



NATIONAL ASSOCIATION OF
SPECIALTY PHARMACY

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November 01, 2021

The Honorable Aaron D. Ford
Attorney General, State of Nevada
Office of the Attorney General
555 E. Washington Avenue, Suite 3900
Las Vegas, Nevada 89101

RE: Nevada Board of Pharmacy Reinterpretation of N.R.S. 639.100(1)(a)

Dear Attorney General Ford:

I write today on behalf of the National Association of Specialty Pharmacy (NASP) and our specialty pharmacy members that operate in the state of Nevada. It is our understanding that the Nevada Attorney General has been requested by the Nevada State Board of Pharmacy (“the Board”) to review the following question: *Does Nevada law require pharmacists dispensing drugs to be licensed?* This question follows the Board’s July 2021 opinion letter that reinterpreted N.R.S. 639.100(1)(a) so that now each pharmacist that works at a non-resident pharmacy must obtain a license from the Board. Previously, the regulation was interpreted so that only the non-resident pharmacy as a whole was required hold the licensure in Nevada, not each pharmacist.

In light of this new regulatory interpretation, and as you review this question, we believe that it is important for you to understand the impact that this rule will have on non-resident specialty pharmacy practice, and ultimately patients who require access to specialty medications in Nevada.

NASP represents the entire spectrum of the specialty pharmacy industry including the nation’s leading specialty pharmacies and practicing pharmacists; nurses and technicians; small and mid-size pharmacy benefit managers (PBMs); pharmaceutical and biotechnology manufacturers of specialty drugs; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; patient advocacy organizations; and technology, logistics and data management companies. NASP defines a specialty pharmacy as a state licensed and registered pharmacy that is accredited by an independent, third-party accreditor and solely or largely provides medications and patient medication management services to patients with complex and chronic diseases requiring expensive and challenging treatment with complex



medication therapies. Specialty pharmacies that work in Nevada have unique expertise in supporting patients with conditions like cancer, multiple sclerosis, cystic fibrosis, and HIV/AIDS.

Regulation Interpretation of Non-Resident Pharmacies Issued by the Board:

On July 22, the Board began informing NASP members that operate as non-resident specialty pharmacies in Nevada that the state had recently changed their interpretation of the state's regulation of non-resident pharmacies. Under the new interpretation, any pharmacist compounding or dispensing any prescription for a patient located in Nevada must obtain a license and register with the Board.

The interpretation of the regulation constitutes a significant shift in policy and has significant negative and consequential impacts on pharmacies and patients. The interpretation was issued independent of any public notice and comment period. N.R.S 233B.061 states that when engaging in rulemaking, including interpretation of a regulation, "all interested persons must be afforded a reasonable opportunity to submit data, views or arguments upon a proposed regulation, orally or in writing." Furthermore, N.R.S 233B.0603 also requires that a notice of intent be shared with the public if adopting or amending an existing regulation, and that the notice of intent must include a statement of the estimated economic effect of the regulation on the business which it is to regulate. The Board did not engage in a public comment period, nor did they issue a notice of intent to review an existing regulation, in violation of the state's rulemaking requirements.

Non-Resident Licensure Interpretation in Other States:

The Board's interpretation of non-resident pharmacy registration makes Nevada the only state to require that all pharmacists who work for a non-resident pharmacy be licensed in Nevada to dispense medications to state residents. This interpretation is neither fair or reasonable, does nothing to enhance patient safety, and threatens to limit patient access to those pharmacies that are unable to respond to this new burdensome and unnecessary requirement that all pharmacists in a non-resident pharmacy take the Multistate Pharmacy Jurisprudence Examination ("MPJE") and pay related fees.

Other states require that for a non-resident pharmacy to register and operate in the state, only the pharmacist-in-charge be state licensed. We believe that this interpretation as implemented in other states is reasonable.

Impact on Specialty Pharmacy:

Specialty pharmacies work with patients that have serious and often life-threatening conditions. These pharmacies dispense medically complex drugs, including drugs that are not routinely available. Specialty medications are not commonly available at retail pharmacies and require specialized staff that are knowledgeable about disease state management for life-threatening



conditions and have specific knowledge about medically complex patient needs to monitor and manage drug adherence. Because of the complexity of specialty drugs, many specialty pharmacies operate from a centralized location and provide services and care to patients across a number of states. For these reasons, many patients in Nevada who are living with medically complex conditions receive their specialty medications from a non-resident pharmacy.

For specialty pharmacies that are providing extensive services to support patients with complex health care management needs and are often the only pharmacy resource for patients, the new regulatory interpretation by the Board is untenable as the costs and the capacity burdens would be restrictive for their ability to operate in the state. Ultimately, for patients with specialty conditions like a rare or orphan disease, multiple sclerosis, cancer, cystic fibrosis, organ transplant, and HIV/AIDS, any potential delay, halt, or disruption in treatment that results from specialty pharmacies being unable to operate in the state due to this regulatory interpretation and its impact threatens the health and livelihood of patients seeking to access their medications. Without access to their specialty pharmacy, patients could face immense setbacks in their treatment, leading to increased emergency room visits, hospital admissions and healthcare costs.

Request of Nevada Attorney General:

The Board's recent interpretation of N.R.S. 639.100(1)(a) will have a significant negative and consequential impact of non-resident specialty pharmacies and their patients. We urge the Attorney General to consider the full impact of the question asked by the Board as well as the impact of the regulatory interpretation and address our urgent concerns by encouraging the Board to reconsider their interpretation of N.R.S. 639.100(1)(a). We want to ensure specialty pharmacies that are safely serving Nevada's residents can continue to do so.

Thank you for your consideration. If we can provide additional information, please contact me at 703-842-0122 or sarquette@naspnet.org.

Sincerely,

A handwritten signature in black ink that reads "Sheila Arquette". The signature is written in a cursive style with a large, sweeping flourish at the end.

Sheila Arquette, R.Ph.
President and CEO