Nevada State Board of Pharmacy

BIENNIAL REPORT

July 1, 2014 – June 30, 2016

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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.
- 3. 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 January, April, July, October, and in Reno in March, 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.

FINANCIAL REPORT

The Board administered an annual budget of approximately 3.7 million dollars for the biennium 2014-2016. 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.

2014-2016 Biennium

- ❖ The 2014-2016 biennium saw continued growth in the Board's various categories of registration and licensure. The number of licensees and registrants increased 5.87% in the last biennium.
 - Controlled substances registrants are largely physicians, but also include dentists, veterinarians, physician assistants, and advanced practice registered nurses.
 - 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, 2014-2016.

License or Registration Category	Change (number)	Percent Change
Controlled Substances Registrations	1312	11.52%
Dispensing Practitioners	-36	-12.37%
Dispensing Technicians and Trainees	-230	-71.65%
Interns	-4	-0.55%
Manufacturers	0	0%
MDEG (Medical Devices/Equipment and Gases)	-54	-7.79%
Pharmaceutical Technicians & Pharmaceutical Technicians-in Training	617	9.50%
Pharmacies (Includes Institutional Hospitals and Ambulatory Surgery Centers)	174	11.07%
Pharmacists	-66	081%
Prescribing Practitioners (APRN's and PA's)	-32	-16.08%
Veterinary Drug Supplier	15	53.57%
Warehouses	1	14.29%
Wholesalers	107	12.02%
TOTALS	1804	5.87%

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, 2014 through June 30, 2016.

ACCOMPLISHMENTS FOR 2014-2016 BIENNIUM

While the 2014-2016 biennium contained two busy years for the Board, accomplishments in several important areas are worth mentioning.

ADMINISTRATIVE ACCOMPLISHMENTS

BOARD STAFF CHANGES

The Board welcomes Kristopher Mangosing, Yenh Long, David Jones and Venkata Kanulolanu to the Reno board staff and Dena McClish and Joe Dodge to the Las Vegas board staff.

- Kristopher Mangosing, Assistant Board Coordinator
 - Kristopher's background includes working as a pharmacy technician at Target from December 2005 to November 2014.
 - Kristopher was hired by the Board of Pharmacy in July 2012 to help with the CDC study, "An Experimental Test of the Effectiveness of the Unsolicited Reporting by a Prescription Drug Monitoring Program."
 - Kristopher currently works with the PMP (Prescription Monitoring Program) aiding with the registration of practitioners and processing PMP reports both solicited and unsolicited.
 - Kristopher also aids with writing the minutes for the Board of Pharmacy meetings and is cross training with licensing including the licensing of seventeen occupations/businesses licensed by the Board.
 - In addition Kristopher is involved in tracking discipline fines and fees.
- Yenh Long, Pharm. D., BCACP, Program Administrator, Nevada Prescription Monitoring Program
 - Yenh received a Bachelor of Science degree in Biology, with a minor in Chemistry from the University of Nevada in May 2008.
 - Yenh then attended Roseman University of Health Sciences and graduated with a Doctor of Pharmacy in South Jordan, UT in June 2011. After graduation, Yenh completed a PGY-1 Pharmacy Practice Residency at the VA Southern Nevada Healthcare System, in Las Vegas, NV in July 2012.
 - Following pharmacy school and residency, Yenh became an Assistant Professor of Pharmacy Practice at Roseman University of Health Sciences in South Jordan, UT. Yenh taught various pharmacotherapy courses, and helped design clinical programs as well as presented continuing education courses to health care professionals.
 - Yenh also had a practice site and precepting role for Roseman University and University of Utah pharmacy students at the Anticoagulation Clinic at Intermountain Medical Center in Murray, UT. In her role as the Interim Clinic Manager for Ambulatory Care Services she collaborated with other health care professionals and was published in 2014 in the journal, Heart Rhythm, and in 2015 in the journal, Clinical and Applied Thrombosis/Hemostasis.
 - Yenh is a Board Certified Ambulatory Care Pharmacist (BCACP), and is also certified through the American Pharmacists Association in Pharmacy-Based Immunization Delivery.

Dena McClish, Investigator

- o Dena joined the Las Vegas Board of Pharmacy staff 11/01/2015.
- Dena has a MBA from Bellevue University in Bellevue, NE and a B.S. degree in Biology with a minor in Chemistry.
- Dena has almost 20 years of investigative experience working for law enforcement entities, city governments, and federal agencies.
- She started her career as a police officer in Omaha, Ne and eventually relocated to Las Vegas, NV
 where she has worked as a compliance manager with the City of Las Vegas Municipal Court as well as
 a compliance and personnel security investigator for various federal agencies to include: the
 Department of Homeland Security, Office of Personnel Management, Department of Defense, and
 the US Department of Justice.

Joe Dodge, Pharm. D, Inspector

- o Joe received his Doctor of Pharmacy degree from the University of Michigan in 1993.
- Joe was the Pharmacy Manager at Option Care home infusion pharmacy from 1993-2005 where he managed a staff of pharmacists and technicians to service over 500 infusion patients. Option Care received and maintained accreditation by both JCAHO and ACHC during his tenure as Pharmacy Manager.
- Joe became General Manager of Option Care in 2005. His duties included supervision and management oversight to 45 employees including marketing, nursing, pharmacy, intake, HR, and reimbursement.
- Joe accepted the role of General Manager of Walgreens Home Infusion in 2007. The facilities he supervised continually were ranked in the top 5 offices in the country based on metrics established by Walgreens corporate offices.

• David F. Jones - Compliance Coordinator

- o Mr. David F. Jones graduated from Arizona State University in 1984 and began his professional career in Nevada in August 1985 as an Auditor for the Nevada Gaming Control Board. In 1990, Mr. Jones became a Certified Public Accountant and started his 23 years of law enforcement service with the Department of Public Safety's Investigation Division. Mr. Jones retired from state service in March 2014 as the Deputy Chief of the Investigation Division.
- While enjoying retirement, Mr. Jones spent the last two years working part-time as a Douglas County Deputy assigned to the Marine 7 boat patrol at Lake Tahoe. In May 2016, Mr. Jones began working part-time as a Compliance Coordinator for the Nevada Board of Pharmacy's Prescription Monitoring Program.
- o Mr. Jones has been married for almost 20 years and is proud to have his son enrolled as a freshman engineering student at UNR for the fall semester.

• Venkata Sravan Kumar Kanulolanu - Statistician

Sravan strongly believes in data driven decision making. Born and raised in India, he graduated from the Andhra University with a degree in Electrical and Electronics Engineering and began his career as a software engineer at Capgemini India. He then went to the University of Nevada, Reno and graduated with a M.S in Mathematics. Recently he started working as a Statistician at the Nevada Board of Pharmacy. During his free time he enjoys reading, running and hiking.

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 2014-2016 biennium (as of July 1, 2016) are shown in the following table.

License or Registration Category	In State	Out of State	Total
Controlled Substances Registrations	11313	73	11386
Dispensing Practitioners	291	0	291
Dispensing Technicians and Trainees	321	0	321
Interns	406	325	731
Manufacturers	3	0	3
Medical Devices, Equipment, & Gases	182	511	693
Pharmaceutical Technicians & Technicians in Training	6085	413	6498
Pharmacies (Includes Institutional Hospitals and Ambulatory Surgery Centers)	613	959	1572
Pharmacists	2394	5720	8114
Prescribing Practitioners	193	6	199
Veterinary Drug Supplier	28	0	28
Warehouses	7	0	7
Wholesalers	31	859	890
TOTALS	21867	8866	30733

LICENSES GRANTED DURING THE BIENNIUM (VIA HEARINGS)

License Type	In State	Out of State
Controlled Substance*	1	NA
Intern *	2	NA
Manufacturer **	1	0
MDEG (Medical Devices/Equipment and Gases) **	35	215
Pharmacy Technician and Trainees *	3	NA
Pharmacist *	12	NA
Pharmacy **	138	337
Practitioner Dispensing *	1	NA
Prescribing Practitioners (APRN's and PA's) *	3	NA
Technician Dispensing & Trainees *		NA
Veterinary Drug Supplier **		0
Warehouse **	1	0
Wholesaler **	10	189

The number of licenses granted for each license type may be different than the number of changes in total licensed facilities due to closures, change of address, and other related issues or out of state facilities during the biennium

Certain licenses are not granted via the hearing process. These are noted above with a single asterisk *. The appearance of any of these licensees at a hearing is required only if are issues with the applicant's application.

All in-state Nevada licenses noted above with a double asterisk ** were approved pending a positive site inspection by the Board staff.

Prescribing Practitioners: Advanced Practice Registered Nurses (APRN) and Physician's Assistants (PA), are required to pass a Nevada Pharmacy Law test prior to licensure to prescribe controlled substances. The APRN test is administered by the Nursing Board and the PA test is administered by the Pharmacy Board.

Out of state pharmacies compounding sterile products must provide a favorable inspection report by the state the pharmacy is licensed in, fill out the Nevada Sterile Compounding Addendum found in the institutional inspection report, and provide the current certifications identifying that all ISO areas passed certification to the ISO level required for that sterile area. These certifications must contain testing and passing of viable particle testing in addition to non-viable particle.

HEARINGS – DISCIPLINE

License Type	Other Discipline (see note)	Revocations	Denied Application	Suspension	Probation or Conditions	Reinstated or Reciprocity	Denial of Reinstatement	Surrender of Registration
MDEG	3		4		1			
Wholesaler			1					
Pharmacy	26		3					
Pharmacist	42	4	3	2	2	1		3
Intern								
Technician/ Technician in Training	2	13	2	2	1	1		
	Pace exam (see page 19)							
Other Discipline numbers are noted only once per entity or person. Administrative orders may have other discipline components as part of the order. If discipline is noted in a specific classification in this chart, the discipline is not noted in the category "other discipline". If a pharmacist was ordered by the Board to complete Your Success Rx, discipline is noted both in this chart and separately under Your Success Rx.								
	Practitioner's Licenses							
Reinstater	ment of	Dispensing	Controlled			ontrolled	Controlled	

Reinstatement of Practitioner's Controlled Substance License	Dispensing Application Denied	Controlled Substance Restricted	Controlled Substance Probation	Controlled Substance License Revoked	Controlled Substance Application Denied	Controlled Substance Surrendered
2		1	1		1	

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:
 - o In January 2016, 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

- 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 better. The Board of Pharmacy takes its regulatory responsibility seriously, and 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. 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 practice acts regulated by the Board 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.

REGULATIONS UNDER ENFORCEMENT BY OUR BOARD INCLUDE THE FOLLOWING:

- 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 453A MEDICAL USE OF MARIJUANA
- Chapter 453B DRUG DONATION PROGRAMS
- ❖ 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
 - o The Cancer Drug Donation Program currently has two pharmacies that have agreed to participate.
- CHAPTER 585 FOOD, DRUGS AND COSMETICS: ADULTERATION; LABELS; BRANDS
- ❖ 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.

VERSA LICENSING AND ENFORCEMENT PROGRAM

- VERSA –coming enhancements
 - o Ability to email certificates.
 - The system will ask licensees a series of questions on business licenses and military information so
 the online system will be able to accommodate questions allowing the licensee to renew online
 based on the answers to the questions. Previously, the ability to renew online was dependent on
 the response to the questions asked.
 - o All around enhancements to VERSA will be implemented in the near future with a system upgrade.
- VERSA has enhanced capabilities for online registration and license renewal.
- Percent of renewals online
 - o 2009 Pharmacists 50%.
 - 2010 All other categories of licensees and registrants totals only/not broken down by category 40% 6,052 on-line (15,131 total).
 - o 2011 Pharmacists 80% 6,440 on-line (8,063 total).
 - 2012 All other categories of licensees and registrants 78.2% 12,515 on-line (16,004 total)
 - o 2013 81.9% 6,430 on-line (7,855 total).
 - 2014 All other categories of licensees and registrants 80.6% 13,691 on-line (16,986 total) (as of December 2, 2014)
 - Controlled Substance 9,209 (87%)
 - Veterinary Dispenser 11 (84.5%)
 - Intern 389 (58%)
 - Manufacturer 2 (65%)
 - MDEG 549 (75%)
 - Pharmacy Technician 4,149 (69%)
 - Pharmacy 1,269 (94%)
 - Practitioner Dispensing 238 (76%)
 - Prescriber (PA, APRN without Controlled Substance License) 162 (75%)
 - Technician Dispensing 295 (49%)
 - Warehouse 0
 - Wholesaler 713 (92%)
 - 2015 Pharmacists 79.9% 6,263 on-line (7,840 total).
- 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 staff, working closely with DoIT staff, continues to make the website more informative and user friendly.
 - o A list of approved Pharmacy Technician Schools is now listed on the website.
- 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 meetings are also posted on the site.
- ❖ The inspection forms for all registrants are now available on the Board website.
- ❖ A <u>Red Flag video</u> about Prescription Drug Abuse prevention has been added to the home page and resources page. The "Red Flag Video" was taped in conjunction with NABP as an educational resource for pharmacists and techs on doctor shopping.

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.
- In addition to annual inspections, Board inspectors conduct pre-opening inspections for all registrants that are approved by the Board for licensure. The pre-opening inspections including Dispensing Doctors, Dispensing APRNs, Dispensing PAs, Hospitals, Ambulatory Surgery Centers, Pharmacies, MDEG providers, Manufacturers and Wholesalers.

PHARMACEUTICAL TECHNICIAN ADVISORY COMMITTEE

❖ The Board approved creation of this committee in July, 2008. The committee meets when needed to discuss technician related issues.

MDEG (MEDICAL DEVICES, EQUIPMENT AND GASES) ADVISORY COMMITTEE

- ❖ The Board created this committee in 2002. The committee meets when needed to discuss medical device, equipment and gas related issues.
- The committee's purpose is to provide recommendations on regulations needed to protect and improve patient safety.

CONTINUOUS FOCUS ON PATIENT SAFETY

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: www.ismp.org/communityRx/aroc. The community pharmacy tools can be found at: www.ismp.org/tools/communitySafetyProgram.asp.
- 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.

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 and Investigator Dena McClish will work with Office Manager/Inspector Seidlinger in reviewing current exam questions and answers each year to ensure that the questions and answers are still valid under Nevada NRS and NAC. Inspector Curras and Investigator McClish will also work with Inspector Seidlinger writing 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 who wish to practice in Nevada. Investigator Ken Scheuber administers the law test in Southern Nevada by appointment, and in Northern Nevada, the test is also given by appointment only. The Advanced Practice Registered Nurse's law exam is administered by the Nursing Board.

PHARMACY STUDENT ROTATIONS

- The Board of Pharmacy is one of the few Boards of Pharmacy nationwide that offers rotations to senior Pharmacy Students.
- The 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.
- The Board office provides a regulatory rotation for pharmacy schools who have students interested in completing a regulation rotation with the Board:
 - The Board office in Reno was host to a rotation for a student from Chicago State University in February of 2015.
 - The Board office in Reno hosted rotations for two students from Idaho State University during the biennium.
 - The Board office in Reno was host to a rotation for a student from Roseman University of Health Sciences during the biennium.
 - o In the past the Board has hosted students from North Dakota State University, Idaho State University, Creighton University and Chicago State University.

LEGISLATIVE ACCOMPLISHMENTS

The Board did not have any bills presented in the 2015 Legislature. It has always been the Board's intent to maintain excellent working relations with the Legislature. The Board is often asked to testify on and assist the Legislature with technical advice, regulations, and implementation of other important programs/statutes that the legislature is considering or that become law.

THE FOLLOWING NEVADA REVISED STATUTES WERE ADOPTED OR AMENDED IN THE 2015 LEGISLATIVE SESSION:

- NRS 453B.120 Board to adopt regulations (effective 10-1-14) Establishes a HIV/AIDS Donation program.
- ❖ AB 158 Auto-injectable epinephrine − Revises and expands provisions relating to obtaining, providing and administering auto-injectable epinephrine in certain circumstances.
- Chapter 453B Cancer Drug Donation Program Enabling statutes creating a Cancer Drug Donation Program and establishing the criteria of the program.
- Senate Bill 459 (effective 5-5-15) -
 - Section 16 amended NRS 639.23507(1) Requires mandatory access and use by practitioners of the prescription monitoring system.

- Requires periodic training for practitioners concerning the misuse and abuse of controlled substances. Sections 15.1 through 15.9 authorizes each licensing Board of the practitioners who are eligible to obtain a controlled substance registration "complete at least 1 hour of training related specifically to the misuse and abuse of controlled substances during each period of licensing."
- Allows for a significant departure from traditional pharmacy law. Section 7 applies to physicians, physician assistants and advanced practice registered nurses who are properly licensed and authorized to prescribe dangerous drugs and controlled substances. This section allows such prescribers to prescribe and dispense an opioid antagonist to a person other than the patient. The statute describes other person as "a family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related drug overdose."
- Section 7(3) extends the authority to possess and administer opioid antangonists. Allows any
 person to possess and administer an opioid antagonist to another person whom he or she
 reasonably believes is experiencing an opioid-related overdose.
- Section 8 allows non-registered persons to store and dispense opioid antagonists pursuant to a standing order from a properly licensed prescriber.
- Section 9 expands the authority of pharmacists by allowing them to dispense an opioid antagonist without a prescription.
- Section 12 provides protections for person who seek medical assistance for another who is experiencing a drug or alcohol overdose.

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.

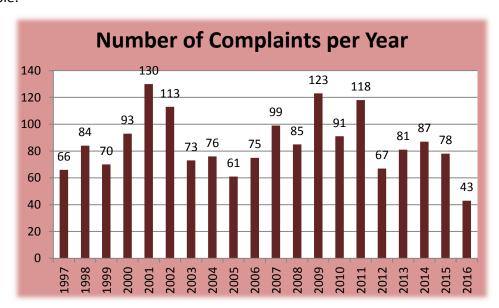
- NAC 453.510 (effective various dates) Adds additional compounds to schedule I
- ❖ NAC 453.520 LCB file R137-14 (effective 12-22-14) Reschedules Hydrocodone single entity or in combination with any other active ingredient, into conformity with federal regulations.
 - Section 1 of the regulation specifies that all hydrocodone combination products are controlled substances in schedule II.
 - Section 2 of the regulation deletes the specified hydrocodone combination products from schedule III.

- Section 3 of the regulation provides the reclassification of hydrocodone combination products does not apply to a prescription for a schedule III hydrocodone combination product that is was issued before December 22, 2014, if the product was dispensed before April 8, 2015.
- ❖ NAC 453.530 LCB file R016-14 (effective 10-24-14) Revises the definition of Keatamin HCL to include it's salts, isomers and salts of isomers to the controlled substances listed in schedule III.
- ❖ NAC 453.450 LCB file R133-14 (effective 6-26-15) This regulation adds tramadol to schedule IV.
- ❖ NAC 639.748 LCB file R014-14 (effective 6-26-15) Revises the provisions governing the presentation of identification by a person who picks up a controlled substance; and providing other matters properly related to.
- NAC 453.540 LCB file R004-15 (effective 8-10-15) This regulation adds suvorexant to schedule IV.
- ❖ NAC 639.050 LCB file R002-15 (effective 12-21-15) Establishes rules for storage and destruction of certain drugs.
- ❖ NAC 639.498 LCB file R002-15 (effective 12-21-15) Establishes rules for the destruction of controlled substances.
- NAC 639.6282 and 639.6305 LCB file R001-15(effective January 2016) Proposed amendments to NAC bring the regulations into compliance with current federal law and enacted under the Drug Quality and Security Act requiring 3PLs to be licensed separately as wholesalers.
- ❖ NAC new LCB file R003-15 (effective 12-21-15) Requires under certain circumstances, an outsourcing facility to obtain a license for the State Board of Pharmacy as a manufacturer, and providing for other related matters. Creates a new licensing category for outsourcing facilities.
- LCB file R002-15 (effective 12-21-15) Requires certain entities collecting controlled substances to provide certain notification and a copy of a certain federally required form to the State Board of Pharmacy, clarifying standards for the disposal of controlled substances, and matters pertaining to the regulation.
- NAC 639.926 (effective January 2016) Amends the regulation that establishes the frequency of controlled substance information transmitted to the Board.
- NAC 453 New (draft to LCB) relates to the Good Samaritan Drug Overdose Act (Naloxone).
- NAC 453.540 LCB File R079-15 (effective 4-4-16) adds Lorcaserin to Schedule IV.
- ❖ NAC 639.921 LCB File R035-16 (effective 4-7-16) Authorizes the sharing of information concerning prescriptions between the computerized systems of licensed pharmacies that are not commonly owned under certain circumstances and other related matters.
- ❖ NAC 453 New and 639 New LCB File R121-15 (effective 4-28-16) requiring a pharmacist who furnishes an opioid antagonist to create and maintain a record containing certain information; requiring a pharmacy to submit such records to the State Board of Pharmacy annually, exempting certain persons to whom an opioid antagonist is furnished from requirements applicable to wholesales and other related matters.

- ❖ NAC 639 New LCB File R058-16 (effective 5-4-16) Establishes standardized procedures for pharmacists furnishing opioid antagonists to certain persons under certain circumstances; authorizing physicians to establish written protocols for the furnishing of opioid antagonists by registered pharmacists; adopting certain requirements for the written protocols established by a physician; requiring certain records to be kept confidential; and other related matters.
- ❖ NAC 639.955 LCB File R036-16 (effective 6-28-16) Penalty for failure to transmit Controlled Substance dispensing data to the PMP.

INVESTIGATION of COMPLAINTS

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 2016 is the number of complaints made through June 30, 2016.

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 or Deputy Secretary J. David Wuest. Based on 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.

Investigators Ken Scheuber and Dena McClish in Southern Nevada, and Deputy Secretary Dave Wuest, 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.

PHARMACIST ASSESSMENT FOR REMEDIATION EVALUATION (PARE)

- The (PARE) is a multi-dimensional assessment that the boards of pharmacy may use as an auxiliary tool when making decisions regarding pharmacist practice deficiencies that are due to noncompliance with pharmacy practice standards, laws or regulations, and result in compromises to patient safety.
- Format of the Assessment
- The PARE is a computer-based assessment that consists of 210 multiple choice questions. Examinees have a maximum of 4.5 hours to complete the exam. The questions will be drawn from three content domains:
- ❖ Medication Safety and the Practice of Pharmacy (Area 1 50% of questions)
- Professional Ethics/Pharmacist Judgment (Area 2 25% of guestions)
- Clinical Pharmacy Practice (Area 3 25% of questions)

Clients Assessed	2014-2016 Biennium	Prior
Pharmacists		
Retail	3	NA
Hospital/Infusion	0	0
Total		

The Pare examination was adopted in the current biennium as an evaluation tool for pharmacists.

PRESCRIPTION CONTROLLED SUBSTANCE ABUSE PREVENTION TASK FORCE

Created in 1997, the Nevada Prescription Controlled Substance Abuse Prevention Task Force (the Task Force) or Prescription Monitoring Program (PMP) is administered by the Board. The Task Force consists of participants from SAPTA, NDI, and healthcare 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.

This biennium, the Task Force began full implementation of online practitioner access to the data. The Task Force has online 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?

- The PMP is a database that contains information regarding controlled substances II, III, IV that are dispensed in Nevada.
- The database is designed to identify potential "doctor shoppers" (a felony)
- The PMP database software vendor is Appriss[®]. The product name is PMP AWARXE.
- How does it work, and who is required to use it?
 - Pharmacies and dispensing practitioners must report their controlled substance dispensations by end of next business day to the PMP database.
 - The database can then be queried by registered users (i.e. prescribers and dispensers), who may use the information to determine if a controlled substance prescription is necessary prior to prescribing and dispensing the controlled substances to the patient.
 - Access to the PMP database is also given to Nevada Division of Investigation (NDI), occupational licensing boards, and other selected law enforcement officials.
 - Staff filters the data submitted for warning signs of abuse, such as multiple doctors or multiple pharmacies
 - o If a patient sets off enough "red flags", the PMP generates an "unsolicited report".
 - The report is sent to NDI, who may use the information to check for active investigations, initiate an investigation, or refer to other law enforcement agencies.
 - The report is also sent to each practitioner and their respective licensing board 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".

- Prescribers are required to obtain and review a patient's PMP report prior to prescribing controlled substances if:
 - The patient is a new patient of the practitioner; OR
 - The prescription is for more than 7 days and is part of a new course of treatment for an existing patient of the practitioner's
- Number of registered users:
 - 61% of licensed prescribers and 53% of licensed dispensers are registered to use the PMP.

WHAT IS NABP PMP INTERCONNECT?

- NABP PMP InterConnect facilitates the secure exchange of PMP prescription data across state lines, allowing participating state PMPs across the United States to be linked. This provides a more effective way of combating drug diversion and drug abuse nationwide. As of July 1, 2016, AZ, AK, CO, CT, ID, IL, IN, KS, MI, MN, NM, ND, OH, SC, SD, UT, WV, WI and Nevada participate.
- Other states are working towards data sharing of PMP information through PMP Interconnect.

EDUCATIONAL PRESENTATIONS DURING THE BIENNIUM:

- Pharmacists/technicians
- Nursing Board
- Nevada Advanced Practice Nurses Association (NAPNA)
- Doctor of Osteopathic Medicine
- Dentists/Hygienists
- Police Department
- Behavioral Health
- o Kiwanis Club
- Surescripts Webinar
- National Association of State Controlled Substance Authorities (NASCSA)
- National Associations of Board of Pharmacy (NABP)
- Credentialing Association
- o Roseman University of Health Science
- Sierra Job Corp
- o Partnership Carson City

In 2015, the Board was awarded the two year Harold Rogers Prescription Drug Monitoring Program PDMP Implementation and Enhancement Grant. A statistician and Compliance Coordinator was hired to

carry out the objectives of the grant to decrease prescription drug abuse and deaths through the enforcement and use of the PMP.

DRUG ABUSE/GOVERNOR'S COMMITTEE

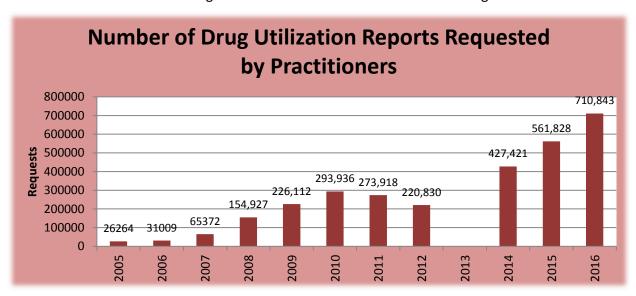
- ❖ The Board of Pharmacy in cooperation with the Medical and Osteopathic Boards, through the Legislative Committee on Healthcare, is addressing the growing issue of prescription drug abuse in Nevada.
- Executive Secretary Larry Pinson serves as a member of National Governors Association Policy Academy on Drug Abuse co-chaired by Governor Sandoval and Governor Peter Shumlin of Vermont.
- Executive Secretary Larry Pinson also serves as a member of Attorney General Adam Paul Laxalt's Substance Abuse Work Group.
- ❖ Executive Secretary Larry Pinson, Deputy Secretary J. David Wuest and General Counsel Paul Edwards are active participants in the Legislative Committee group, "Industry Coalition on Prescription Drug Abuse", and are all actively participating with Mr. Wuest usually attending meetings in person.
 - O The Committee is studying the abuse of prescription narcotic drugs, the monitoring of usage by patients, and developing methods to address and prevent prescription drug abuse.

SUPPORT OF LAW ENFORCEMENT

- ❖ The Board staff actively supported the various law enforcement agencies in their efforts to lower drug amounts available for trafficking.
 - o Task Force on Unlicensed Health Care and Scope of Practice issues.
 - The Task Force on Unlicensed Health Care has completed its mission, which was culminated during the last legislative session in a law that grants health care boards "cite and fine" authority against unlicensed health care activity. The Board has used this authority in cases involving pharmacists and intern pharmacists who have failed to renew their licenses or simply did not get licensed as well as against some of the medi-spa activity that the Board has investigated.
 - A major focus of the task force is the unlicensed health care individuals who are preying on low income and the immigrant population in Nevada.

CONTROLLED SUBSTANCE TASK FORCE DATABASE UTILIZATION

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



Note: the figure for 2012 and 2016 is the number of requests through June 30, 2016.

Data for the 2nd half of 2012 and the data for 2013 are unavailable.

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

Board Reports (available on website)

- Biennial 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.
- Governor's Code of Conduct Submission Report (every January of odd years)
- Comprehensive Review of Nevada Administrative Code (every 3 years).

WHAT LIES AHEAD FOR THE 2016-2018 BIENNIUM

Several foreseeable issues lie ahead for the Board in the 2016-2018 biennium and beyond, including:

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.

http://bop.nv.gov/resources/PrescriptionDrugAbusePreventionVideo/

EDUCATIONAL PRESENTATIONS

The Board staff has been extremely active on providing live presentations both on site and via telephonic call in, and also in creating and posting video continuing education on the Board website. These presentations cover a variety of subjects.

- Continuous development and presentation of CE to practitioners, pharmacists and pharmacy technicians. http://bop.nv.gov/services/Continuing_Ed/
- CE for law enforcement and with law enforcement.
- o Continuous education for fellow health care boards.
- o Continuous education of the public through public meetings and JTNN.
- The Board Executive Secretary has addressed practically every medical discipline in Nevada on prescription drug abuse, as well as presentations to the National Association of Boards of Pharmacy; the Attorney General's Work Force; Project Echo through UNR and JTNN; Child Death Review Committee and the Washoe County Social Works Department. Continuing education presentations

have been offered by practically all senior staff (Executive Secretary, General Counsel, Deputy Executive Secretary, Inspectors and Investigators) and our Prescription Monitoring Program (PMP) Administrator on the use of Nevada's PMP.

CONTINUING EDUCATION IN NEVADA PHARMACY LAW

- The Board of Pharmacy Executive Secretary, Larry Pinson, Deputy Secretary J. David Wuest, Inspector Luis Curras, Inspector Joe Dodge 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.
- ❖ Inspector Curras will also provide live telephone Nevada law continuing education throughout the biennium.

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*.

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.

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.
 - o 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

- "What lies ahead?"
- The Board continues to bring forward regulations needed to protect the public based on facts presented by various government agencies and law enforcement.
- The Board continues to actively participate both statewide and nationally on addressing pharmaceutical drug abuse and abuse prevention.

- 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. Many 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.
 - The Board is addressing the changes enacted in Federal rules for compounding pharmacies with the passage of the Drug Quality and Security Act (DQSA) by the Congress and signed into law by the President.
 - The Drug Quality portion of the act classifies pharmacy into one of two categories 503A traditional pharmacies and 503B outsourcing pharmacies.
 - 503A pharmacies compound patient specific prescriptions under USP 795 and USP 797 (United States Pharmacoepia)
 - 503B pharmacies/facilities may compound for office use and must comply with more stringent rules under cGMP (current Good Manufacturing Practices).
 - The Board intends to train inspectors on cGMP to inspect to and ensure compliance by Nevada 503B licensed pharmacies with cGMP requirements.
 - The Board will additionally be addressing changes necessary to Nevada regulation relating to hazardous sterile and non-sterile pharmaceutical compounding. The FDA removed requirements for hazardous compounding from chapters 797 and 795 and finalized a new chapter, chapter 800, to the United States Pharmaceopia. Chapter 800 deals exclusively with hazardous compounding. Pharmacies compounding hazardous drugs must be compliant with the new USP chapter by May 2017.
 - 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.