NABP Wins CMS Approval to Accredit Suppliers of Durable Medical Equipment

NABP received approval on November 22, 2006, from the Centers for Medicare and Medicaid Services (CMS) to become an accrediting organization for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

NABP’s DMEPOS-accreditation program, which meets all of CMS’ quality standards, targets state-licensed pharmacies that provide a limited line of durable medical equipment. The primary goal of the program is to ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS.

NABP’s new role as an accrediting organization for DMEPOS suppliers fulfills, in part, Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which requires the Secretary of Health and Human Services to establish and implement supplier quality standards, to be applied by recognized independent accreditation organizations. A division of the United States Department of Health and Human Services, CMS has designated 11 independent accreditation organizations to apply the quality standards to DMEPOS suppliers.

As the program is phased in over the next few years, suppliers in designated areas will be required to meet the quality standards and accreditation requirements in order to provide DMEPOS items for which Medicare Part B makes payment, as well as to receive or retain a supplier billing number for use in submitting claims.
DMEPOS (continued from page 1)

for reimbursement for items or services covered by Medicare.

In conjunction with the accreditation requirement, CMS is implementing a competitive bidding program, which mandates that only those suppliers who submit bids and contract with CMS will be eligible to provide select DMEPOS items to Medicare beneficiaries.

Suppliers participating in the competitive bidding program will be required to meet the quality standards and obtain accreditation.

The accreditation requirement, along with the competitive bidding program, is being phased in over several years. The first phase of competitive bidding will begin in 10 of the largest metropolitan statistical areas (MSAs) in 2007, the second phase in 80 of the largest MSAs in 2009, and the third phase in other areas after 2009. As of press time, CMS had not yet identified which MSAs will be included in Phase I of the competitive bidding program.

Surveys will include a review, evaluation, and monitoring of the DMEPOS supplier, its performance, and compliance with CMS quality standards. NABP’s DMEPOS accreditation will be valid for three years, after which time accredited suppliers may submit a renewal application.

NABP will continuously monitor accredited facilities by addressing beneficiary complaints, conducting pharmacy and pharmacist disciplinary screenings through the Association’s current national Clearinghouse Database, using self-assessment instruments, and unannounced surveys of suppliers suspected or found to be noncompliant or in violation of state and/or federal laws. If the supplier carries other DMEPOS products that NABP does not accredit, NABP will coordinate with other accrediting organizations to conduct surveys and determine eligibility for accreditation.

CMS’ DMEPOS-supplier quality standards are published on the CMS website at www.cms.hhs.gov/competitiveACqforDMEPOS.

NABP’s program is unique because of its extensive knowledge of pharmacy practice and its close tie with pharmacy and the state Boards of Pharmacy.”

NABP President
Lawrence H. Mokhiber, MS, RPh

NABP’s DMEPOS accreditation program specifically targets suppliers who possess a current valid pharmacy license and who distribute only a limited number of DMEPOS products and services. NABP will accredit certain DMEPOS products in the following categories, as well as services associated with distribution of these products:

- diabetic equipment and supplies;
- enteral and parenteral nutrients, equipment, and supplies;
- orthotics;
- mobility aids;
- wound care supplies;
- urological supplies;
- medical supplies; and
- respiratory products and supplies.

Surveys will include a review, evaluation, and monitoring of the DMEPOS supplier, its performance, and compliance with CMS quality standards. NABP’s DMEPOS accreditation will be valid for three years, after which time accredited suppliers may submit a renewal application.
Podcasts on NABP Web Site Provide Expert Commentary on Counterfeit Drugs

The following podcasts are available:

Episode 1: Carmen A. Catizone, executive director/secretary of NABP, discusses the state and federal government roles in securing safe drugs and the work NABP is doing in conjunction with the states. Sponsored by a grant from Pfizer Inc, the Counterfeit Drug Information section of the Web site also provides several other informative resources:

- extensive background on prescription drug counterfeiting;
- ways of identifying and reporting counterfeit drugs;
- a list of the most commonly counterfeited drugs;
- ways to stop counterfeiting;
- Congressional briefings;
- state and federal legislative updates;
- media coverage of federal indictments, FDA alerts, and discoveries of illicit distribution sources; and
- links to further resources.

NABP maintains that patients have a right to expect the medicines they buy through appropriate channels to be safe and effective. By providing comprehensive information and assisting boards of pharmacy to keep counterfeit drugs out of the supply chain, NABP is helping to ensure that those expectations are met.

Episode 2: Congressman Mike Rogers (R-8-MI) addresses a Congressional briefing on the importance of HR 5156, a bill that calls for strengthening criminal penalties against those who have participated in the production, distribution, and sale of counterfeit drugs.

Episode 3: John Theriault, vice president of global security for Pfizer Inc, gives examples of individuals who have suffered adverse effects from counterfeit drugs, seizures of counterfeit drugs, ties with organized crime and terrorism, and clandestine Internet pharmacies.

Episode 4: Chris Zimmerman, vice president of security and regulatory affairs for AmerisourceBergen, explains the role of pharmaceutical wholesalers in delivering products from manufacturer to pharmacies, how criminals enter the wholesale system, and actions that can be taken to fix the system.

Sponsored by a grant from Pfizer Inc, the Counterfeit Drug Information section of the Web site also provides several other informative resources:

- extensive background on prescription drug counterfeiting;
- ways of identifying and reporting counterfeit drugs;
- a list of the most commonly counterfeited drugs;
- ways to stop counterfeiting;
- Congressional briefings;
- state and federal legislative updates;
- media coverage of federal indictments, FDA alerts, and discoveries of illicit distribution sources; and
- links to further resources.

NABP maintains that patients have a right to expect the medicines they buy through appropriate channels to be safe and effective. By providing comprehensive information and assisting boards of pharmacy to keep counterfeit drugs out of the supply chain, NABP is helping to ensure that those expectations are met.
Attorneys’ Fees
By Dale J. Atkinson, JD

Professional licenses, like those held by pharmacists, and facility permits, like those held by pharmacies, are essential to the license holders to legally practice a chosen profession. As educational requirements increase and the costs associated with obtaining a professional degree and ultimate licensure by the regulatory board rises, so with it grows the vigor with which individuals defend maintenance of such governmental recognition. It may be argued that more individuals are administratively accused of violating the practice acts and more formal complaints are pursued to an administrative hearing. This defense of licensure status may be tied to the consequences of adverse action by the regulatory boards (ie, loss of business, loss of insurance reimbursement, loss of Drug Enforcement Administration [DEA] recognition).

As a result, accused licensees may be more apt to engage the services of an attorney to defend against administrative charges. The importance of the board’s authority to recoup its costs and attorney’s fees has been the subject of previous columns and discussions related to the effective and efficient operations of the boards of pharmacy.

In addition, procedural issues related to the relationship between an accused and his or her attorney may present interesting issues in need of resolution by the board of pharmacy/hearing officer/administrative law judge. Consider the following.

A physician was accused of violating the practice act by the Medical Licensing Board. The administrative accusations were based upon alleged actions of malpractice involving several patients. Also, the hospital revoked the physician’s staff privileges, which likely precipitated the formal accusations initiated by the Board.

The licensee sought legal representation and discussed the matter with attorneys from a law firm. The attorneys explained that the matter was serious due to the gravity of the charges, and defense of the administrative proceedings could become very expensive due to the number of patients and witnesses involved. The attorneys estimated that the fees and costs could run “up to $200,000.”

In January 2002, correspondence was sent from the law firm to the licensee indicating the terms of the representation, including the facts that the matter would be billed on an hourly basis, that the licensee would pay for services in a timely manner, and that costs were merely an estimate and would not set a limit on the fees. The agreement also called for a $15,000 retainer and indicated that an additional retainer of the same or greater amount could be required. Finally, the agreement stated that the attorneys could withdraw from the engagement with consent or for good cause. Good cause included the failure to pay the bills on time. In February 2002, approximately one
month after receipt, the licensee signed the retainer agreement and returned it with the initial $15,000 fee.

In April 2002, the attorneys requested that the licensee deposit an additional retainer of $50,000. The licensee paid an additional $32,363.42, and the attorneys continued to represent the licensee before the Board. The attorneys provided monthly statements indicating the fees incurred to date. In June 2002, the attorneys requested an additional retainer of $50,000, which the licensee was unable to produce. Several pieces of correspondence and e-mails were initiated by the attorneys to the licensee identifying the complexity of the case and the fact that the attorneys' fees were estimated to be significant. Based upon new amended charges by the Board, the attorneys notified the licensee in writing of the added Board charges and that the matter required a minimum of $250,000 in fees and an additional $50,000 in costs. The licensee did not deposit the requested fees with the attorneys.

In December 2002, the attorneys terminated their relationship with the licensee. In January 2003, the licensee attended a settlement conference without representation and the Board refused to grant him a continuance on the March 2003 hearing. The licensee obtained a new attorney who was unable to attend the March 2003 hearing due to a conflict. The Board refused to grant a continuance. The licensee entered into a settlement agreement to close his practice for six months in exchange for a continuance for the hearing until September 2006.

The licensee filed a civil lawsuit against the attorneys for “abandonment” based upon an alleged violation of section 284 and for breach of contract. Section 284 refers to a clause within the Code of Civil Procedure, which provides that an attorney “in an action or special proceeding may be changed at any time before or after judgment or final determination” under certain circumstances, which include that (1) both the client and attorney consent, and their consent is filed with the clerk or entered in the minutes, or (2) by order of the court. The licensee alleged that section 284 applied and that the attorneys did not comply with either of the requirements for withdrawal. The attorneys filed a motion for summary judgment, which was granted by the trial court stating that section 284 did not apply to an administrative matter. The licensee appealed the matter to the Court of Appeals.

After a review of the standard of review on appeal, the appellate court addressed the issue of abandonment under section 284. Specifically, the licensee argued that the trial court erred in finding that section 284 was not applicable in administrative proceedings. The court noted that the plain language of the act contemplates attorney removal from “court” proceedings, rather than administrative proceedings. Section 284 refers to filings made with the clerk or entered in the minutes or by order of the court.

The appellate court also defined the meaning of “action” as an “ordinary proceeding in a court of justice” and “every other remedy is a special proceeding.” It held that by definition, these proceedings occur only in courts of justice and the licensee is dealing with an administrative proceeding.
Accredited Facilities Increase Steadily as Wholesale Distributors Continue to Submit VAWD Applications

The number of Verified-Accredited Wholesale Distributor® (VAWD®) facilities continues to grow as NABP continues to receive and process applications. To date, NABP has received 264 VAWD applications, 87% of which were received in the past six months. This recent influx is consistent with NABP’s expectations that the majority of applications would be filed at this time due to the state of Indiana’s September 30, 2006 deadline for wholesale distributors to achieve VAWD accreditation in order to be licensed. While the majority of applicants for VAWD accreditation are those wholesale distributors doing business in the state of Indiana, many applications are from wholesale distributors not required by Indiana or other states and are pursuing VAWD accreditation on a voluntary basis.

Feedback from wholesale distributors in the midst of accreditation, as well as those who have completed the process, has been supportive of NABP’s procedures. Wholesale distributors have freely provided all information requested and facility staff has complimented NABP on the thoroughness of the VAWD inspectors. There are three components to the accreditation process: Application Evaluation/License Verification; In-Depth Policy and Procedures Review; and an On-site Inspection. To ensure the most timely accreditation, the three components can be performed concurrently. For example, policy and procedure review can take place while awaiting license verification and additional documentation related to the application. The following is an overview of each component of the VAWD process.

**Application Evaluation/License Verification**
Processing for every VAWD application begins the day of receipt. As part of this component, supplemental documents are evaluated for compliance with the VAWD Criteria, applicable criminal and financial background checks are performed through NABP’s contracted vendor, and discrepancies or missing information are compiled to be sent back to applicants for clarification. Also during this time, wholesale distributors’ licenses are verified through the state boards and NABP’s Clearinghouse to ensure that they are valid and in good standing.

**In-Depth Policy and Procedure Review**
As part of the second component of the VAWD accreditation process, an in-depth examination of wholesale distributors’ facilities is performed in seven key areas:

1. Licensure;
2. Facility;
3. Personnel;
4. Record Keeping;
5. Authentication and Verification;
6. Returned, Damaged, and Outdated Drugs; and

If a policy or procedure is not clear on how a task is performed, it will be noted for particular examination during the on-site inspection. Additional areas of focus that go beyond the standard inspection criteria are also identified and noted at this time for inclusion in the on-site inspection.

(continued on page 7)
States Recognize VAWD in Efforts to Unify Regulations and Thwart Prescription Drug Counterfeiters

Throughout 2006, state legislatures and boards of pharmacy continued to address the dangers that counterfeit drugs present to the nation’s drug distribution system by adopting wholesale drug distributor licensing and pedigree legislation or regulations.

As a part of their efforts to secure their states’ distribution systems, many states recognize third-party accreditation, such as NABP’s Verified-Accredited Wholesale Distributors® (VAWD®) program, as a means of implementing the licensing provisions of the new laws, while mitigating the fiscal and operational impact on the board. VAWD accreditation provides assurance that a wholesale distributor employs all appropriate practices for the safe distribution of prescription drugs from manufacturers to pharmacies. In addition, VAWD provides a uniform set of standards that can alleviate inconsistencies between states.

In 2006, Colorado, Mississippi, Nebraska, and Vermont joined Indiana and Oklahoma in recognizing VAWD or other third-party accreditation in enacted legislation. Several other state boards of pharmacy are also considering regulations that would recognize VAWD or other third-party accreditation.

In NABP’s recently released 2007 Survey of Pharmacy Law, many states indicated that they would recognize a VAWD-accredited facility for the purpose of meeting the licensure requirements in their respective states. In addition to the aforementioned states that already recognize VAWD or other third-party accreditation, the following states indicated their inclination to follow suit:

- Connecticut
- Delaware
- Idaho
- Iowa
- Massachusetts
- Montana
- New Jersey
- North Dakota
- South Carolina
- South Dakota

NABP anticipates that many state legislatures and boards of pharmacy will address the wholesale drug distributor licensing and pedigree issues in 2007. The Association also anticipates that states will continue to recognize VAWD or other third-party accreditation as a part of their initiatives.

More information on VAWD, including a list of VAWD-accredited distributors, is available on the NABP Web site at www.nabp.net.

VAWD Applications

On-site Inspection

Facility inspections are performed by trained inspectors who contract with and are managed by NABP. Currently, NABP has 35 inspectors available to perform site inspections. Inspections last approximately two days, and typically there are two inspectors assigned to each site visit. To gain a greater understanding of the facility they will be inspecting, inspectors participate in the review of the policy and procedure documents as well as other provided documentation. After the site inspection is complete, the inspectors compile a report and forward this to NABP. Based on the inspectors’ findings, NABP will submit to the facility areas in need of improvement. Once these issues are resolved, a recommendation as to whether or not to award accreditation will be made.

To facilitate the application review process, applicants are advised to ensure that there is complete and/or consistent information; authorization for background checks on the designated representative and/or supervisor has been provided; and the company’s policies and procedures and list of customers/vendors are supplied. These items will expedite the arrangement of a facility inspection date.

Indiana requires its licensed wholesalers to obtain and maintain VAWD or other third-party accreditation, and several other states recognize VAWD as a third-party accreditation program. A number of boards have requested NABP’s assistance in developing uniform wholesale drug distributor legislation and regulations. The boards have also asked that the legislation and regulations include authority for them to recognize third-party accreditation programs.

NABP looks forward to announcing many more accreditations over the next several months. Please visit www.nabp.net for a complete list of VAWD-accredited facilities.
Portland: A Naturally Perfect Location for 103rd Annual Meeting Attendees to Unite

The perfect setting for NABP’s 103rd Annual Meeting, Portland, OR, will not only offer attendees the chance to participate in important business sessions and timely continuing education (CE) programming, but will also provide the opportunity to take a stroll in the “Best Walking Town in America,” which the city was deemed by the April 2006 issue of Prevention magazine.

Originally inhabited by Native Americans, the area now known as Portland began as a beautiful rainforest on the Willamette River halfway between Oregon City and Fort Vancouver. Around 1823, Euro-American settlers wishing to occupy the land carved out a large area known as “the clearing,” establishing basic farmsteads and raising livestock. During the 1830s development continued as former employees of the North West Company and Hudson Bay Company trappers, which included a large amount of French Canadians, took over the land.

In 1843, two Americans from the east, William Overton and Asa Lovejoy, saw the land’s potential and purchased 640 acres (one square mile) for a total of $0.25 in order to found a town site. Not more than a few years after their purchase, Overton, tired of his investment, sold his portion to Francis W. Pettygrove. When the time came to name their town, Pettygrove, a native of Portland, ME, and Lovejoy, a Boston, MA attorney, found themselves in disagreement. Relying on a coin toss, Pettygrove’s luck prevailed and the almost Bostonians became Portlanders.

Serving as a river port for the Pacific Northwest, Portland became a favorable location for overseas trade and was quickly labeled as a marketing center. In 1850, 800 residents populated Portland. Residents began to export their farm surpluses and import manufactured goods, drawing in additional traders and farmers. The population grew steadily, but in order to promote continued growth and convince families to settle on Portland farms, Congress passed the Oregon Donation Land Claim Act. The Act awarded each single man above 18 years of age, 320 acres of land and each couple married by December 1, 1850, a total of 640 acres. Needless to say, Portland’s population continued to escalate.

Portland’s Many Nicknames

Portland was incorporated in 1851 and its rapid increase in population led to the need for further land development. Directly attributed to California’s booming trade and the gold rush, Portland emerged as a leading trade center, drawing in traders and workers from all over the world. The sudden necessity for additional space left little time for loggers to clear the stumps of trees that had been cut down, leading to one of the town’s first nicknames, “Stumptown.” Residents of Portland were said to have used the stumps as stepping stones to avoid the muddy unpaved streets, jumping from stump to stump and even whitewashing the stumps to increase their visibility.

By 1910, Portland’s population saw a dramatic increase to more than 200,000 residents after the hosting of the 1905 Lewis and Clark Centennial Exposition, which attracted exhibitors and visitors from around the world. Although no official city council resolution has been passed, many Portlanders believe Portland’s official
city name to be “the City of Roses.” Christened in 1988, by visitors to an Episcopal Church convention, the nickname came about when the Portland Rose Society was formed. To this day, Portland is known for its plentiful and diverse gardens and lush green parks. Some of the most well known gardens include the International Rose Test Garden, where roses of every color and variety display their exquisiteness; the Japanese Garden, which offers visitors tranquility, beauty, and relaxation through its five formal garden styles; the Portland Classical Chinese Garden, where orchids, bamboo plants, and waterfalls reveal themselves throughout its winding paths; the Portland Memory Garden, dedicated to sufferers of Alzheimer’s disease and specially designed for wheelchair-bound visitors; and the Leach Botanical Garden, a 15-acre park located in a residential southeast neighborhood. Every year since 1907, Portland holds a Rose Festival to celebrate the city’s most beloved flower.

Local Sites and Attractions

Annual Meeting attendees will be pleased to find that Portland, the big city with a small town feel, offers an endless amount of activities and sites to its visitors. When not enjoying the Annual Meeting programming, attendees can find themselves mingling with the locals at the Portland Saturday Market, partaking in one of Portland’s many walking tours, or visiting one of Portland’s beautiful gardens mentioned above.

The Portland Saturday Market, also open on Sundays, is an open-air arts and crafts market that operates from March through December 24, rain or shine.

Meeting programming, Best of Portland, an award winning walking tour, offers an enlightening historical overview of Portland through views of downtown, the Cultural District, and the waterfront. Tours take place daily at 10 AM lasting two-and-a-half hours. The cost is $15 per adult. For those more interested in sampling the flavors and culture of Portland, the Epicurean Excursion is a fun way to meet the artisans in their shops and taste the best of Oregon – local produce, teas, jams, beer, pizza, coffee, sorbettos and gelatos, fresh chocolate truffles, and artisan breads. It is recommended that tour participants not eat prior to the tour. This delicious experience begins every Friday and Saturday at 10 AM and lasts three-and-a-

(continued on page 10)
Portland (continued from page 9)

half hours. The all inclusive cost is $59 per person.

Although Portland is known as a walker’s paradise – its people-friendly city blocks were made shorter than most – non-walking tours are also available. Portland Ducks features land and water tours complete with an unsinkable Hydra Terra amphibious tour vehicle, which means that it is half bus and half boat. The tour explores various sites in downtown Portland before floating onto the Willamette River for an alternative view of the city. This tour is available Friday through Sunday, begins at 1:30 pm, and lasts about two-and-a-half hours. The cost of the tour is $25.

Additional sites of interest are the Pittock Mansion, a beautiful estate symbolizing the growth of Portland; the Portland Art Museum, the oldest museum in the Northwest; and the Oregon Museum of Science and Industry located on Portland’s waterfront. For more information on these sites and the attractions mentioned above please see the sidebar below.

Transportation
Portland, although more of a walking and bicycling city, provides plenty of easy-to-use transportation. The TriMet bus system (www.trimet.org) thoroughly covers the city and its suburbs, with fares as low as $4.25 for an all-day ticket. Transportation is free of charge in TriMet’s Fareless Square, which includes most of downtown Portland and Metropolitan Area Express (MAX) stations from the Rose Quarter to Lloyd Center. The MAX, TriMet’s 44-mile light rail system, offers door-to-door access to many visitor attractions. Annual Meeting attendees may also use the MAX to get from the Portland International Airport to the Hilton Portland & Executive Tower, site of the Meeting, by taking the Red Line, just $2 per person, to the Pioneer Square North MAX Station. The hotel is two blocks south of the station.

Taxies and shuttles are also available from the airport to the hotel. Taxies are available near the baggage claim and shuttle services. The approximate cost is between $30 and $38 per person and may take anywhere from 20 to 40 minutes to arrive at the hotel depending on traffic. The Blue Star Shuttle also stops near the baggage claim and runs every 30 minutes. The shuttle costs $14 per person and reservations can be made by calling 503/249-1837. For a listing of the taxi cab services available please visit www.portofportland.com/Grnd_Trans.aspx.

Downtown Portland provides an additional mode of transportation, the Euro-designed Portland Streetcar, which links the downtown Cultural District, the Pearl District, the Nob Hill/ Northwest Neighborhood, and the RiverPlace neighborhood. Visit the Portland Streetcar Web site at www.portlandstreetcar.org for schedules and route maps.

The Vintage Trolley, a special heritage streetcar service run by a nonprofit corporation, runs along two routes, the Lloyd District-Downtown Portland route, available on Sundays only, and the Portland Streetcar route, available on Saturdays and Sundays. This trolley is completely free of charge since it runs within Fareless Square.

For more information about the 103rd Annual Meeting, please visit NABP’s Web site at www.nabp.net.

Portland Attractions

For additional information on the Portland sites and attractions mentioned in this article, please refer to these Web sites and phone numbers.

Legal Briefs
(continued from page 5)
before the Medical Licensing Board.

The licensee argued that a proceeding before the Board is a “judicial action” because the hearing is held in an administrative law court, presided over by a specially trained judge and prosecuted by the state attorney general’s office. The licensee also argued that a medical board proceeding is a special proceeding of a civil nature. Finally, the licensee also argued that an interpretation that section 284 does not apply to medical board proceedings is against public policy as creating differing standards in administrative proceedings from those in judicial proceedings.

The appellate court rejected the arguments of the licensee distinguishing the cited cases from the current situation. It stated that while administrative and judicial proceedings may share in certain characteristics, such does not transform the nature of an administrative proceeding into one of a judicial action as contemplated. The court also held that administrative proceedings are not special proceedings of a civil nature. It cited that because there are rules of professional conduct for attorneys designed to protect the clients and the relationship, public policy issues are not implicated.

Finally, the licensee argued that section 284 applied because there was nothing in the applicable procedural law (the Government Code) that barred the application of the Code of Civil Procedure to administrative proceedings. The licensee cited several sections of the Code of Civil Procedure that applied to administrative proceedings through the Government Code. The court rejected this argument stating that while the Government Code incorporates certain standards from the Code of Civil Procedure, “one cannot than conclude that all of the provisions of the Code of Civil Procedure were incorporated.”

Under contract analyses, the court also rejected the breach of contract claims. Thus, the court held that section 284 did not apply to administrative proceedings, that the attorneys did not breach the contract with their former client, and that withdrawal was allowed. Boards of pharmacy must be aware of how the attorney-client relationship may impact administrative proceedings, including the withdrawal or removal of legal representatives.


Setting the Standards for Experience

The Task Force on Standardizing Student Pharmacist Experiential Requirements met December 7-8, 2006, at NABP Headquarters to establish uniform behind-the-counter training standards to prepare students for pharmacy practice. The task force comprised the following members (from left): Karen M. Ryle, Executive Committee Liaison; Peter H. Vlasses, Accreditation Council for Pharmacy Education (ACPE); Avery L. Spunt, Midwestern University Chicago College of Pharmacy; Richard A. Jones, Idaho Board of Pharmacy; Gay Dodson, Texas State Board of Pharmacy; Brad Cannon, American Association of Colleges of Pharmacy; Benjamin Fry, Texas State Board of Pharmacy; Kevin Mitchell, Ohio State Board of Pharmacy; Arlene Flynn, American Association of Colleges of Pharmacy; Patricia F. Donato, New York State Board of Pharmacy; Elizabeth Scott Russell, Virginia Board of Pharmacy; David Todd Bess, Tennessee Board of Pharmacy; Michael Rouse, ACPE; James E. Turner, Ohio State Board of Pharmacy; and Edward McGinley, New Jersey Board of Pharmacy.
International Agencies Crack Down on Diabetes Treatment Scams

Government agencies in the United States, Mexico, and Canada are cracking down on Internet scams selling bogus cures and treatments for diabetes.

The US Federal Trade Commission (FTC) and Food and Drug Administration (FDA), working with the neighboring countries, have launched an international campaign to stop the commercial sale of fraudulent therapies. “We will not tolerate practices that raise false hopes and bilk consumers of precious health care dollars,” Margaret O’K. Glavin, FDA’s associate commissioner for regulatory affairs, said in a press release.

The joint effort, as of October 2006, had issued approximately 180 warning letters and other advisories to Internet outlets in the three countries. Citing violations of the Federal Food, Drug, and Cosmetic Act, FDA warning letters targeted firms marketing dietary supplements with claims to treat, cure, prevent, or mitigate diabetes. The FDA letters warn firms that failure to promptly correct the violations may result in “enforcement action without further notice,” which may include “seizure of violative products and/or injunction against the manufacturers and distributors of violative products.” The FDA warning letters are available online at www.cfsan.fda.gov/~dms/dialist.html.

The international campaign started with an Internet sweep by the International Consumer Protection and Enforcement Network (ICPEN), an organization of law enforcement authorities; members of the Mexico, US, and Canada Health Fraud Working Group (MUCH); and the attorneys general offices of Alaska, Michigan, Ohio, Virginia, and Wisconsin. Based on findings from this sweep, FTC sent warning letters for deceptive ads to 84 US and seven Canadian Web sites targeting US consumers and referred 21 foreign-based sites to the partnering governments. Thus far, many firms have responded to the warnings by changing their claims or removing their pages from the Internet, and several others are in contact with FTC.

Sellers of Pseudoephedrine Products Now Need DEA Self-Certification

In addition to following new retail regulations, sellers of over-the-counter (OTC) medications containing pseudoephedrine, ephedrine, and phenylpropanolamine now must complete a self-certification process, which includes training their employees on the new regulations and procedures.

The final stage of the self-certification process requires sellers to complete an online application on the Drug Enforcement Administration’s (DEA) Office of Diversion Control Web site. Upon receipt of the application, DEA sends a confirmation e-mail, which generates a self-certification certificate.

The regulations are components of the Combat Methamphetamine Epidemic Act of 2005, which became effective in two stages: the first phase on April 8, 2006, and the second phase on September 30, 2006. The Act establishes new requirements for retail sales of OTC products containing ephedrine, pseudoephedrine, and phenylpropanolamine, which can be used to manufacture methamphetamine illegally.

In September 2006, DEA issued an interim final regulation to implement elements of the Act. DEA is promulgating this rule to incorporate the statutory provisions and make its regulations consistent with the new requirements. This action establishes daily and 30-day limits on the sales of scheduled listed products to individual patients and requires record keeping on most sales.
A copy of the rule is available on the DEA Web site at www.deadiversion.usdoj.gov/meth/irule.htm.

iPLEDGE Loosens Prescribing Restrictions for Isotretinoin

A recent update to iPLEDGE, a risk management program to reduce the risk of fetal exposure to isotretinoin, eliminated the 23-day lock-out period for males and females of non-childbearing potential. This change does not affect female patients of childbearing potential.

Isotretinoin is used to treat severe recalcitrant nodular acne. Fetal exposure to isotretinoin poses a high risk of severe birth defects.

Prior to the iPLEDGE update, all patients prescribed isotretinoin had to fill their prescription within seven days of their office visit. If they missed this window, they had to wait another 23 days before they could receive the drug. The update allows males and females of non-childbearing potential to have a new prescription filled after the seven-day window has expired.

Both patients and prescribers, however, must complete the iPLEDGE qualification process again to ensure that the patients have met all criteria, including patient counseling in the iPLEDGE system. Pharmacists must continue to authorize every isotretinoin prescription using the iPLEDGE system.

To have a prescription for isotretinoin filled, all patients (including males and females of non-childbearing potential) must be registered with iPLEDGE, have a prescription from a doctor who is registered with iPLEDGE, and fill the prescription at a pharmacy that is registered with iPLEDGE. More information is available on the FDA MedWatch Web site at www.fda.gov/medwatch/safety/2006/safety06.htm#Isotretinoin.

Regardless of the country from which the drugs are purchased or in which they are sold, Health Canada considers this practice the same as “advertising and selling unapproved drugs in Canada,” the letter states.

Health Canada says it is concerned that the advertisement or sale of unapproved drugs “opens the door for entry into the Canadian market of products of substandard quality and, possibly, of counterfeit origin.” Noncompliant pharmacies are subject to punitive actions up to and including search, seizure, and prosecution.

The letter from Health Canada is accessible online at www.safemedicines.org/resources/documents/safesourcing.pdf.

Canadian Restrictions on Unapproved Drugs Extend to Foreign Trade

Health Canada recently posted a letter on the Partnership for Safe Medicines Web site (www.safemedicines.org) clarifying its ban on the sale of unapproved drugs.

Canada’s Food and Drugs Act and Food and Drug Regulations prohibit advertising or selling, at retail or via the Internet, drugs that are not approved for sale in Canada. Addressing provincial pharmacy associations and regulatory authorities, the letter specifies that this prohibition applies to all Canadian pharmacies selling over the Internet, “even in cases where the unapproved drugs do not enter Canada but are dispensed by foreign pharmacies and delivered to patients outside of Canada.”

Posts in Transition

Louise Foster Jones is no longer the executive director of the Alabama State Board of Pharmacy. Until the position is filled, Mitzi Ellenburg, assistant to the executive director, will be accepting all correspondence for the Board.

Virginia “Giny” Herold has been appointed interim executive officer of the California State Board of Pharmacy, replacing Patricia F. Harris, BA, former executive officer, while the Board seeks a permanent replacement for the post.

Lisa Salmi will serve as the acting executive director for the Washington State Board of Pharmacy, replacing former Executive Director Steven Saxe, RPh, FACHE. The Board is currently recruiting
Feature News

PPSG Report Shows Improved State Policies on Medical Use of Opioids

A recent report by the Pain & Policy Studies Group (PPSG) reveals improvement in state policies governing the medical use of opioid medications. The report, “Achieving Balance in State Pain Policy,” is the group’s third evaluation of such policies over a six-year period. Affiliated with the University of Wisconsin School of Medicine and Public Health, PPSG evaluated states for balanced policies “with a potential to enhance pain management while avoiding the potential to interfere with such treatment.”

The report reveals improvement in state policies between 2003 and 2006, with 19 states demonstrating improvement in pain policies and no states showing weakened policies. Improvement in policies was demonstrated in two major ways: (1) the adoption by state health care regulatory boards of policies encouraging pain management, palliative care, or end-of-life care; and (2) the repeal by state legislatures of restrictive or ambiguous policy language, including multiple- or single-copy prescription programs. Of the 19 states with improved pain policies, Michigan and Virginia each received an “A” (based on an “A” to “F” grading system), a grade never before given prior to the 2006 report, thanks to regulatory policies that solidly promote, while creating no barriers to, effective pain control. In addition, 82% of the states received a “C” or better, up from 49% in 2000 and 67% in 2003.

Although progress is being made, Aaron Gilson, PhD, associate director of United States policy research for PPSG, is still concerned. “Despite this progress,” he notes, “most states still face the challenge of removing their remaining policy barriers, communicating the new or revised policies to healthcare practitioners and ensuring that the spirit of these policies are put into practice.”

Overall, PPSG favors policies recognizing that (1) controlled substances are necessary for public health; (2) pain management is part of quality medical practice; (3) medical education should include pain management and palliative care; and (4) patient care facilities have a responsibility to assess and treat pain.


Call for Committee, Task Force Volunteers

NABP is seeking volunteers from its active member boards of pharmacy to serve on the Association’s 2007-2008 committees and task forces. Interested executive officers, board members, and board staff are encouraged to submit a letter of interest and a current résumé or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone by Friday, May 25, 2007.

Letters should outline the volunteer’s applicable experiences and accomplishments, along with the reasons he or she wishes to be considered for appointment to a committee or task force.

All materials will be forwarded to NABP President-elect Oren M. Peacock, Jr, who will make the appointments when he becomes NABP president following the Association’s 103rd Annual Meeting.
Oregon Patient Safety Commission Begins Safety and Quality Effort

By Dave Widen, MBA, RPh, and Leslie Ray, PhD, RN

The Patient Safety Commission has begun working with retail pharmacies in Oregon to develop a voluntary and confidential reporting program to reduce the risk of adverse drug events. The Commission is a semi-independent state agency governed by a 17-member board of directors appointed by the governor and confirmed by the Senate. It is the only organization in Oregon exclusively dedicated to promoting a culture of patient safety with an emphasis on shared data, quality improvement, and quick absorption of new approaches. It is explicitly nonregulatory and nonpunitive.

The Commission has already experienced significant success with its hospital reporting program, where 51 of 57 hospitals have signed participation agreements. These 51 hospitals provide 98% of all hospital care in Oregon. Now well on its way to introducing a reporting program for retail pharmacies, the Commission represents a safe haven where pharmacies can share confidential patient safety information without fear of legal consequence.

It is known that most medication dispensing errors occur with refills rather than new prescriptions and that distractions and interruptions are major impediments to accuracy. However, much is unknown about errors in the retail environment as compared to hospital settings. The potential risks are real and growing as the profession of pharmacy struggles with fewer pharmacists and aging baby boomers requiring greater numbers of medications. The goal for the retail pharmacy adverse event reporting program is to better understand where and how adverse events occur, then to create and share strategies for reducing the risk of patient harm.

In developing the reporting program, the Patient Safety Commission established an advisory group with representation from retail pharmacy chains, independent pharmacies, Oregon State University College of Pharmacy, and the Oregon State Pharmacy Association. The advisory group and others helped the Commission define adverse events; create a safe, confidential nonpunitive reporting framework; and pilot the program to test its feasibility. The group also helped draft administrative rules to guide the reporting program. The next step is to gain public comment on the rules (available on the Commission’s Web site at www.oregonpatientsafety.org). The Commission encourages pharmacists to review the proposed rules and to offer ways that we might work together for patient safety.

The health care quality and patient safety movement is making itself felt within the pharmacy world, and Oregon is one of the first states to respond. With more than 700 retail pharmacies statewide, the Commission and Oregon's pharmacists have an unparalleled opportunity to demonstrate creative leadership by implementing effective programs to increase pharmacy accuracy and decrease adverse events.

Reprinted from the Oregon State Board of Pharmacy Newsletter, Volume 27, No. 4 November 2006

Around the Association (continued from page 14)

Kristina Genovese and Ronald L. Petrin have been reappointed as members of the New Hampshire Board of Pharmacy. Their terms expire September 6, 2011.

Sandra Keans has been reappointed as a public member of the New Hampshire Board of Pharmacy. Her term expires October 14, 2011.

The New York State Board of Pharmacy has reappointed the following members. Their terms expire September 30, 2011.

• John P. Navarra
• Hao (Jimmy) Tran
• Daniel Villa
• Richard Zeitoun

Elizabeth I. Gregg has been reappointed as a member of the Ohio State Board of Pharmacy. Her term expires June 30, 2010.

James O. Spoon, DPh, has been reappointed to the Oklahoma State Board of Pharmacy, with a term expiration date of June 30, 2011.

Roger B. Fitzpatrick, RPh, has been reappointed to the Utah Board of Pharmacy. His term expires June 30, 2010.
Meeting Disaster Head-On

The Task Force on Emergency Preparedness, Response, and the US Drug Distribution System met November 16-17, 2006, at NABP Headquarters to draft a model for helping the boards of pharmacy prepare for times of crisis. Pictured from left: Robert Giacalone, Ohio State Board of Pharmacy; Mitch Rothholz, American Pharmacists Association; Dennis Jones, South Dakota State Board of Pharmacy; Lisa Robin, Federation of State Medical Boards; Ruth Conroy, Walgreens; Walt Slijepcevich, Pfizer Inc; Judy Gardner, Georgia State Board of Pharmacy; Donald Taylor, Maryland Board of Pharmacy; Sara St Angelo, Indiana Board of Pharmacy; William Cover, Indiana Board of Pharmacy; Joseph Whaley, Inside Pharmacy Department Delivery; Michael Brimberry, Texas State Board of Pharmacy; Carl Aron, Louisiana Board of Pharmacy; David Flashover, New York State Board of Pharmacy; Michael Duteau, New York State Board of Pharmacy; and Richard Palombo, NABP Executive Committee Liaison.