



Nevada State Board of Pharmacy

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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 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. Having said that, we presently have thirty-three 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 summary of the chapter by chapter review of our regulations is below and a spreadsheet of the regulation-by-regulation review is included.

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. Specifically, the problems for which these regulations were established are obvious given the alarming increase in drug abuse in Nevada. Often our regulations parallel federal enactments by the DEA. Impact of these regulations, both good and bad is difficult to judge; i. e. Does scheduling a drug actually decrease abuse of that drug? Does the cost of law enforcement outweigh the cost of diversion to business; the cost of rehab and drug related crime to our communities? Do these regulations and their enforcement help to prevent our youth from experimenting with drugs often leading to addiction? The regulations are clearly written, most often simply listing drugs and chemicals in various schedules.

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") These regulations are necessary to ensure that properly trained, educated and licensed people are the only ones with the authority to possess and administer dangerous drugs and controlled substances. Costs are recovered through licensing fees and the impact of ensuring safe medication practices is obvious. These regulations are clearly written and establish the necessary parameters for health care professionals with respect to the handling of drugs.

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 our 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 pharmacists 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.

Chapter 639 was established to regulate pharmacists and the practice of pharmacy, pharmacy being one of the most regulated of all professions nationwide. The value to the public is obvious, that being safe medication practices, therefore the necessity of these regulations. Drug therapy today is complicated and not without adverse effects and drug interactions. Costs of enforcement are recovered through licensing fees and costs to business are part of providing pharmacy service. The regulations are written clearly and are not addressed in other sections of law.

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