or call center situations from some Internet prescribing sites. Benjamin Gluck, MA, JD, a criminal defense attorney, presented the program “Case Strategy: How to Investigate an Internet Pharmacy” at the NABP 104th Annual Meeting and discussed the differences of Internet prescribing on what he terms “online questionnaire +” sites and cross-coverage/call-center scenarios. The former he describes as sites that feature United States doctors prescribing US medications, a medical questionnaire, medical records for the existing prescription, and telephone contact with the patient. The latter also features US doctors prescribing US medications and telephone contact with the patient.

Coverage and call center scenarios, however, differ from the Internet sites in an important way: More extensive medical records are theoretically available, even though they may not be reviewed, and the patient has a pre-existing physician-patient relationship with the doctor who has arranged coverage.

According to FSMB’s Robin, it is the access to medical records that makes the key difference between prescribing sites like Gluck’s “online questionnaire +” sites and cross-coverage situations. “They have to be able to attain medical records at least,” Robin says, and notes that in cross-coverage situations, the physician on call “should have access to [the patient’s] medical history” – information that would indicate contraindications to potential avenues of treatment, for example.

The Challenge

The challenge of telemedicine is to translate crucial elements of acceptable standards of care – for prescribing, these include a valid patient-prescriber relationship that includes a physical examination, and access to the patient’s medical records – into the digital age. No one denies the public health value of expanding health care access to underserved populations, but the public health is not served if that expanded care is substandard.

Perhaps, over time, proponents of expanded definitions of telemedicine will be supported by increasingly sophisticated technology that will allow a broader perception of how to combine the promises and pitfalls of the Internet. At present, however, legislators, regulators, and industry groups tend toward caution – and thus far, the public health has been best protected by adhering to accepted interpretations of good medical practice.
Developing Drug Repository Programs Raise Concerns, Boards of Pharmacy Contribute Expertise in Creation of Regulations

Increasing prescription costs continue to raise concerns for those struggling to purchase critical medications. As a possible solution, more states are considering implementation of drug donation or repository programs, which allow certain institutions, and in some cases individuals, to donate unused medications. These programs can be distributed to the medically indigent. Currently, 35 states allow drug repository programs to exist, according to the 2009 Survey of Pharmacy Law. Though some states have working programs today, many are still awaiting promulgation of rules in order to make them operational.

In December 2008, NABP surveyed the state boards of pharmacy about recycling unused medications and found that eight of the 19 boards that responded allow drug repository programs to exist or operate, while at least two are awaiting development of rules prior to implementation. The survey was conducted as a follow up to a February 2006 survey on this issue. Of those boards that responded to both the 2006 and the 2008 surveys, five did not allow for drug repository programs to exist or operate in 2006, but now have programs or laws in effect to do so. See the August 2006 NABP Newsletter article “State Boards’ Donation Programs for Unused Prescription Medications Balance Patient Needs, Safety,” for details on the results of the February 2006 survey.

In several states, the boards of pharmacy have worked closely with their state legislatures to develop regulations for these programs. In 2007, North Dakota Governor John Hoeven signed House Bill 1256 into law authorizing the state prescription drug repository program. While the program was developed at the request of the American Cancer Society, the North Dakota State Board of Pharmacy was responsible for developing the criteria for the establishment of the program and handling the registration of participants for the receipt and dispensing of the donated items.

Similar to North Dakota, the Pennsylvania State Board of Pharmacy, which specifically allows for a cancer drug repository program, and the Virginia Board of Pharmacy are responsible for promulgating regulations for their states’ programs; however, according to the December 2008 survey, neither program is operational yet as both are still in the rule development and approval process.

Safety Concerns

As indicated above, state legislators will often implement drug repository programs and empower the boards of pharmacy to develop rules and oversee the programs. The boards’ expertise in the distribution of safe and effective medications is a necessary component in the development of regulations for such programs as it ensures that the public health and safety remains the top priority. In fact, pharmaceutical manufacturers that produce drugs that must be distributed through restricted distribution programs, including isotretinoin and thalidomide, see the boards of pharmacy as integral to ensuring that all the proper safeguards are in place. According to one biopharmaceutical company representative, “while lawmakers usually exclude controlled substances from the donation programs, oftentimes other higher risk medications are not explicitly prohibited from donation and redistribution.”

Food and Drug Administration (FDA) has implemented restricted distribution programs for approximately 15 different drugs that require registration with the manufacturer and patient education. In some cases, these requirements also include registration by the prescriber and dispenser. The number of medications that require special attention by manufacturers and, subsequently, state-run repository programs, is on the rise.

Several states, including Arizona, Colorado, Kansas, Michigan, and Virginia have explicitly excluded drugs for which FDA has required a restricted distribution program to be in place, notes the company representative. Effective this year, the Kansas State Board of Pharmacy promulgated KAR 68-18-2, which specifies that a qualifying center or clinic shall not accept or dispense an unused medication that can be dispensed only to a patient or resident registered with the drug manufacturer." Regulations such as this one further assist in protecting the public health and safety. Without safeguards in place, some fear that the medication could be inadvertently redispensed to another patient outside of the FDA-mandated restricted distribution program.

As in Kansas, Arizona proposed rule R4-23-1203, Eligible Prescription Medications, which specifically states:

A prescription medication may be donated to a physician’s office, a pharmacy, or a health care institution that participates in the prescription medication donation program if the prescription medication . . . is not a . . . drug that can only be dispensed to a patient registered with the drug’s manufacturer, because donation could be distributed to a . . . . . .
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prevent the manufacturer from maintaining required patient registration data.  
A few states such as Delaware, Oklahoma, and South Carolina permit, under limited circumstances, pharmacists to “return” or “reuse” medications, but specifically indicate that they do not allow for a drug repository or donation program to exist. According to Delaware regulation 5.11, products under the direct control of a health care professional, that are packaged in manufacturer unit dose or tamper-proof unopened bulk containers, with the tamper-proof seal intact, including unused multi-dose punch cards, may be redispensed in accordance with expiration dating in the customized patient medication package, but partially used products may not be redispensed.  
In addition, the regulation prevents medication that potentially has been diverted or adulterated, is not secure, or is expired from being placed back in the distribution system by prohibiting returns or exchanges by any pharmacist or pharmacy after having been taken from the premises where sold, distributed, or dispensed.  
Likewise, the Oklahoma State Board of Pharmacy developed a program that, under limited circumstances, allows specific facilities to donate unused medications through its non-central repository program, the Unused Prescription Drug Program for Oklahoma's Medically Indigent. After conducting several trials, the Board developed rules for the program that allow Oklahoma licensed nursing homes, approved Oklahoma licensed assisted living centers, and licensed prescription drug manufacturers to donate unused medications for distribution to indigent patients as specified in OAC Title 535, Subchapter 12. The state has approximately 36 charitable clinics with pharmacies that are able to receive these unused prescription drugs. In addition to these pharmacies, county-operated pharmacies are allowed to receive and dispense the unused medications.  
According to the Tulsa County Medical Society, in Tulsa County, a total of 47,878 prescriptions have been filled from the time the program was implemented in November 2004 to February 2009, an average wholesale value of $4,894,000.

Drug Donation Programs

Drug donation and repository programs have been implemented in several states; however, hesitations remain. Various factors contribute to these hesitations, including questions of how to ensure the efficacy and safety of a medication, how to regulate the medications and those distributing them, and how to assign liability in situations where medications have left the normal chain of distribution.  
In December 2008, NABP convened the Task Force on Medication Collection Programs in Tucson, AZ, to discuss methods of medication collection and disposal. During this meeting the task force addressed reuse of medications and recommended that NABP work with the boards of pharmacy and appropriate state and federal agencies, such as Food and Drug Administration, to research programs for the reuse of previously dispensed medications. The focus of the research would be to ultimately determine whether safe and legally compliant methods can be utilized.  
After reviewing several prescription medication repository programs currently in existence, task force members discussed the societal value of such programs and why medications should be reused instead of destroyed. They acknowledged that medications in long-term care facilities are maintained within a closed distribution system and, thus, may be appropriate for reuse. However, any programs in the community pharmacy setting would necessitate different requirements, as they raise questions about medications that have left the normal drug distribution channel and their likelihood of having been maintained in a controlled climate and monitored environment. The standards for these medications should be the same as the standards required of all other medications and must ensure that the medications dispensed are non-adulterated and non-misbranded.  
Task force members also agreed that any medication collection programs for reuse must be compliant with all state and federal regulations, including standards of the United States Pharmacopeial Convention, to ensure public safety. The full task force report, which was approved by the NABP Executive Committee at its February 2009 meeting, is available on the NABP Web site at www.nabp.net, under News/Press.

Safeguarding Patient Safety: NABP to Explore Methods of Medication Repository Programs

Feature News
The Iowa Prescription Drug Corporation (IPDC), which began operating its repository program in May 2007, voiced the importance of maintaining the quality and effectiveness of medications, stressing that patient safety is of utmost concern at all times as is ensuring in its program that “all [long-term care] medications are under the continuous control of a health care professional . . . verified by a licensed pharmacist for accuracy . . . [and] scrutinized for integrity and proper expiration dating.”

Overseen by the Iowa Department of Public Health in cooperation with the Iowa Board of Pharmacy, the IPDC program was established to improve the health of low-income Iowans by authorizing medical facilities and pharmacies to redispense prescription drugs and supplies that would otherwise be destroyed. From March 2007 to December 2007, the repository received medication donations of almost 319,000 dosage units, valued at an estimated $292,000. During that same time period, almost 142,000 dosage units of medication, worth an estimated $150,000, were distributed through the program to indigent patients.

### Handling Liability

Though patient safety is the primary concern with repository programs, the issue of liability has also been raised. Several states have included or are attempting to include language in their rules to address this subject. In the December 2008 survey on recycling unused medications, Paul Boisseau, immediate past executive secretary of the New Hampshire Board of Pharmacy, responded that “the Board is currently seeking additional legislation that would include pharmacies and pharmacists participating in a donation program to be covered under the existing Limited (liability) Immunization section of the law,” which currently protects only manufacturers of the donated drugs.

According to Boisseau, the state will need to expand this language to make it applicable to pharmacies and pharmacists in order for the prescription drug program to be viable.

Iowa and South Carolina also address liability in their rules. The Iowa Administrative Code exempts drug manufacturers, as well as others such as pharmacists, acting in good faith, from criminal prosecution, civil liability, and disciplinary action for injury to or the death of an individual to whom a donated prescription drug is dispensed as directed in chapter 641—109.11(135M) Exemption from disciplinary action, civil liability and disciplinary action for injury to or the death of an individual to whom a donated prescription drug is dispensed.

A donor of a cancer drug or supplies, or a participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies . . . are immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to donating, accepting, distributing, or dispensing cancer drugs or supplies pursuant to this article.

Addressing liability issues is just one step in developing and implementing these repository programs. Various concerns remain regarding their ability to maintain and ensure the efficacy of donated medications, and most importantly, their ability to protect the patients who are receiving them.

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**Legal Briefs**

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respond to the peculiar, if not arbitrary, expectations of the Board.”

The appellate court concluded that the licensee complied with the spirit of the Board order and that the trial court erred in affirming the sanction. Thus, it reversed the trial court holding and remanded the matter back to the Board to vacate the original order.

Under circumstances that dictate potential reentry into practice under specified conditions, boards of pharmacy are encouraged to examine sanctions intended to ensure public protection, while affording disciplined licenses with an opportunity for reinstatement. However, boards are encouraged to carefully craft such reinstatement conditions to ensure a reasonable opportunity for compliance and parameters ascertainable by the board and future boards that may rule on reinstatement requests.

*Sutton v State Board of Pharmacy, 2008 WL 5390466 (App Ct OH 2008)*
Newly Accredited VAWD Facilities

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

<table>
<thead>
<tr>
<th>Facility Name</th>
<th>City, State</th>
<th>Accreditation Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gulf South Medical Supply, Inc</td>
<td>Omaha, NE</td>
<td>February 2, 2009</td>
</tr>
<tr>
<td>McKesson Corporation dba McKesson Drug Company</td>
<td>Honolulu, HI</td>
<td>February 2, 2009</td>
</tr>
</tbody>
</table>

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

Surveyors Obtain Valuable Information during NABP Accreditation Training

On March 11-12, 2009, NABP surveyors convened for accreditation surveyor consultant training. Held at NABP Headquarters, the training provided critical information on the Verified-Accredited Wholesale Distributors® (VAWD®) and Verified Internet Pharmacy Practice Sites™ (VIPPS®) programs as well as an in-depth look at the components and tools of the durable medical equipment, prosthetics, orthotics, and supplies accreditation survey process. Pictured above from left to right: Ed Kraus, Chuck Young, Leo Norton, Donald Williams, Richard Berta, Philip Carter, Bob Gale, Kent Walker, Peggy Walkup, Rich Paul, Christine Higgins, Kenneth Rodgers, TJ Bondurant, Jeff Osman, Michael Karnbach, Jason Smith, Ronnie Higgins, and Frank Kaufman.

Newly Accredited DMEPOS Facilities

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

<table>
<thead>
<tr>
<th>Facility Name</th>
<th>City, State</th>
<th>Accreditation Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community Pharmacy</td>
<td>Denton, TX</td>
<td>January 28, 2009</td>
</tr>
<tr>
<td>Heena Vital Rx, Inc</td>
<td>Chicago, IL</td>
<td>January 28, 2009</td>
</tr>
</tbody>
</table>

A full listing of accredited DMEPOS facilities is available on the NABP Web site at www.nabp.net.
Final Rule to Strengthen Health Care Workers’ Right of Conscience Stirs Public Debate

The final rule to strengthen health care workers’ right of conscience was published in the Federal Register on December 19, 2008. Entitled “Ensuring That Department of Health and Human Services (HHS) funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law,” it took effect on January 20, 2009, the day President Barack Obama took office. The rule gives workers employed by any health care facility receiving federal funds the right to opt out of providing health care services they find morally objectionable. It not only targets such controversial medical practices as abortion, but also affects pharmacy services such as dispensing birth control and emergency contraception.

Specifically, the final rule clarifies that such protections apply to both institutional health care providers and individual employees working for recipients of certain Department of Health and Human Services (HHS) funds. It also requires recipients of certain HHS funds to certify in writing their compliance with laws protecting provider conscience rights. The certification requirement is to be phased in by October 1, 2009, the start of federal fiscal year 2010. In the event that an employer of health care workers does not comply with the regulations, HHS “will consider all legal options, including termination of funding, [and] return of funds paid out in violation of health care conscience protection provisions . . .” the rule states. The rule designates the HHS Office for Civil Rights as the entity to receive complaints of discrimination as described by existing laws and this regulation.

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HHS Proposes to Rescind Bush’s 11th Hour Conscience Clause

The Department of Health and Human Services (HHS) has issued a proposal to rescind the December 19, 2008 final rule to strengthen health care workers’ right of conscience. The rule was promulgated by HHS during President Bush’s last days in office. The rule met with a flurry of legislative and legal activity by opponents eager to repeal the move, as well as support from proponents who want to protect it.

HHS received numerous comments, many of which assert that “the rule would limit access to patient care and raised concerns that individuals could be denied access to services, with effects felt disproportionately by those in rural areas or otherwise underserved,” HHS states in the background information for the withdrawal proposal published in the March 10, 2009 Federal Register.

HHS further states that such questions “warrant further careful consideration . . . to ensure [the rule’s] consistency with current Administration policy . . . and [to] reevaluate the necessity for regulations implementing the statutory requirements.”

While illuminating the controversy surrounding the issue, none of the legislative and legal actions initiated to repeal the rule (see article “Final Rule to Strengthen Health Care Workers’ Right of Conscience,” in this issue of the Newsletter) were the deciding factor. HHS explains in the Federal Register that the proposal to rescind the rule is being issued pursuant to the authority of 5 USC 301, which empowers the head of an Executive department to prescribe regulations “for the government of his department, the conduct of his employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.” HHS also cites its responsibility to consider the economic burden that would result from implementing the December 19 rule, estimating that costs associated with the rule’s certification requirements at $43.6 million per year.

To determine whether to rescind the final rule in part or in its entirety, HHS accepted comments through April 9, 2009. In particular, HHS sought further information on (1) the scope and nature of the problems necessitating federal rulemaking and how the current rule resolves them; (2) whether the rule reduces access to information and health care services, particularly by low-income women; (3) whether the rule provides sufficient clarity to minimize the potential for harm resulting from any ambiguity and confusion; and (4) whether the objectives of the rule might also be accomplished through non-regulatory means, such as outreach and education.
nabp newsletter

Public Debate
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Rule Bolsters Existing protections

The new rule essentially amplifies existing federal protections of health care workers’ rights of conscience, pursuant to the Church Amendments, the Public Health Service (PHS) Act, and the Weldon Act. In addition to defining certain key terms, the final conscience clause rule is designed to ensure that recipients of HHS funds know about their legal obligations under existing federal health care conscience protection laws by requiring written certification by certain recipients that they will comply with all three statutes, as applicable. The rule also excuses people who refuse to provide the service from having to refer patients to someone who will. This protection, however, does not extend to health care entities or institutions, which would have to arrange to provide any information or service otherwise required by law.

Opponents of the rule argue that, since such protections were already in place, the new rule is unnecessarily punitive, and that a worker’s personal moral code should not interfere with a patient’s right to receive lawful medical treatments. Proponents of the rule, on the other hand, say the existing laws needed to be clarified and amplified to ensure that health care workers are not forced to choose between good professional standing and a clean conscience.

Bills Seek to Overturn New Rule

Long before the new “conscience clause” took effect, several legislators and attorneys general were scurrying to block its passage or, in the event that it did take effect, to immediately nullify it. In August 2008, when the rule was proposed, then-Democratic presidential nominee Barack Obama spoke out against it, affirming his commitment to protect women’s health and reproductive rights. On November 20, 2008, then-Senator Hillary Rodham Clinton of New York and Senator Patty Murray of Washington introduced to the Senate a bill (S 20) called the “Protecting Patients and Health Care Act” that sought to prevent HHS from implementing the new rule. The bill was referred to the Senate Committee on Health, Education, Labor, and Pensions. This bill failed to advance before the end of the Congressional session.

Colorado Representative Diana DeGette, with the support of 24 representatives who signed on as co-sponsors, introduced a similar bill (HR 570) by the same name in the House on January 15, 2009, to render the new rule impotent. The language of the bill is short and to-the-point: “The final regulations issued by [HHS] … shall have no force or effect.” The bill has been referred to the House Committee on Energy and Commerce.

Another attempt to kill the new conscience clause takes aim at all eleventh-hour actions set in motion by an outgoing president. Known as the “Midnight Rule Act,” the bill (HR 34) was introduced on January 6, 2009, by Representative Jerrold Nadler of New York. It would implement restrictions on any rules adopted in the final 90 days of a presidential administration, delaying the effective date of any such rules until 90 days after the agency head is appointed by the incoming president, with certain exceptions for rules determined to be time-critical.

Under the proposal, the agency head appointed by the new president would have up to 90 days after being appointed to formally disapprove of a “midnight rule” by publishing a statement of disapproval in the Federal Register and sending a notice of disapproval to the congressional committees of jurisdiction. The act, which would apply to any rule adopted on or after October 22, 2008, has been referred to the House Committee on the Judiciary.

Eight States File Suit

Eight states and two private family-planning organizations have filed lawsuits asking federal courts to overturn the new rule. Connecticut Attorney General Richard Blumenthal filed suit on January 15, 2009, on behalf of his state, as well as California, Illinois, Massachusetts, New Jersey, Oregon, and Rhode Island. The lawsuit alleges that the rule violates federal law, women’s rights, and states’ rights to enforce their own laws.

“The federal government is impermissibly interfering with constitutional rights and carefully crafted and balanced state measures protecting patients and women, particularly rape victims who may require immediate access to emergency contraception,” Blumenthal says in a January 15 news release posted on his Web site.

New York Attorney General Andrew M. Cuomo on January 16 joined Connecticut and the six other states in the lawsuit to challenge the rule, saying it would conflict with a state law requiring hospitals to provide rape victims with information on all their legal options, including emergency contraception. “New York State has struck a solid balance between protecting the reproductive rights of women and the personal beliefs of healthcare providers,” Cuomo says in a January 16 news release posted on his Web site. “These new regulations would undermine those protections and our commitment to ensuring that women, especially victims of rape or sexual assault, have access to the services and information they need to safeguard their help.” In the same news release, New York Governor David A. Paterson calls the regulations “a disturbing attack on the rights of women to access lawful health care.”

Supporters Vow to Defend Rule

Supporters of the regulation have pledged to defend it, arguing that the rule is needed to stop religious discrimination. The right of conscience, supporters maintain, should be enforced

(continued on page 90)
Participants Can Earn 9.75 Hours of Continuing Pharmacy Education Credit During NABP 105th Annual Meeting in Miami

The NABP 105th Annual Meeting, “NABP MIAMI: Quality Care – It’s Hot! Hot! Hot!” to be held May 16-19, 2009, at the Hyatt Regency Miami Hotel in Miami, FL, offers attendees the chance to earn up to 9.75 contact hours (0.975 continuing education units) of Accreditation Council for Pharmacy Education-approved continuing pharmacy education (CPE) credit. The CPE is designed to address current issues affecting the regulation of pharmacy practice. All Annual Meeting participants will have the opportunity to attend four joint CPE sessions. In addition, there will be a special pre-meeting CPE session as well as two sessions held concurrently: one geared for state board of pharmacy executive officers and members and the other for compliance staff.

Saturday, May 16
Pre-Meeting CPE
Maxims, Monarchy, and Sir Thomas More

Board of pharmacy members may face a variety of conflicts as they pursue their goal of protecting the public health. This session will feature a member of Periaktos Productions, LLC, who will perform an adaptation of Sir Thomas More’s last hours prior to his execution. During that time he explores his own “private conscience vs. public loyalty” issues – issues that also face today’s health professional boards. Following the presentation, facilitators Jay Campbell, RPh, JD, executive director, North Carolina Board of Pharmacy, and Michael A. Moné, BS, JD, FAPhA, vice president anti-diversion and senior regulatory counsel, Cardinal Health, will conduct a panel discussion based on the featured ethical dilemmas. Participants will earn 2.75 contact hours (0.275 CEUs) of CPE credit. This session is sponsored by Pearson VUE.

Sunday, May 17
Joint CPE
Educational Poster Session – CQI on Fire

The highly interactive Educational Poster Session – “CQI on Fire” will feature various noteworthy poster presentations relating to continuous quality improvement efforts by boards of pharmacy members and students and faculty at schools and colleges of pharmacy. One hour of interactive participation with presenters will qualify attendees for 1 contact hour (0.1 CEU) of CPE during this 3.5 hour session.

Joint CPE
DEA Update

Joseph T. Rannazzisi, deputy assistant administrator of the Drug Enforcement Administration (DEA), will provide attendees with an update to the administration’s priorities, including DEA’s Suspicious Order Reporting Requirements and the Healthcare Distribution Management Association’s compliance guidelines addressing this issue. Other topics to be discussed include DEA’s plans for the disposal of controlled substances, and the Ryan Haight Online Pharmacy Consumer Protection Act. Participants will earn 1 contact hour (0.1 CEU) of CPE credit. This session is sponsored by CVS Caremark Corporation.

Monday, May 18
Joint CPE
Patient Counseling – “Catch the Wave”

Focusing on counseling issues, this CPE session will discuss “where counseling is today” and why the current business model and patients’ expectations discourage interactive counseling. During this session a professional facilitator Jody Shields, BS, consultant, Align Organizational Development and Training, will assist participants in suggesting innovative counseling models and techniques. In addition, Bruce Scott, MS, RPh, FASHP, chief pharmacist and senior vice president, Medco Health Solutions, Inc; Jay Campbell, RPh, JD, executive director, North Carolina Board of Pharmacy; and Neil MacKinnon, MS (Pharm), PhD, FCSHP, associate professor, pharmacy administration and associate director of research, Dalhousie University College of Pharmacy, will present their points of view. Participants will earn 2 contact hours (0.2 CEUs) of CPE credit. This session is sponsored by Walgreen Co.

Tuesday, May 19
Executive Officer and Board Member CPE
Compounding Inferno – “For Office Use”

In this session, participants will learn about current state regulations pertaining to compounding for physicians’ office use, including developments regarding the compounding of controlled substances for office use. Speakers include Richard Sands, RPh, CPh, statewide pharmaceutical program manager, Florida Department of Health, and Lisa D. Ashworth, RPh, clinical pharmacist, Children’s Medical Center Dallas, Center for Cancer and Blood Disorders.

Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit. This session is sponsored by Humana Pharmacy Solutions.

Compliance Officer CPE
e-Tools “Out of Hand!”

As the pharmacy profession moves toward implementing more electronic tools, some of these applications are proving to be more helpful than others. During this session participants will discover the problems related to e-prescribing software, and learn how boards can benefit from utilization of (continued on page 95)
Register for NABP 105th Annual Meeting in Miami: It’s Hot! Hot! Hot!

Registration is still available for the 105th Annual Meeting, “NABP MIAMI: Quality Care – It’s Hot! Hot! Hot!” to be held May 16-19, 2009, at the Hyatt Regency Miami Hotel in Florida.

Attendees are encouraged to register directly online using the new and improved online registration form by visiting the Meetings section of the NABP Web site at www.nabp.net. A printable registration form can also be downloaded by anyone wishing to mail or fax the form to NABP. NABP offers attendees three payment options: (1) mailing in the payment, (2) using a credit card, or (3) paying in Miami.

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

NABP Still Accepting Travel Grant Applications from Voting Delegates for 105th Annual Meeting in Miami, FL

NABP is currently accepting travel grant applications for the 105th Annual Meeting from qualified state board of pharmacy voting delegates. The travel grant was established by NABP in an effort to assist boards in sending representatives to the Annual Meeting so that they may participate in important business sessions, including discussing and voting upon resolutions, electing NABP Executive Committee members and officers, and attending educational sessions regarding current issues facing pharmacy regulators.

This travel grant defrays the costs for designated voting delegates by providing funds for travel expenses, including airfare, hotel rooms, meals, taxis, parking, and tips. Qualified voting delegates will have the opportunity to receive up to $1,200 in grant monies to attend the NABP 105th Annual Meeting. The grant does not include Annual Meeting registration fees.

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

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

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

The NABP 105th Annual Meeting will take place May 16-19, 2009, at the Hyatt Regency Miami Hotel in Florida. For more information about the 105th Annual Meeting, visit the NABP Web site at www.nabp.net.

Public Debate
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like any other civil rights statutes. Proponents assert that existing laws to protect rights of conscience previously had not been clarified or enforced through implementing regulations. This lack of regulations, they say, led to confusion and a lack of awareness within the health care community regarding the existing protections, and, thus, policy makers or health care workers may have been unaware of the laws and therefore may have been violating them without realizing it, or they may have been subject to discrimination without knowing they have legal recourse. This ambiguity exposed health care workers to discrimination, potentially forcing them to choose between acting against their conscience or leaving their job.

Proponents of the new rule further hold that neither the state nor professional licensing bodies should be permitted to impose treatment or referral mandates that violate individuals’ right of conscience. Supporters have written to HHS saying that better health care comes from workers who practice what they believe and are not compelled to do otherwise.

Rule Seeks to Balance Interests

The rule, as described in the Federal Register, is intended to balance the right of patients to obtain legal health care services, and that of health care workers to refuse to provide services to which they object through raising awareness of federal health care conscience protection laws. HHS stresses that the rule does not change the long-standing right of patients to access legal reproductive health care services.
NABP 105th Annual Meeting • May 16–19, 2009 • Hyatt Regency Miami Hotel • Miami FL

105th Annual Meeting Program

Saturday, May 16, 2009

9 AM - 7 PM
Registration/Information Desk Open

1:30 - 4:30 PM
Pre-Meeting CPE
Maxims, Monarchy, and Sir Thomas More
Sponsored by Pearson VUE
ACPE #205-000-09-001-L03-P
(0.275 CEUs – 2.75 contact hours)

5 - 6 PM
Annual Meeting Orientation

7 - 10 PM
President’s Welcome Reception
Sponsored by Medco Health Solutions, Inc
Honoring NABP President Rich Palombo, RPh, and his wife Sandi
Dinner will be served.
Dress: business casual

Sunday, May 17, 2009

6:30 AM - 5:15 PM
Registration/Information Desk Open

7:30 - 8:30 AM
Fun Run/Walk
Sponsored by Pfizer Inc
Meet in hotel lobby.

8 - 11:30 AM
Joint CPE
Educational Poster Session – CQI on Fire
ACPE #205-000-09-002-L05-P
(0.1 CEU – 1 contact hour)

8 - 11:30 AM
Hospitality Brunch
Sponsored by Celgene Corporation

Educational Table Top Displays
• Accreditation Council for Pharmacy Education
• Drug Enforcement Administration
• Food and Drug Administration
• LegitScript, LLC
• National Association of Boards of Pharmacy
• Pearson VUE
• Pharmacy Technician Certification Board
• United States Pharmacopeial Convention

Noon - 4 PM
First Business Session
Presiding: Rich Palombo, RPh, NABP President
• Welcome Remarks
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/Secretary
• Presentation of Colors
• National Anthem
• Keynote Address
  Tucker Carlson, Senior Campaign Correspondent, MSNBC
• Call to Order
• Greetings from the Host State
• Report of the Executive Committee
  Oren M. Peacock, Jr, RPh, Chairperson, NABP Executive Committee
• Recognition of Sponsors

• President’s Address
  Rich Palombo, RPh, NABP President

• Report of the Treasurer
  William T. “Bill” Winsley, MS, RPh, NABP Treasurer

• Announcement of Candidates for Open Executive Committee Officer and Member Positions

Monday, May 18, 2009

7 AM - 2 PM
Registration/Information Desk Open

7 - 8:15 AM
NABP/USP Breakfast
Sponsored by United States Pharmacopeial Convention

8:15 - 10:15 AM
Joint CPE
Patient Counseling – Catch the Wave
Sponsored by Walgreen Co
ACPE #205-000-09-004-L03-P
(0.2 CEUs – 2 contact hours)

10:30 AM - noon
Second Business Session
Presiding: Rich Palombo, RPh, NABP President

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

Additional information on the continuing pharmacy education (CPE) sessions is available in the Meetings section on the NABP Web site, www.nabp.net, under CPE Descriptions.
Montana PharmAssist Program Demonstrates Benefits to Patients

The January 2009 Montana Board of Pharmacy Newsletter states that direct involvement in medication management is the future of pharmacy and that the profession cannot expect third-party payers to recognize the cognitive services provided unless the profession participates in programs that can demonstrate benefits to patients. Providing medication counseling and advice is a daily function of the pharmacy profession, but it is hard to quantify this benefit when these services are still tied to the sale of a product. However, a program that allows for face-to-face interaction with the patient and provides a written report of those recommendations (without the sale of a product) to both the patient and his or her physician is now available.

The Montana PharmAssist Program is an opportunity for pharmacists to provide medication management services while being reimbursed for their time. According to the Board Newsletter, the Montana Department of Public Health and Human Services (DPHHS) developed this program to give its citizens a tool to help control their medication costs and to maximize their drug therapy. Since this is a new program, pharmacist and patient participation is needed to ensure the program receives continued funding.

In addition, the Board Newsletter states that the successful implementation of this program could lead to other third-party payers following suit and recognizing the cognitive services that a pharmacist can provide.

The initial procedure involves some training, which counts as continuing education and is provided free of charge. Once the training is complete and a contract is signed with DPHHS, the pharmacist will be placed in a pool of other contracted pharmacists based on geographic location. Patients are allowed to request a particular pharmacist by name if they choose.

Any pharmacist (not just a PharmAssist pharmacist) may recommend the PharmAssist Program to a patient if the pharmacist feels that the patient may benefit from a medication management intervention (polypharmacy, compliance, etc.). Once an intervention is recommended to the patient, the patient or caregiver can call to request a patient application from the program. The Mountain-Pacific Quality Health Foundation will review the returned patient application to ensure the patient stands to benefit from the intervention. Once validated, the approving authority will send the patient’s information to a certified pharmacist in the geographic region of the patient.

The certified pharmacist will then review the packet and look for drug interactions, therapeutic duplications, and cost-saving alternatives. A face-to-face consultation will then take place to discuss problems with the patient’s current drug regimen and to suggest improvements. The individual pharmacist will be paid $50 for the initial 15-minute consultation and $25 for each additional 15 minutes (maximum of $125 for the initial meeting). Patients may be approved for a follow-up consultation that may be compensated for up to $75. Any Montana resident is eligible for PharmAssist regardless of income or insurance coverage.

Washington Board Sets Requirements for Technician Certification

Beginning in 2009 all new applicants for pharmacy technician certification in Washington must meet new credentialing requirements. Applicants must pass a Washington State Board of Pharmacy-approved national standardized certification examination and successfully complete a Board-approved training program.

Board-approved examinations are provided by programs or organizations accredited by the National Commission for Certifying Agencies (NCCA). Approved programs are listed on the NCCA Web site at www.ncca.org under NCCA Accreditation. Pharmacy technicians holding a Washington State credential issued prior to 2009 do not have to take a national examination. The Board does not require pharmacy technicians to maintain national certification, and continuing education credits are not mandatory for renewal.

MN Board Discusses Internet Pharmacy Rules, Prescription Drug Abuse

As was noted in the October 2008 Minnesota Board of Pharmacy Newsletter, the Board recently disciplined five pharmacists and one pharmacy (continued on page 94)
State Board News

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for involvement with Internet drug outlets that offered to arrange for the sale of legend drugs. The Web sites paid physicians and a physician assistant, licensed in other states, to write prescriptions based on questionnaires filled out by customers. Those purported prescriptions were then made available electronically to the pharmacists who worked at two licensed Minnesota pharmacies. The pharmacists shipped legend drugs to customers located across the country, and one of the pharmacies shipped controlled substances. The actions of the pharmacists violated a number of state and federal laws and rules.

The October Newsletter referenced a law passed by the Minnesota Legislature in 2008 establishing that prescriptions for controlled substances and certain other drugs (butalbital, tramadol, muscle relaxants, and erectile dysfunction drugs) are not valid unless the prescriptions or orders are based on a documented patient evaluation, including an in-person examination, adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment. Pharmacists are prohibited from knowingly dispensing prescriptions that do not meet the criteria for a valid prescription.

The Board also explains in the October issue the ways in which the requirement for an in-person examination can be met.

Congress passed a similar law in October 2008 – the Ryan Haight Online Pharmacy Consumer Protection Act. This law specifies that “no controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.” It defines “valid prescription” as one issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of the patient. A practitioner who has not conducted an in-person evaluation is permitted to write a controlled substance prescription for a patient only at the request of a practitioner who has conducted an in-person evaluation of that patient.

Under this new federal law, the requirement for an in-person evaluation does not apply when a practitioner is engaged in the practice of telemedicine. The Board notes that some illegitimate Internet drug outlets try to legitimize their actions by claiming that the physicians working for them contact customers by phone and are therefore engaged in the practice of telemedicine.

Minnesota law, however, is stricter than the federal law in this regard. First, physicians in other states who wish to provide telemedicine service to Minnesota residents must pay a fee and register with the Minnesota Board of Medical Practice. In addition, prescriptions for controlled substances, butalbital, tramadol, muscle relaxants, and erectile dysfunction drugs are valid when issued by a consultant practitioner who is providing services by means of telemedicine only if a referring practitioner has performed an in-person examination. Typically, patients of the illegitimate Web sites have not been referred to the physicians working for the Web site.

The Ryan Haight Act also requires Internet drug outlets to identify the business, pharmacists, and physicians who are associated with the Web site on the home page of the Web site. The new law also empowers a state attorney general to shut down an illegitimate Web site anywhere in the country, rather than only barring sales to consumers in his or her state.

The Minnesota Pharmacists Foundation (MPF) recently launched a program designed to increase awareness about the dangers of prescription drug abuse. The program, AWARE, was inspired by the death of St Cloud, MN resident Justin Pearson who passed away on December 25, 2006, from an overdose of prescription drugs. Pearson had ordered these drugs online and obtained them from pharmacies around the country, including at least one in Minnesota. The Minnesota Board of Pharmacy is one of several organizations partnering with MPF in this effort to increase awareness. Among other activities, AWARE is partnering with the DARE program to connect local pharmacists and physicians with DARE officers to provide education in schools and communities. More information is available at www.awarerx.org.

North Carolina Board Stresses Rules Governing Internet Pharmacy

In its January 2009 Newsletter, the North Carolina Board of Pharmacy discusses its Internet pharmacy rules as they relate to the recently passed Ryan Haight Online Pharmacy Consumer Protection Act. Both the federal Controlled Substances Act generally and the Ryan Haight Act specifically make clear that their requirements are in addition to, and not in lieu of, stricter state requirements. According to the North Carolina Board its rules governing Internet pharmacies are, in several respects, stricter than those found in the Ryan Haight Act. For instance, North Carolina rules govern the provision of any prescription medication through the Internet (continued on page 95)
FDA Expands Warning to Consumers about Tainted Weight Loss Pills

On January 8, 2009, Food and Drug Administration (FDA) expanded its nationwide alert to consumers about tainted weight loss pills that contain undeclared, active pharmaceutical ingredients. On December 22, 2008, FDA warned consumers not to purchase or consume 28 different products marketed for weight loss. Since that time, FDA analysis has identified 41 more tainted weight loss products that may put consumers’ health at risk. The complete list of drugs is available on the FDA Web site.

USP Transfers MEDMARX and MERP Reporting Programs

In a decision to focus full attention and resources on its core standards-setting activities, United States Pharmacopeial (USP) Convention announced that it would transfer its reporting programs, MEDMARX® and the Medication Errors Reporting Program, to Quantros and the Institute for Safe Medication Practices, respectively. USP stated in a news release that it will continue to use data from these and other programs “to enhance its standards-setting activities to promote patient safety and safe medication use.”

FDA/CDC Partnership Addresses Accidental Drug Overdosing

FDA has joined with the Centers for Disease Control and Prevention (CDC) in a new program to support research into the prevention of unintentional drug overdoses in adults. Unintentional poisoning is now the second leading cause of unintentional injury and death for Americans, with 23,618 deaths in 2005. Of these deaths, approximately 95% were due to drug overdoses, and more than half of these were associated with prescription drugs. Such overdoses can be the result of accidental overdose or abuse of drugs. The CDC and FDA grants, which were made available to eligible public and private organizations in late 2008, will be allocated for research that evaluates novel approaches to drug overdose prevention. More information is available on the FDA Web site.

2009 NABP Awards (continued from page 81)

science degree from New Haven State Teacher’s College.

By exemplifying the Association’s mission, these leaders have shown their dedication to protecting public health and will be honored at the NABP Annual Awards Dinner to be held Tuesday, May 19, 2009, from 7 - 11 pm.

For more information on the NABP 105th Annual Meeting, “NABP MIAMI: Quality Care – It’s Hot! Hot! Hot!” visit the meetings section of the NABP Web site at www.nabp.net.

Annual Meeting CPE (continued from page 89)

Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit.

Joint CPE

Standardization of Technician Education – Want it? Need it?

During this session, attendees will participate in discussions focusing on what is necessary to standardize pharmacy technician education and its implementation. Speakers include Michael J. Rouse, BPharm (Hons), MPS, assistant executive director, International and Professional Affairs, Accreditation Council for Pharmacy Education; Kevin N. Nicholson, RPh, JD, vice president, Pharmacy Regulatory Affairs, National Association of Chain Drug Stores; and Janet L. Teeters, RPh, MS, director, Accreditation Services Division, American Society of Health-System Pharmacists.

Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit.

Additional information about the 105th Annual Meeting is available on the Meetings section of NABP’s Web site, www.nabp.net.
Register now for the NABP 105th Annual Meeting.
See page 90 for details.