# NEVADA STATE BOARD OF PHARMACY

# **BIENNIAL REPORT**

JULY 1, 2006 - OCTOBER 31, 2008

# **NEVADA STATE BOARD OF PHARMACY**

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#### INTRODUCTION

The Nevada State Board of Pharmacy serves and protects Nevada's citizens by promoting safe and effective prescription drug practices through vigorous and effective regulation of Nevada's pharmacists, pharmaceutical technicians, intern pharmacists, dispensing and prescribing practitioners, physician's assistants, nurse practitioners, pharmacies, wholesalers, providers and wholesalers of medical devices, equipment, or gases, manufacturers, and warehouses that store prescription drugs. Basically, anything that touches on prescription drugs and their use, sale, or handling, is monitored and regulated by the Board.

The Board is made up of six pharmacists and one public member. To accommodate the public and affected licensees, the Board meets eight times a year, half in Las Vegas and half in Reno. The Board meetings are usually two days long, the first day being dedicated to disciplinary matters and the second day being dedicated to the remaining Board business such as regulatory hearings, licensing matters, and presentations from law enforcement and the pharmacy industry. The Board prides itself on maintaining good and useful relations with the pharmacy industry, pharmacist associations, trade organizations, schools of pharmacy, and other state and federal agencies.

The 2006-2008 biennium saw continued growth in the Board's various classes of registration and licensure. Since the last biennial report, the Board saw an 8.17% growth in the number of in-state pharmacies. The number of in-state pharmacists was a negative 0.47%. A major contributing factor to the slight decline was the change in California's

pharmacy regulations recognizing the NABPLEX licensing exam (See regulatory development). Technician registrations increased 54.08% since the last biennial report and Technicians in Training increased 72.71% (See regulatory development). The number of Pharmacy Interns registered increased 29.94%. Controlled substances registrations (largely physicians, but also including dentists, veterinarians, physician assistants, and nurse practitioners) grew 20.12% in the last biennium. The number of medical devices, equipment, and gases (MDEG) registrants increased 12.5% from the previous biennium. Over the biennium, the Board saw a 17.3% increase in licensees and registrants.

This Biennial Report, mandated by NRS 639.060, will be a brief overview of the significant developments and activities of the Board from July 1, 2006 through October 31, 2008.

#### **ACCOMPLISHMENTS FOR 2006-2008 BIENNIUM**

While the 2006-2008 biennium contained two busy years for the Board, accomplishments in several important areas are worth mentioning:

#### ADMINISTRATIVE ACCOMPLISHMENTS

- ❖ Conversion to VERSA Licensing and Enforcement Program
  - o VERSA has enhanced capabilities for online registration and license renewal. 35% of pharmacists renewed their registration online in 2007. 40% of licensees/registrants in all other categories renewed on line in 2008 (as of November 6, 2008).
  - o VERSA provides for real time online investigation documentation.
  - o VERSA provides enhanced versatility allowing Board staff to control various functions, reports, etc.
  - o VERSA includes an inspection module to streamline inspections and allow real time monitoring of inspections.
  - o VERSA has enhanced management of cash (licensing fees) features.
- ❖ Website Redesign/Continuing Improvement In June 2006, the Board went live with a completely redesigned website, bop.nv.gov. Working closely with DoIT staff, the Board has continued to make the website more informative and user friendly. Some of the features of the website include: Links for consumers, registrants and licensees can renew their registration or license online, and frequently asked questions and the latest version of regulations being considered are available for viewing, download or printing.



- Pharmaceutical Technician Advisory Committee The Board approved creation of this committee in July, 2008. The first meeting will be held in December, 2008. The purpose of the committee is to involve technicians in discussing and identifying pharmacy issues that can be addressed to improve patient safety.
- ❖ MDEG (Medical Devices, Equipment and Gases) Advisory Committee The Board created this committee in 2002. The committee purpose is to provide input on regulations needed to protect and improve patient safety. The committee also helps keep the Board informed on changes in the industry, both regulatory and technology based, that need to be addressed by the Board.

- ❖ Controlled Substance Abuse Prevention Task Force In addition to the legislative action noted under legislative accomplishments, the Board, by regulation, changed the reporting of controlled substances dispensed by pharmacies and other licensed entities dispensing controlled substances from every two weeks to weekly. The change allows a physician to have the most current data on a patient's use of controlled substance medications thus allowing the physician to better evaluate a patient's controlled substance medication history prior to prescribing medications for the patient.
- ❖ Change of General Counsel In October 2008, Louis Ling left the position of General Counsel after 17 years to accept the position of Executive Director of the Nevada State Board of Medical Examiners. The Board and Staff thank Louis for his hard work and dedication to protecting the public. The Board selected Carolyn Cramer, J.D. as the new General Counsel for the Board. The Board and Staff welcome Carolyn to her new position.
- ❖ Inspector-Investigator With the continuing increase in licensees and registrants, the Board authorized the hiring of a new Inspector-Investigator. The interview process has been completed, and the new Inspector-Investigator position will be filled in November. This position will be filled with a pharmacist who will also have administrative duties in addition to inspecting and investigating. This position will require travel throughout the state.

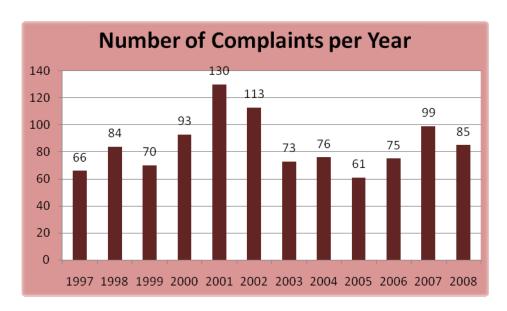
#### LEGISLATIVE ACCOMPLISHMENTS

The Board did not have any bills presented in the 2007 Legislature. It has always been the Board's intent to maintain excellent working relations with the Legislature, and this sometimes is best promoted by not seeking the Legislature's assistance and collaboration. Even without its own bill, the Board still assisted the Legislature with technical advice, regulations, and implementation of two important programs that came from the 2007 Legislature:

- ❖ ABI28 Implementation Establishes a code of conduct for marketing a drug or medical device to health care professionals. ABI28 requires that all wholesalers or manufacturers who employ a person to sell or market a drug, medicine, chemical, device, or appliance in Nevada must comply with certain requirements regarding their marketing practices.
- ❖ Controlled Substance Abuse Prevention Task Force (CSTS) The CSTS was strengthened with the requirement that practitioners must access the database in certain situations prior to prescribing controlled substances. Along with this requirement, the Board made regulatory changes to the reporting time frame. (See regulatory development)

## COMPLAINTS, INVESTIGATIONS, AND DISCIPLINE

Investigating and prosecuting consumer complaints is one of the Board's primary missions. The following table shows the number of investigations of complaints conducted by the Board for all the years for which data is available:



Note: the figure for 2008 is projected based upon complaints made through October, 2008.

#### REGULATORY DEVELOPMENTS

Regulations are a necessary response to an ever-changing practice like pharmacy, and the Board prides itself on its ability to respond quickly with pertinent regulations to keep current with the latest developments in the practice of pharmacy. The Board's most noteworthy regulatory developments for this biennium demonstrate the Board's cooperation with members of its regulated community and the Board's responsiveness to its fast changing environment:

- \* ASC (Ambulatory Surgical Centers) Oversight by Consultant Pharmacists All centers must contract with a pharmacist to establish, maintain and review policies and procedures. The policy shall establish procedures, without limitation, for the storage of, disposition and when necessary the destruction of contaminated, damaged, or expired medications. The consultant pharmacist will audit compliance with policy and procedures at least once a quarter and will periodically audit for compliance with controlled substance laws and regulations. The consultant pharmacist will conduct a performance audit at least once a month using a random selection of records, including, without limitation, records relating to the purchasing, storing, administering and dispensing of drugs and investigational drugs.
- ❖ Technicians The significant increase in Technician (54.08%) and Technician in Training (72.71%) registrations is related to the increase 8.17% of in state pharmacies licensed and a regulatory change increasing the ratio from 2:1 to 3:1 of technicians allowed per pharmacist. The purpose of the regulation adopted by the board was to have more highly trained individuals performing the initial data entry of critical medical information. The Board also reviewed and approved The Institute for the Certification of Pharmacy Technicians as the second approved technician certification body in Nevada. PTCB (Pharmacy Technician Certification Board) is the other approved certification body.
- Compounding Regulations The Board finalized the regulatory requirements for compounding medications, including documentation of compounding, testing requirements related to compounding and other components involved in compounding both sterile and non-sterile compounds.
- Immunization Regulations Nevada remains one of least immunized states in the nation. The Board amended the immunization administrative code to allow pharmacists who are trained and certified to

administer immunizations to adults and to children regardless of age. Immunizations must occur under a physician's protocol or on a written prescription for an individual patient. The regulation also requires pharmacists to submit data on all immunizations they administer to the Nevada State Immunization Program. The Annual Immunization Report 2008 – Immunizations by Pharmacists is available from the Board of Pharmacy on request.

- ❖ Off Site Cognitive Services Allows, after review and approval from the Board, a company to have pharmacists work off site doing medication review, data input and other cognitive services. This will allow pharmacists in pharmacies more time to spend communicating with and counseling their patients.
- ❖ VAWD (Verified-Accredited Wholesale Distributors®) Certification of Wholesalers − To earn VAWD accreditation, the wholesale distributor facility must be legitimate, validly licensed in good standing, and employing security and best practices for safely distributing prescription drugs from manufacturers to pharmacies and other institutions. VAWD applicants will undergo a vigorous compliance review including an on-site examination of the wholesale distributor facility as well as criminal background checks for designated representatives and other responsible persons and screening through NABP's (The National Association of Boards of Pharmacy) National Clearinghouse of Licensure, Certification, and Accreditation. Wholesale distributors' eligibility for VAWD accreditation is judged in seven key areas: licensure; facility; personnel; record keeping; authentication and verification; returned, damaged, and outdated drugs; and policies and procedures.
- Changes in Controlled Substance schedule II regulations to enhance patient care
  - O Do not fill before dating Allows a physician to write multiple schedule II prescriptions for a patient. The physician dates each prescription with the actual date written, and then writes a do not fill before date on the prescription.
  - o Verbal verification of prescription date written Allows a pharmacist to verify a date written on a schedule II medication thus preventing the patient from having to return to the physician for another prescription.
  - Tendering of a prescription If a schedule II prescription is tendered to a pharmacist prior to the 16<sup>th</sup> day after the prescription was written, the pharmacist may initial and make note of the date tendered on the prescription. The pharmacy may then fill the prescription at any time up to 6 months after the actual date the prescription was written. This change will enhance patient care and service by allowing the patient to fill a prescription when the patient needs the medication, rather than filling the prescription because the prescription is only valid for 15 days.
- Pharmacist Shortages in Nevada Nevada continues to be one of the states with the greatest shortage of pharmacists. To help this relieve this shortage, the board has passed a regulation to allow reciprocity with California and Florida.
  - o Florida and California now accept the National Association of Boards of Pharmacy Licensing Exam (NABPLEX®) for reciprocity of a license or registration or by score transfer. In past years, other states did not reciprocate or score transfer licenses with California or Florida since California and Florida did not accept the NABPLEX® exam. The National Association of Boards of Pharmacy (NABP®) reciprocity rules require the pharmacist to reciprocate or score transfer from a state where they have taken the NABPLEX® exam.
- ❖ Your Success Rx In collaboration with Your Success Rx, Inc., a Carson City company, the Board has referred pharmacies and pharmacists to an intensive program (usually three days long) by which the pharmacies and pharmacists are assessed as they practice. The results have been positive to both the Board, which can now get problem pharmacies and pharmacists some specific and direct assistance, and to the disciplined pharmacies and pharmacists. The Board looks forward to continued use of this program to continually improve the practice of pharmacy for disciplined pharmacies and pharmacists. Your Success Rx

assessed ten pharmacists, one pharmacy and one hospital over the last biennium. Your Success Rx program includes, but is not limited to, an initial interview process, workplace evaluation and practice site visit plus presentations on multiple topics including error prevention and counseling.

# PRESCRIPTION CONTROLLED SUBSTANCE ABUSE PREVENTION TASK FORCE

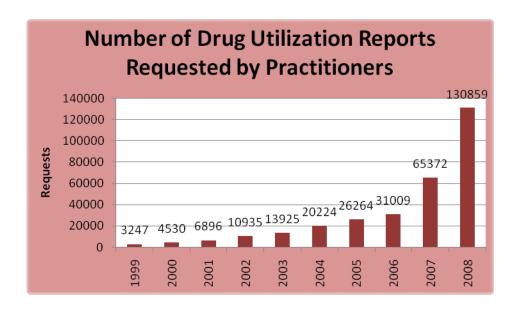
Created in 1997, the Nevada Prescription Controlled Substance Abuse Prevention Task Force (the Task Force) is administered by the Board, the Bureau of Alcohol and Drug Abuse (BADA), and the Department of Public Safety (DPS). A multi-disciplinary panel oversees the operations of the Task Force, and the panel includes representatives from: the Board, BADA, DPS, physicians, dentists, other medically-related licensing boards, practitioners' associations, and prosecuting attorneys' offices. The panel meets once or twice a year to set policy and to discuss the operation of the program.

The Task Force's first-in-the-nation Pre-Criminal Intervention Program has become a model for the nation. The program identifies patients who appear to be misusing and abusing prescription controlled substances and intervenes with these patients through a Pre-Criminal Intervention Officer who directs the patients into treatment and monitors their progress. The intent of the program, and it seems to be working, is to treat a person's addiction rather than to put the person into the already overburdened criminal justice system. Through this program, the Task Force has been able to successfully intervene with over 100 patients, most of who have succeeded in ending their destructive cycles of prescription controlled substance addiction.

The Task Force has recently hired an intervention officer for Northern Nevada with the goal to continue the success and expand the Pre-Criminal Intervention Program to Northern Nevada.

This biennium, the Task Force began full implementation of online practitioner access to the data. This access is 24/7. This has worked great efficiencies for the practitioners because they are getting their data online, often within minutes of their request and while the patient is still in the office, rather than receiving the data three or four days later. The Task Force will be seeking additional federal grants to sustain and expand the program in the upcoming biennium.

Practitioner usage of the Task Force is shown in the following chart:



In the past 11 years there has been tremendous growth in requests for task force drug utilization reports. In 1997, the first year of the CSTF, there were a total of 480 requests for the report.

Note: the figure for 2008 is projected based upon requests through November 15, 2008.

#### FINANCIAL REPORT

The Board administers an annual budget of approximately \$1.4 million. All of the Board's revenues come from licensing, certification, and registration fees: the Board receives no state general fund money. The Board has itself audited annually by Houldsworth and Russo. The recommendations made in the last two audits to increase the Board's efficiency and accountability have been implemented.

#### LICENSURE REPORT

The Board issues and regulates 12 categories of licensure and registration. The Board's total licensure counts at the end of the 2006-2008 biennium (as of November 1, 2008) are shown in the following table.

LICENSE OR REGISTRATION CATEGORY	IN STATE	OUT OF STATE	TOTAL
Pharmacists	1872	6526	8398
Pharmaceutical Technicians	3556	273	3829
Pharmaceutical Technicians-in Training	829	0	829
Interns	585	53	638
Pharmacies	623	304	927
Wholesalers	45	453	498
Manufacturers	1	0	1
Warehouses	5	0	5
Controlled Substances Registrations	8500	0	8500
Dispensing Practitioners	232	0	232
Prescribing Practitioners	278	0	278
Medical Devices, Equipment, & Gases	210	78	288
TOTALS	16736	7687	24423

### WHAT LIES AHEAD FOR THE 2008-2010 BIENNIUM

Several foreseeable issues lie ahead for the Board in the 2008-2010 biennium and beyond, including:

- ❖ Hospital Regulations Review and rewrite hospital regulations to include the recently passed compounding regulations adopted by the Board to meet USP (United States Pharmacopeia) 795 and 797 standards for compounding non sterile and sterile compounds and to address new technology and standards of care.
- ❖ Compounding Regulations Ongoing training of inspectors on USP 795 and 797 standards and inspecting for compliance on the newly passed compounding regulations that address all aspects of compounding non sterile and sterile compounds as adopted by board to meet USP (United States Pharmacopeia) 795 and 797 standards.
- ❖ Continuous Focus on Patient Safety The Board is committed to continual examination of all practice sites and to exploring ways to maximize patient safety. This examination includes addressing safety in the use of anesthesia in ASC (Ambulatory Surgical Centers) and in practitioner's offices. A priority of the Board is to coordinate with other major boards and the Department of Health to continually review and revise standards and develop methods of monitoring sites to ensure the highest level of safety for all patients.
- ❖ Inspecting for Quality and Safety An important part of the inspection and compliance process is the focus of the board on educating and inspecting for Quality and Safety. The Board is proactive in providing information on minimizing medication errors by the communication of information to the Board's registrants and licensees. The information provided comes from studies done by the medication safety focused organizations, including ISMP (Institute for Safe Medicine Practice), that study and evaluate causes of medication errors.
- ❖ Electronic Record Keeping Current administrative code requires that a handwritten initial or signature of the practitioner is required on some documents and records. The Board is amending administrative code to allow for electronic documentation and record keeping if the practitioner desires to keep electronic records.