Nevada State Board of Pharmacy

BIENNIAL REPORT

July 1, 2010 – June 30, 2012

431 Plumb Lane Reno, Nevada 89509 (775) 850-1440 Fax: (775) 850-1444 Website: http://bop.nv.gov/ E-mail: pharmacy@pharmacy.nv.gov

THE BOARD

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Jenine Davis Investigator/Inspector Pre-criminal Intervention Officer

Arlene Marshall Administrative Assistant

Shirley Hunting Board Coordinator

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Carolyn Cramer, J.D.

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Lisa Hedaria Administrative Assistant

Jeri Walter Board Coordinator

Las Vegas Office

Luis Curras, RPh. Inspector Daniel Garcia Investigator Ken Scheuber Investigator

Ray Seidlinger, RPh., Inspector/Las Vegas Office Manager

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INTRODUCTION

NRS 639.060 BIENNIAL REPORT TO GOVERNOR.

Before September 1 of each even-numbered year, for the biennium ending June 30 of that year, the Board shall report to the Governor upon the condition of pharmacy in the State of Nevada. The report must contain:

- 1. A summary of the proceedings of the Board for the year.
- 2. The names of all pharmacists registered under this chapter.
- A complete statement of all fees received. [Part 7:286:1913; A 1951, 290; 1953, 588]— (NRS A 1965, 62; 1967, 1643; 1969, 1459; 1983, 1505)

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, hospitals, ambulatory surgical centers, 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. The Board meets approximately every 6 weeks alternating between Las Vegas and Reno. The Board meets in Las Vegas in March, May, July and September and in Reno in January, June, September and December. 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.

2010-2012 Biennium

- The 2010-2012 biennium saw continued growth in the Board's various categories of registration and licensure. The number of licensees and registrants increased 5.2% in the last biennium.
 - Controlled substances registrants are largely physicians, but also include dentists, veterinarians, physician assistants, and nurse practitioners.

- Dispensing practitioners are licensed to dispense medications to their own patients. The practitioner is required to meet all record keeping, counseling and labeling requirements that a pharmacy must follow.
- Ambulatory Surgery Centers are licensed under the institutional classification along with hospitals. The data on the number of Hospitals and Ambulatory Surgery centers is included as part of the pharmacy count total.
- The table below shows the change in the number of licensees and registrants for all regulated categories, by category, since the last biennium, 2010-2012.

License or Registration Category	Change (number)	Percent Change
Controlled Substances Registrations	434	4.9%
Dispensing Practitioners	(57)	14.9%
Dispensing Technicians and Trainees	60	19.4%
Interns	(5)	0.7%
Manufacturers	1	50.0%
MDEG (Medical Devices/Equipment and Gases)	282	57.9%
Pharmaceutical Technicians & Pharmaceutical Technicians-in Training	452	8.8%
Pharmacies (Includes Institutional Hospitals and Ambulatory Surgery Centers)	108	10.1%
Pharmacists	30	0.4%
Prescribing Practitioners (APN's and PA's)	(86)	24.6%
Warehouses	0	0%
Wholesalers	131	22.7%
TOTALS	1350	5.2%

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, 2010 through June 30, 2012.

ACCOMPLISHMENTS FOR 2010-2012 BIENNIUM

While the 2010-2012 biennium contained two busy years for the Board, accomplishments in several important areas are worth mentioning:

ADMINISTRATIVE ACCOMPLISHMENTS

BOARD STAFF CHANGES

• The Board wishes to thank the following individuals for their contributions to and focus on protection of the public.

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Jeri Walter

- Jeri will be retiring at the end of December 2012.
- Jeri will have worked at the Board of Pharmacy for 17 years and 3 months when she retires at the end of December.
- Jeri's background includes working for four years at the National Judicial College as course administrator handling national judicial education programs and grants. Prior to the National Judicial College, Jeri worked for IBM in assets and administration and Bally Systems as an Executive Secretary.

Fred Ackermann

- Fred dedicated 45 years of service to the people of the United States with the US Army Military Police and the citizens of Nevada.
- Fred retired from the Board of Pharmacy in March, 2011 after nearly 14 years of service to the Board as an investigator and supervisor of the Board office in Las Vegas. Fred brought his law enforcement background to the Board and established operational and procedural standards for investigations, inspections and was responsible for hiring and training staff members for the Las Vegas office of the Board.
- Fred's background includes criminal investigator for the Provost Marshal, US Army, Henderson Police Department, and State of Nevada Department of Public Safety, Investigation Division, in various roles including District Supervisor.

Ron Shockey

- Ron retired from the Board of Pharmacy in June, 2012.
- Ron's background includes working at Desert Springs Hospital prior to working for the Board. Ron also worked in retail pharmacy in Las Vegas and Colorado. Ron also served as a reserve police officer while he worked in Colorado.
- Ron was a member of the National Association of Boards of Pharmacy (NABP) law review committee.
- Ron provided both live and telephone Nevada Pharmacy Law continuing education statewide.

• The Board wishes to welcome the following individuals to the Board staff.

Jenine Davis

- Jenine began working with the Board as an Intervention officer in August, 2008. Since January 2011 Jenine has also worked with the controlled substance task force and as an inspector.
- Jenine's background includes working as a detective with the Nevada Department of Public Safety, Investigative Division and as an assistant controlled and internal auditor.

Ken Scheuber

- Ken began his service as an Investigator with the Board March 1st, 2011.
- Ken's background includes working in retail drug sales for 38 years in such diverse positions as store manager, national product manager, director of store development and district manager.

Luis Curras

- Luis began his service with the Board in June, 2012.
- Luis's background includes working at Sunrise Hospital for the last five years including as a staff pharmacist responsible for various medical floors, ICU, emergency room and charge pharmacist. Luis worked as a clinical supervisor the last 18 months he worked at Sunrise. Prior to Sunrise Luis worked at North Vista Hospital and Valley Hospital and was Director of Pharmacy at Nathan Adelson Hospice.

Shirley Hunting

- Shirley joined the Board Reno staff in July, 2012. Shirley will be assuming Jeri Walter's role as Board coordinator when Jeri retires in December, 2012.
- Shirley's background includes working for Magellan Medicaid Administration as a pharmacy program support assistant, First Health Services as an administrative assistant and Washoe Medical Center as Secretary to the Director of Pharmacy.
- The Board also wants to thank and acknowledge the Board staff for sharing their knowledge and time in the training of the new staff members. The dedication of each staff member has made the transition efficient and transparent.

LICENSURE REPORT

The Board issues and regulates the following license or registration categories. The Board's total licensure counts at the end of the 2010-2012 biennium (as of July 1, 2012) are shown in the following table.

License or Registration Category	In State	Out of State	Total
Controlled Substances Registrations	9,270	0	9,270
Dispensing Practitioners	326	0	326
Dispensing Technicians and Trainees	369	0	369
Interns	382	311	693
Manufacturers	3	0	3
Medical Devices, Equipment, & Gases	502	207	709
Pharmaceutical Technicians & Technicians in Training	5,168	430	5,598
Pharmacies (Includes Institutional Hospitals and Ambulatory Surgery Centers)	587	590	1,177
Pharmacists	2,159	6,089	8,248
Prescribing Practitioners	326	0	326
Veterinary Drug Supplier	5	0	0
Warehouses	6	0	6
Wholesalers	32	677	709
TOTALS	19,063	8,313	27,376

HEARINGS – LICENSES GRANTED DURING THE BIENNIUM

License Type	In State	Out of State
Controlled Substance	1,480	0
Intern	149	82
Manufacturer	2	0
MDEG (Medical Devices/Equipment and	334	338
Gases)		
Pharmacy Technician and Trainees	2,003	179
Pharmacist	209	207
Pharmacy	39	169
Practitioner Dispensing	113	0
Prescribing Practitioners (APN's and PA's)	93	0
Technician Dispensing & Trainees	265	0
Veterinary Drug Supplier	3	0
Warehouse	0	0
Wholesaler	10	183

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HEARINGS – DISCIPLINE

License Type	Revocations	Denied Application	Suspension	Probation	Reins	tated	-	ial of tement	Surrender of Registration
Pharmacy	0	2	0	0	(0		C	0
Pharmacist	5	3	1	3		}		3	1
Technician/ Technician in									
Training	28	15	2	1	3	3		2	0
Other Discipline	(see note)		Pharmacists			Pharmacies			es
			21		17				
Your Success Rx	(see Your Succe	ss Rx)							
Other Discipline components as p the category "ot in this chart and	oart of the orden her discipline".	r. If discipline i If a pharmacy	s noted in a spe was ordered by	cific classific	ation in	this ch	art, the d	iscipline is	not noted in
Practitioners License			ontrolled Substa Restricted	ance C	ce Controlled Substan Probation				olled Substance rrendered
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COMPREHENSIVE REVIEW OF REGULATIONS

- Pursuant to Governor Sandoval's Executive Order (2011-01) to complete a comprehensive review of the regulations of the State Board of Pharmacy with respect to the protection of the public's health, safety and welfare without discouraging economic growth, we offer the following report:
- As a general statement, the Board of Pharmacy feels that the regulations subject to our enforcement has been, is, and always will be a non-static "working" set of regulations that have been constantly and appropriately amended to reflect the ever changing realm and technological advances within our scope. The world of medicine and the utilization of medications therein, are in a constant state of flux and most often for the The Board of Pharmacy takes its regulatory responsibility seriously, and better. continuously reviews all of its regulations, oftentimes at the request of industry who needs regulatory change to progress their businesses. Many times a balance must be sought between the good and the evil of drug therapy, as is evidenced by our country's alarming epidemic of prescription drug abuse. Regardless of our ever changing environment, the Board of Pharmacy takes pride in being one of the most efficient licensing boards in the nation with respect to swiftly, accurately and safely processing new applications for any of our 17 different licensing categories, including the licensing of new business entities in Nevada (i.e. pharmacies, wholesalers, manufacturers, medical device & gas companies). We are often complemented on our efficiency and willingness to work with new businesses to get them licensed.

- As technology has moved forward, the Board of Pharmacy has been responsive, but always with public safety in mind. Accuracy in our field is paramount given the nature of many of our new and potent medications. Having said that, we presently have thirtythree regulations that have been adopted by the Board, approved by the Legislative Committee on Regulations, filed with the Secretary of State, but have not yet been codified by the Legislative Counsel Bureau. Among these approximately 200 pages of regulatory changes, is a 65 page compounding practices section that is the culmination of a five year regulatory effort to modernize the practice standards for the compounding of pharmaceuticals ensuring appropriate patient safety. One of the resulting challenges of regulations not being codified is the creation of confusion among our licensees and the general public in attempting to understand just what standards are in place.
- The regulations under enforcement by our Board include three chapters and, with the above in mind, a chapter by chapter review of the regulations administered by the Board follows:
- Chapter 453 CONTROLLED SUBSTANCES
 - This chapter (controlled substances) is probably the most active with respect to revision, primarily due to its subject matter. Consequently, it has been continually reviewed and revised as is evidenced by our regulatory preparation for electronic prescribing; the strengthening of Nevada's Prescription Monitoring Program (PMP); methamphetamine abuse and the role that over-the-counter products have played as precursors (pseudoephedrine); and finally, the scheduling of synthetic cannabinoids ("Spice") and "bath salts" or "synthetic cocaine". We will continue to monitor the world of drug abuse and regulate accordingly for the protection of the public and in particular, our youth.
- Chapter 454 POISONS, DANGEROUS DRUGS, HYPODERMICS AND DEVICES
 - This chapter regulates the authority to possess and administer or use dangerous drugs and devices which obviously affects other licensing boards and has been statutorily updated as the need has arisen. (i.e., "medical assistants")
- Chapter 457 CANCER
 - Although not usually one of our regulatory chapters, the Board of Pharmacy was mandated by the legislature to develop regulations for a "Cancer Drug Donation Program" this past year. That process has been completed, and there are currently two pharmacies that have agreed to participate.

- Chapter 639 PHARMACISTS AND PHARMACY
 - Chapter 639 is the heart of the Board's regulatory responsibility, and again, is continually updated as health care moves forward. An example of our progressive regulatory activities is the relatively new immunization by pharmacist's initiative which has proven quite effective. The impact of the availability of immunizations of all kinds through pharmacies by pharmacists appears to be significant. Nevada being one of the "worst immunized" states in the nation illustrates the importance of our efforts and its impact on public health.
- The primary regulatory concern identified by the development of this report is the need for a complete overhaul of our institutional regulations. Present institution regulations do not reflect the modern practice of medicine in today's hospitals and correctional institutions. Present regulations were implemented over twenty years ago and apply to both hospitals and correctional facilities, which in today's world, have only one similarity, that being the number of beds. It is anticipated that changes are necessary in all three practice acts and will require a regulatory overhaul that will take several years and a ton of work. We cannot say what the final product will look like, however this agency will not compromise the safety of the public, the health of Nevada's citizens, our public trust, or the respect of the pharmacists and pharmacies that we regulate. We will continue to make regulatory changes in the future to meet the demands of both the Legislature and the public we serve, but feel that the regulatory challenge of updating institutional regulations should be our focus.
- In December 2011, Executive Secretary Larry Pinson submitted a comprehensive list of all administrative codes in which Executive Secretary Pinson identified each code as to the following:
 - Value to the public
 - Is the regulation necessary
 - Could/Do other regulations address the same problem
 - Is the regulation clearly written
 - Cost of the Regulation to the agency/state
 - Time and money
 - Adverse impact of regulation and cost to business
 - Time and money

VERSA LICENSING AND ENFORCEMENT PROGRAM

- VERSA has enhanced capabilities for online registration and license renewal.
- Percent of renewals online-
 - 2009 Pharmacists 50%
 - 2011 Pharmacists 8063 renewals on line 81%
 - 2010 All other categories of licensees and registrants 40%
 - 2012 All other categories of licensees and registrants will renew prior to November 1, 2012
- VERSA provides enhanced versatility allowing Board staff to control various functions, reports, etc.
- VERSA includes an investigation module to streamline investigations and allow real time monitoring of investigations.
- VERSA also has enhanced management of cash (licensing fees) features.

BOARD WEBSITE

- The Board of Pharmacy website was completely redesigned per Governor Brian Sandoval's direction to make all state websites consistent in design, look and feel. After closely working with the State Department of Information, the new website was activated in July 2012.
- The Board staff, working closely with DoIT staff, has continued to make the website more informative and user friendly.
- Agendas provided by Board staff to Board members for future meetings and the latest version of regulations being considered are now available in portable document format (PDF) for viewing, download and printing. The minutes of previous meeting are also posted on the site.
- The inspection forms for all registrants are now available on the Board website.



INSPECTIONS

- A cover letter is now sent to registrants informing the registrant that the registrant needs to print and fill out the appropriate registrant self assessment form. The form is available on the Board website.
- The Board of Pharmacy continues to focus on medical safety education in the Board's Inspecting for Safety presentations and when inspectors conduct their annual inspections of registrants.
- There were a total of 1,084 inspections scheduled from July 1, 2011 to June 30, 2012.
- 73 licensed entities registrations were closed during the July 1, 2011 to June 30, 2012 time frame.
- In addition to annual inspections, Board inspectors conduct pre-opening inspections for all registrants that are approved by the Board for licensure including Dispensing Doctors, Hospitals, Ambulatory Surgery Centers, Pharmacies, MDEG providers. Manufacturers and Wholesalers.

PHARMACEUTICAL TECHNICIAN ADVISORY COMMITTEE

- $\circ~$ The Board approved creation of this committee in July, 2008. The committee meets quarterly.
- The primary focus and discussion of the committee during the biennium has been prescription drug diversion in pharmacies.

MDEG (MEDICAL DEVICES, EQUIPMENT AND GASES) ADVISORY COMMITTEE

- \circ $\;$ The Board created this committee in 2002. The committee meets on a quarterly basis.
- The committee's purpose is to provide recommendations on regulations needed to protect and improve patient safety.
- Two items reviewed this biennium were unlicensed scooter rentals in hotels for guests and proper procedures for CPAP administration.
- See regulatory developments Updated MDEG Administrator Qualifications

CONTROLLED SUBSTANCE ABUSE PREVENTION TASK FORCE

- The Task Force database went live with new software vendor, RelayHealth, in February 2011.
- The Task Force moved their office from Carson City to Reno, April 2011.
- The Task Force provided de-identified data to UNR for a grant funded study with Reno PD to analyze controlled substance prescription trends.
- The Task Force entered in to an agreement with a research company, Abt. Associates, to analyze if unsolicited reports, which are sent to alert prescribers and dispensers of patients who are "doctor shopping", reduce medical costs.
- The Task Force began receiving controlled substance prescription data from some Indian Health Service facilities in Nevada.

CONTINUOUS FOCUS ON PATIENT SAFETY – CONTINUING EDUCATION

- A continuing important part of the inspection and compliance process is the focus of the board on educating and inspecting for Quality and Safety.
- The Board website has a link to a free online option for registrants to complete the required 1 hour of Nevada law through Pharmacist's Letter.
- The Board encourages pharmacy managers to focus technician and technician in training continuing education on prevention of medication errors and other continuing education that is relevant to and applicable within the technician and technician in trainings scope of practice.
- The Board inspection forms include ISMP (Institute for Safe Medicine Practices) recommendations on how to improve an individual's practice to improve patient safety.
 - The Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities for Change is now live on the ISMP website. The document can be found at: <u>www.ismp.org/communityRx/aroc</u>. The community pharmacy tools can be found at: <u>www.ismp.org/tools/communitySafetyProgram.asp</u>

- A video of the Preparing for Regulatory Inspections and Medication Safety Practices has been taped and is available on the "Pharmacist's Letter" website. The program is free to all Board registrants and is accredited for 1 hour of Nevada Law CE towards the Nevada Law CE biennial requirement.
- Continuing Education for ISMP Risk Assessment In the interest of education on prevention of medication errors the Board approved 4 hours of continuing education credit for pharmacists and continuing education credit hours for technicians up to 11 hours certified by the pharmacy manager for reviewing the *Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities for Change*.
- Executive Secretary Larry Pinson presented the Board's ongoing focus on "Inspecting for Safety" to NABP in Boston and Investigator Joseph Depczynski presented his PowerPoint presentation on "Inspecting for Safety" at NABP in Philadelphia in May, 2012.
- Executive Secretary Pinson and Investigator/Inspector Depczynski continued to present PowerPoint "Inspecting for Safety" presentations throughout the state during the recently completed biennium.
- The Board of Pharmacy continues to reach out to practitioners in a number of ways such as through articles in professional publications; soft education through its inspection efforts (i.e., educating practitioners about what is expected of them and reviewing the regulations that control their practices); the disciplinary process to try and curb professionals whose conduct violates Board statutes and regulations; and in some cases intervention by law enforcement when appropriate. The Board will continue its efforts to work with practitioners to bring their medical practices into compliance in its effort to protect the public.
- Executive Secretary Larry Pinson is presently working on a second law video to be provided via the internet.

CONTINUING EDUCATION IN NEVADA PHARMACY LAW

- The Board of Pharmacy Executive Secretary, Larry Pinson, Inspector Luis Curras and Inspector/Investigator Joe Depczynski conduct live continuing education programs on pharmacy law for pharmacists, interns, technicians and technicians in training throughout the biennium to provide the one hour of Nevada pharmacy law that the Board of Pharmacy requires pharmacists and technicians to complete per biennium.
- $\circ\;$ Inspector Curras will also provide live telephone Nevada law continuing education throughout the biennium.

INVESTIGATIONS

 Investigators Daniel Garcia and Ken Scheuber in Southern Nevada and Joe Depczynski and Jenine Davis in Northern Nevada investigate complaints received by the Board and provide the results of their investigations to the Board of Pharmacy discipline review committee for possible administrative hearing.

MULTI-STATE JURISPRUDENCE EXAMINATION (MPJE)

- Inspector Curras is the new Nevada representative on the National Association of Boards of Pharmacy (NABP) law review committee. Inspector Curras will review current exam questions and answers each year to ensure that the questions and answers are still valid under Nevada NRS and NAC. Inspector Curras will also write new Nevada pharmacy law exam questions and answers for the MPJE examination.
- The MPJE combines federal and state specific questions to test the pharmacy jurisprudence knowledge of prospective pharmacists. It serves as the pharmacy law examination in participating jurisdictions.

NEVADA LAW EXAMS FOR PHYSICIAN ASSISTANTS AND ADVANCED NURSE PRACTITIONERS -

 The Board offices in Northern and Southern Nevada administer a pharmacy law exam to all Physician Assistants and Advanced Nurse Practitioners who wish to practice in Nevada. Investigator Daniel Garcia, administers the law test in Southern Nevada by appointment and in Northern Nevada the test is also given by appointment only.

DRUG ABUSE

- Rural Methamphetamine Abuse Inspector/Investigator Depczynski represents the Board of Pharmacy on a national committee on rural methamphetamine abuse.
- The Board of Pharmacy in cooperation with the Medical and Osteopathic Boards, through the Legislative Committee on Healthcare, is addressing the growing issue of prescription drug abuse in Nevada.
 - See Controlled Substance Task Force Database (AB326 NRS 453.1545)
- Executive Secretary Pinson, lectures to various groups on the problem of increasing drug abuse in Nevada.

PHARMACY STUDENT ROTATIONS

- The Board of Pharmacy is one of the few Boards of Pharmacy nationwide that offers rotations to senior Pharmacy Students.
- The fourth year students are exposed to pharmacy law from the regulatory perspective. The students do research projects, take part in staff meetings and attend Board of Pharmacy hearings.
- Two pharmacy schools had students do a student rotation with the Board:
 - Idaho State University
 - 3 students
 - Creighton University
 - 1 student

LEGISLATIVE ACCOMPLISHMENTS

The Board did not have any bills presented in the 2011 Legislature. It has always been the Board's intent to maintain excellent working relations with the Legislature. The Board is often asked to assist the Legislature with technical advice, regulations, and implementation of other important programs that came from the 2011 Legislature.

SUPPORT OF LAW ENFORCEMENT

• The Board staff actively supported the various law enforcement agencies in their efforts to lower drug amounts available for trafficking.

TASK FORCE ON UNLICENSED HEALTH CARE AND SCOPE OF PRACTICE ISSUES

- Executive Secretary Larry Pinson and General Counsel Carolyn Cramer continue to be a part of Frankie Sue Del Papa's task force.
- The major focus of the task force is the unlicensed health care individuals who are preying on low income and the immigrant population in Nevada.

CANCER DONATION (NRS 457.500-595)

During the 2009 Session the Nevada Legislature enacted the Cancer Drug Donation Program.

- This program allows participating pharmacies to accept cancer medications used in the course of cancer treatment that were previously dispensed by a Nevada pharmacy. The drugs may be re-dispensed to Nevada residents who are currently being treated for cancer.
- Pharmacies can choose to be a part of this program by filling out a short form found on the Board website and be approved by the Board prior to participation (on the menu bar select Resources and then Cancer Drug Donation Program). Participation in the program is voluntary and the pharmacy can elect not to participate at any time. Patient recipients must be approved by the Board of Pharmacy.
- The patient must be a resident of Nevada, diagnosed with cancer, who presents a prescription written by a Nevada licensed practitioner, along with written authorization for participation by the Board.
- Donated drugs must have been originally dispensed by a licensed Nevada pharmacy; must have an expiration date greater than 30 days; must be in the original, unopened, sealed package; must not be temperature sensitive; and must not be controlled substances, compounded or from a clinical trial.
- The pharmacy is required to keep the medication donated to the program in a separate location from their normal drug stock and document transfer of medication on the forms provided by the Nevada State Board of Pharmacy. All forms can be found on the website.
- If you are interested in becoming a participating pharmacy or would like more information on the Cancer Drug Donation Program; please visit the Nevada State Board of Pharmacy

website, Chapter 457 of Nevada Administrative Code, or Nevada Revised Statute Chapter 457.

TELEPHARMACIES, REMOTE SITES AND SATELLITE CONSULTATION (AB370 – NRS 639.NEW)

- Authorizes the establishment of remote sites and satellite consultation sites for the dispensing of prescriptions, and telepharmacies, connected to the remote sites by computer link, video link and audio link to enable a registered pharmacist or a dispensing practitioner at the telepharmacy to oversee the dispensing of prescriptions to patients at a remote site or satellite consultation site.
- This bill exempts the site from the requirement that every pharmacy must be managed by a registered pharmacist.
- This bill requires the Board of Pharmacy to establish "service area."
- This bill also sets other criteria for telepharmacy, remote sites and satellite consultation.

CONTROLLED SUBSTANCE TASK FORCE DATABASE – (AB326 NRS 453.1545)

- Now includes the contact information of each person who elects to access the database of the program.
- The Board shall provide Internet access to the database of the program to each practitioner who is authorized to write prescriptions for and each person who is authorized to dispense controlled substances listed in schedule II, III or IV who elects to access the database of the program; and completes the course of instruction described in the statute.
- Section 9 of this bill requires the Legislative Committee on Health Care to conduct a study of the abuse of prescription narcotic drugs and the manner of monitoring and addressing such abuse in this State and to submit a written report to the Director of the Legislative Counsel Bureau for transmittal to the next regular session of the Legislature on or before January 15, 2011.
- Larry Pinson, Executive Secretary, and Carolyn Cramer, General Counsel, are active participants in the Legislative Committee group that is studying the abuse of prescription narcotic drugs, the monitoring of usage by patients, and developing methods to address and prevent prescription drug abuse.

RETURNED DRUGS PROGRAM EXPANSION TO NON-PROFIT PHARMACIES (SB197)

 NRS 639.2676 sets the requirements for reissue of unused drugs transferred to a nonprofit pharmacy.

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 2012 is the number of complaints made through June 30, 2012.

In addition to investigating written complaints the investigators spend a significant amount of time supporting other Board investigators with onsite visits and on complaints that need to be investigated but do not reach the stage of assigning a Nevada Board of Pharmacy case number.

Each complaint the Board receives is reviewed by Executive Secretary Larry Pinson. Based on his review, a case number may be assigned to the complaint or an investigator may be asked to follow up on the complaint, to gather more information. If there is verifiable evidence or information to warrant assigning a case number for an investigation, a case number will be assigned.

REGULATORY DEVELOPMENTS

Due to a regulatory freeze by Governor Brian Sandoval, regulatory activity consisted only of matters necessary for the protection of the public health.

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.

IMMUNIZATION (NAC 639.297 - NAC 639.2978)

- Nevada remains one of least immunized states in the nation.
- The Annual Immunization Report April 1, 2010 March 31, 2011 Immunizations by Pharmacists is available from the Board of Pharmacy on request.

CONTROLLED SUBSTANCE ABUSE PREVENTION TASK

 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.

<u>SCHEDULING OF DANGEROUS DRUGS, PRECURSORS, BATH SALTS AND SYNTHETIC CANABINOIDS AS</u> <u>CONTROLLED SUBSTANCES (NAC 453.510 – NAC 453.520 – NAC 453.550)</u>

- In response to requests by law enforcement and other government entities the Board adopted emergency regulations to schedule drugs, certain precursors of controlled substances, bath salts and synthetic cannabinoids.
- These substances are being abused widely and have resulted in harm to Nevada citizens up to and including death.
- The Board will continue to monitor the world of drug abuse and regulate accordingly for the protection of the public and in particular, our youth.
- The Nevada State Board of Pharmacy, in the past year, has had three requests from law enforcement to include certain synthetic substances in controlled substance Schedule I, making them illegal to possess or sell in Nevada. The first rulemaking was for five synthetic cannabinoids ("spice" type drugs) with an effective date of May 5, 2011. The second rulemaking was for six substituted cathinones ("bath salts" or "synthetic cocaine") with an effective date of February 15, 2012. The third rulemaking was begun as an emergency regulation signed by Governor Sandoval for six more synthetic cannabinoids, and was adopted by the Legislative Commission with an effective date of May 30, 2012. In summary, the Board of Pharmacy has scheduled 17 substances in controlled substance Schedule I. Hopefully, making them illegal quickly will address the public health and safety needs raised by the Governor and the state's law enforcement agencies. We anticipate additional substances being added to Schedule I as they emerge in our state and become a threat to our public health.

UNLICENSED DISPENSING OF CONTROLLED SUBSTANCE AND DANGEROUS DRUGS

• The Nevada State Board of Pharmacy has renewed its efforts to confront unlicensed dispensing of controlled substances and dangerous drugs by medical personnel. The Board has visited a number of medical practices that dispense dangerous drugs and controlled substances without proper regulatory authority or are misusing their authority. In some instances the practitioners at these medical facilities, some of which are known as "medi-spas" or "medical spas," have no lawful authority to possess, administer, or dispense controlled substances. In other instances, practitioners at such facilities have the appropriate registrations but are using the registrations in ways that violate the laws of Nevada.

MDEG ADMINISTRATOR QUALIFICATIONS (LCB FILE R003-09 – NAC 639.694)

- Specifies the qualifications necessary for an individual to be the administrator of a medical products provider or medical products wholesaler; notification within 3 days of a change of administrator; MDEG not to operate more than 10 days without an administrator and other related matters.
- Requirement of the MDEG administrator to be on site at the facility 40 hours per week or if open less than 40 hours, on site the number of hours the facility is open.

FULFILLMENT PHARMACIES (NAC 639.7125)

- Allow a registered mail order pharmacy to act as a fulfillment pharmacy.
- Better regulates and clarifies the practices of a fulfillment pharmacy with respect to consumer understanding and patient safety.

MINIMUM REQUIREMENTS FOR WORK AREA AND EQUIPMENT - (NAC 639.525)

- Amends the regulation to require a programmable thermometer in freezers and refrigerators that store pharmaceuticals.
- The device must have an alarm that records and alerts the pharmacist when the freezer or refrigerator temperature falls outside the range required in the regulation.
- For refrigerators the range is 36 degrees to 46 degrees Fahrenheit.
- For freezers the temperature must be below 32 degree Fahrenheit.
- If a pharmaceutical requires storing at a temperature other than the above range, the freezer or refrigerator programmable device must be set to alert when the temperature is outside the range required for safe storage of the pharmaceutical.

BONAFIED THERAPEUTIC RELATIONSHIP – (NAC 639.753 NAC 639.945)

- Defines the therapeutic relationship between a patient and a practitioner for the purposes of dispensing certain drugs and controlled substances and describes the provisions relating to acts or practices declared to be unprofessional conduct.
- Allows a patient incarcerated in a correctional facility to be examined by a practitioner via a teleconferencing system with the assistance of a PA or APN on site with the patient.

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 assessed pharmacies and pharmacists. The Board looks forward to continued use of this program to continually improve the practice of pharmacy for both pharmacies and pharmacists.

Clients Assessed	2010-2012 Biennium	Jan 2006 July 2012	
Pharmacists			
Retail		14	28
Hospital/Infusion		6	4
	Total	20	32
Site Inspections			
Retail		8	8
Hospital/Infusion		0	2
	Total	8	10

• The first referral to Your Success Rx was in January of 2006.

• The Your Success RX training program consists of one-on-one time with the pharmacist and focuses on the specific systems and operations of their current practice site and how they interact and affect those systems. Your Success Rx reviews safe practice behaviors and error prevention, as well as discusses patient counseling techniques, the handling of medication errors and customer service excellence. Your Success Rx offers several workplace personality tests which help the individual assess their strengths and weaknesses within their practice. Several weeks later, Your Success Rx makes an on-site visit to assess areas for focus and/or make suggestions for implementing new systems or improving systems currently in use. During the on-site visits, Your Success Rx assesses the systems and operations of the specific practice location. These assessments vary depending upon the type of pharmacy practice; however, the assessment typically consists of an in-depth look at the current policies and procedures, systems of communication, training manuals, operations, etc., of each location. Written reports which include suggestions for improving efficiency and effectiveness of current operations are provided to the pharmacist and facility.

PRESCRIPTION CONTROLLED SUBSTANCE ABUSE PREVENTION TASK FORCE

Created in 1997, the Nevada Prescription Controlled Substance Abuse Prevention Task Force (the Task Force or PMP – prescription monitoring program) is administered by the Board. The Task Force consists of participants from SAPTA, NDI, and health licensing boards, Medicaid, professional organizations, pain management practitioners, impaired professional help groups and industry. 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.

In August of 2008 the Task Force hired a part-time intervention officer for Northern Nevada. This position was federally grant funded. The federal grant ended June 30, 2012.

The Task Force has been able to successfully intervene with over 160 patients in Northern Nevada, with a part-time intervention officer. Most of the patients have succeeded in ending their destructive cycles of prescription controlled substance addiction.

This biennium, the Task Force began full implementation of online practitioner access to the data. The Task Force has on-line 24/7 access to registered users of the system. This has worked effectively for the practitioners because they are getting their data online, often within minutes of their request and while the patient is still in their office, rather than receiving the data three or four days later.

- What is the PMP?
 - Database with thresholds and a goal of identifying potential "doctor shoppers" (a felony) and referring the shopper for treatment.
 - States are working towards data sharing of PMP information.

- How does it work?
 - Pharmacies and dispensing practitioners must report their controlled substance prescriptions at least once weekly.
 - Staff filters the data submitted for warning signs of abuse, such as multiple doctors or multiple pharmacies.
 - If a patient sets off enough "red flags", the task force generates an "unsolicited report".
 - > The report is sent to each practitioner and each pharmacy that the patient has visited.
 - It is then up to each of these professionals to determine how to best handle their patient.
 - > The PMP is not for law enforcement "fishing".
 - The Board employs one intervention officer with a case load of about 30 patients to help the patient get into treatment.
 - > Impact:
 - Only 21% of licensed prescribers and 14% of licensed dispensers are registered to use PMP.
 - With intervention:
 - The average number of prescriptions per patient drops from 150 to 46 per year.
 - The average number of practitioner visits drops around 37%.
 - The average number of dosage units obtained drops 43%.

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- The task force has recommended to the Legislative Committee on Health Care to begin tracking Schedule V controlled substances. By tracking Schedule V controlled substances, the Task Force will be able to apply for additional grants.
- The Task Force has also recommended that practitioners be required to register with the Task Force as a condition of licensure with the Board of Pharmacy.
- Executive Secretary Larry Pinson continues to give presentations to various practitioner groups on the "cultural problem" of prescription drug abuse and use in the United States. These efforts are paying off by educating the medical community on the widespread use/abuse of controlled substances. Executive Secretary Larry Pinson's work with the state dental community has made great strides in educating the dental community on use and abuse.

- > Americans comprise approximately 6% of the world population.
- > Americans consume 60% of all manufactured drugs.
- Americans consume 80% of the world's supply of opiates.
- Americans consume 75% of the world's supply of oxycodone.
- Americans consume 99% of the world's supply of hydrocodone.
- Nevada:
 - #2 for hydrocodone
 - #2 for oxycodone
 - #4 for methadone
 - #7 for codeine
 - #17 for meperidine
- > 5% of practitioners prescribe 88% of the controlled substances.

ELECTRONIC PRESCRIBING OF SCHEDULE II CONTROLLED SUBSTANCES

Board has approved the electronic prescribing of Schedule II controlled substances as long as the practitioner and pharmacy systems conform and are certified as compliant with DEA standards.

CONTROLLED SUBSTANCE TASK FORCE DATABASE UTILIZATION

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



Note: the figure for 2012 is the number of requests through June 30, 2012.

In 1997, the first year of the CSTF, there were a total of 480 requests for the report.

FINANCIAL REPORT

The Board administers an annual budget of approximately 1.9 million dollars for the biennium 2010-2012. All of the Board's revenues come from licensing, certification, and registration fees: the Board receives no state general fund money. The Board is audited annually by the Kohn Colodny CPA firm .

Board Reports

- Siennial Report (NRS 639.060) Legislative, Regulatory and Administrative overview.
- Biennial AB128 Manufacturer and Wholesaler Compliance Audit Report (NRS 639.570 3.) Companies Compliant with AB128 Code of Conduct Annual Certification of Compliance.
- Annual Immunization by Pharmacists Report (NRS 649.065) Immunizations administered by Pharmacists and includes Nevada immunization rates compared to US immunization rates.
- Annual Returned Drugs Report (NRS 639.063) -Return of drugs by exempt facilities to a provider pharmacy for re-issue to patients in that facility.

WHAT LIES AHEAD FOR THE 2012-2014 BIENNIUM

Several foreseeable issues lie ahead for the Board in the 2012-2014 biennium and beyond, including:

HOSPITAL REGULATIONS – "HOSPITAL REGULATION REVISION COMMITTEE"

- 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.
- The Hospital Regulation Revision Committee has met twice to lay the groundwork on updating hospital regulations.
- \circ Keith Macdonald, RPh, has been appointed the Chair of the Revision Committee.

PRESCRIPTION DRUG ABUSE PREVENTION MEASURE

• The Board staff is working with law enforcement both in Northern and Southern Nevada studying the abuse of prescription narcotic drugs, the monitoring of usage by patients, and developing methods to address and prevent prescription drug abuse.

EDUCATIONAL

- Continuous development and presentation of CE to practitioners, pharmacists and pharmacy technicians.
- CE for law enforcement and with law enforcement.
- Executive Secretary Larry Pinson is the scheduled Kick-Off speaker for the upcoming statewide drug summit.
- Continuous education of the public through public meetings and JTNN.
- Continuous education for fellow health care boards.

THE BOARD AND STAFF HAVE TAKEN A LEADERSHIP ROLE WITH OTHER BOARDS

- The Board staff continues to coordinate with other health care boards on public safety relating to medical issues, both licensed and unlicensed entities.
- In combating:
 - Unlicensed health care in Nevada.
 - Review of scope of practice issues in health care.
 - Oversight of medical spas.
 - This includes a national resolution with the National Association of Boards of Pharmacy (NABP) regarding the oversight of medical spas.

WORKSHOPS AND PUBLIC HEARINGS TO ADOPT NEW NEVADA ADMINISTRATIVE CODE

• The Board continues to bring forward regulations needed to protect the public based on facts presented by various government agencies and law enforcement.