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# Nevada Rare Disease Advisory Council

# State of Nevada Governor’s Advisory Council on Rare Disease 2022 Annual Report

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## Introduction

In the United States, the Food and Drug Administration (FDA) defines a rare disease as any disease that affects fewer than 200,000 Americans. Our European Colleagues consider a disease rare when it affects less than 1 in 2,000 people. Regardless the contrastingly different attitudes towards what constitutes a rare disease; these number at first glance may seem insignificant. However, considering that there are more than 7,000 known rare diseases which affect approximately 25 million people. This is roughly translated to about 10% of the U.S. population. Rare diseases are far more common than the term” rare disease” implies.

Rare diseases are a significant contributor of chronic illness, disability, and premature death in both children and adults. They take a disproportionate share of our health care dollars and generate an enormous administrative burden on the healthcare industry as a whole because of their complexity and the expense of, in most cases, inadequate medical interventions.

A Rare Disease Advisory Council (RDAC) is an advisory body providing a platform for the rare disease community to have stronger voice in state government. RDACs address the needs of rare patients and families by giving stakeholders an opportunity to make recommendations to state leaders on critical issues including the need to increased awareness, diagnostic tools and access to affordable treatments and cures. In 2015, the first state advisory council on rare diseases was created in North Carolina. Since the inception of the first RDAC, several states have established their own RDACs, and the national trend is taking hold with rare disease stakeholders across the country diligently working to establish a mechanism to allow improved representation of the this historically underserved and often misunderstood population of people.

The formation of the Nevada Rare Disease Advisory Council (“the Council”) was formed under SB 315 during the 2019 session of the Nevada Legislature. The council was assigned several specific duties; one of which is to compile an annual report that includes a summary of the council’s activities and any recommendations of the council for legislation or other policies.

The Nevada RDAC respectfully submits the second official Nevada Rare Disease Advisory Council (RDAC) annual report. We are proud to offer a summary of the Councils activities as well as our recommendations for legislation and policy improvements.

## How Does Nevada Rank Nationally?

Since 2015, the National Organization of Rare Disorders (NORD) has reported on its State Report Card project with the goal of evaluating how effective states are in meeting the needs of their citizens with rare diseases. Although, the report card scores state on many eight (8) specific and relevant policy and access areas; it is important to note that this grading criteria is not exhaustive and there are many, many important factors impacting the lives of rare disease patients that need to be addressed even though they are not reflected in this ranking.

## Nevada’s Report Card

Medicaid Financial Eligibility: **A**

Medicaid Eligibility (% of FPL) for Childless Adults: **A**

Medicaid Eligibility (% of FPL) for Parents of a Dependent Child: **A**

Medicaid Eligibility (% of FPL) for Pregnant Women: **C**

Medicaid Eligibility (% of FPL for Family) for Children: **B**

Medical Nutrition**: B (**coverage for any condition for which medical nutrition is a medically necessary component of effective treatment).

Private Insurance Coverage Requirements: **B**

Private Insurance Covered Disorders: **C**

State Coverage Requirements: **B**

State Covered Disorders: **A**

Newborn Screening**: B**

Screening for RUSP Core Conditions: **C**

Adding Screens: **B**

Funding: **B**

Dried Blood Spot (DBS) Use: **D**

Advisory Committee: **A**

Prescription Drug Out-of-Pocket Costs: **F**

Protecting Patients in State-Regulated Insurance: **C**

Initial Plan Duration: **C**

Renewals: **D**

Maximum Duration: **C**

Rare Disease Advisory Councils (RDAC): **PASS**

Step Therapy**: F**

Step therapy is a process by which insurers (public or private) require patients to take one or more alternative medications before they can access the medicine prescribed by their provider. While this is done by insurers as an attempt to control health care costs, step therapy has been increasingly applied to patients with little regard for their medical situation or treatment history.

Telehealth: **PASS**

Nevada’s report card has remained unchanged from the initial RDAC annual report submitted for the 2021 calendar year. Despite ongoing outreach to several government agencies including Medicaid to address prescription drug & step therapy issues as well the many factors impeding access to care for many Nevadans with rare diseases- we remain in an unacceptable rating on critical issues.

The council does not currently have advisement authority on prescription formularies or other access matters for rare disease and therefore is prevented from advising on standards of care therapy or cost reduction pathways to pursue in this regard.

The council continued to provide feedback that current Medicaid Service Manuals for conditions are severely outdated and encourage prescription patterns that are not in line with current best practice. Similarly, it was conveyed that the use of national PBMs such as Magellan do not adequately provide services consistent with the specific needs of Nevada.

The council appreciates that Nevada faces many challenging as a state and we urge the Governor’s office to recognize that patients in any state with rare diseases present fundamentally different challenges from those of more common diseases. In Nevada, these challenges are exacerbated by outdated policy, inadequate reimbursement models (billing guides), uninformed protocols for access to care and a complete lack of effective collaboration between the various stakeholders. We have a long way to go in Nevada and if the RDAC is to be successful at fulfilling the important objectives outlined in SB 315 we must first start with improved collaboration.

The following pages provide a status report on each of the duties assigned to the Nevada RDAC through SB 315; including an overview of the RDAC’s legislatives objectives and the councils’ recommendations based on their initial activities with an emphasis on the work completed in 2022.

[1] Objectives may appear out of numerical order, as certain activities and recommendations apply to more than one objective.

# Status Report on Duties assigned to the Nevada RDAC through SB 315, 2022 RDAC Activities and Legislative Objectives, including Council Recommendations

## Objective #1 & #11:

**Objective #1 – Perform a statistical and qualitative examination of the incidence, causes and economic burden of rare diseases in Nevada.**

**Objective #11 – Develop a registry of rare diseases diagnosed in Nevada to determine the genetic and environmental factors that contribute to such rare diseases**

Activities:

a. The council has established a data base/registry of a small number of rare diseases identified in Nevada; this data is exclusive to pediatric cancer, inherited bleeding & clotting conditions, and newborn screening conditions (Sickle Cell Disease as an example). These conditions were identified by the RDAC to be the initial areas of focus council.
b. Ongoing data collection efforts have been challenging due to the lack of infrastructure support for these efforts.
c. The ability to conduct a statistical and qualitive examination of the incidents, causes, and economic burden of rare disease in Nevada is not likely to be accomplished without adequate funding to the RDAC.

Recommendations:

d. The establishment of a well-defined strategic plan to establish the infrastructure and financial support required for the RDAC to accomplish the duties assigned to the council by The Governor’s office in objective 1 & 11. The RDAC is not likely to be successful at its objectives without the foundational data required to showcase the true burden of rare disease within the state.
e. The Council respectfully requests authorization to proceed with presenting one Bill Draft Request (BDR) during each legislative session moving forward. Without the ability to pursue meaningful changes at the legislative level, the Nevada RDAC will not be able to accomplish its objectives.
f. The Council continues to recommend that the Nevada Department of Health and Human Services (DHHS) include Council input when establishing regulations and an advisory committee for all claims payor database. Approaches could include presentation of tentative regulations for Council meeting review or the inclusion of Council members in the advisory committee itself. This approach would better facilitate the appropriate inclusion and categorization of rare diseases to facilitate a potential future statistical analysis. As of November 1, 2022, we have not been invited to present to the Patient Protection Commission or notified of meetings that may have arisen for this topic.

## Objective #2:

Objective # 2 – Receive and consider reports and testimony concerning rare diseases from persons, the Division, community-based organizations, providers of health care and other local and national organizations whose work relates to rare disease.

Activities:

a) The Council has received several personal and professional testimony of experiences with rare disease. Additionally, the Council has collaborated with the Patient Protection Committee and built professional relationships with the National Organization for Rare Disorders, and local clinicians burdened with trying to improve care for patients with rare disease.
b) Through community-wide collaboration the council has established a Nevada RDAC website with the goal of expanding awareness of and involvement with the NV-RDAC to expand the capabilities of objective #2. NVRDAC – Nevada Rare Disease Advisory Council

Recommendations:

a. The Council continue to foster additional partnerships to continue to receive testimony. The Council recommends the NV- RDAC website to developed further to adequately compile resources and education for consumers and clinicians.

## Objective #3 & #7:

Objective # 3: Increase awareness of the burden caused by rare disease in Nevada.

Objective #7: Increase awareness among providers of health care of the symptoms of and care for patients with rare disease.

1. Activities: The Council Educational Subcommittee continues to develop educational content for all levels of rare disease involvement from community support resources, clinicians, and patients. Currently, the Educational Subcommittee is working on uploading diagnosis specific information to be included in the Council website. This content will connect consumers to clinicians and community support by name of diagnosis as opposed to specialty which has delayed appropriate connections.

2. Recommendations:

    a. The Council seeks assistance from DHHS to compile a more complete directory of state clinicians under a taxonomy which more clearly identifies their skill in rare disease. It is too common for insurance directories to overlap community providers obfuscating the reality of the state's shortage and mandating patients see preferred clinicians regardless of the panel's skill in rare disease.

b. The Council will continue to provide and seek testimony on the burden of rare disease at state and national meetings.

c. The Council requests a meeting with the DHHS to improve reimbursement for rare disease care.

d. The Council will continue to work hand in hand with NORD and websites such as FindZebra to improve information in the state.

**Objective #4 & #9:**

*Objective # 4 - Identify evidence-based strategies to prevent and control rare disease*

*Objective # 9 - Determine the effective methods of collecting data concerning cases of rare diseases in Nevada for the purpose of conducting epidemiological studies of rare disease.*

1. Activities: Data is required to develop evidence-based strategies. Currently, Nevada has no such centralized registry nor database from which to compile evidence-based strategies specific to Nevada. The Council has heard from multiple rare disease experts who have been successful in developing care pathways but who struggle with, sustainably, providing this care.

2. Recommendations:
    a. As such expertise is housed in specific statewide centers of excellence, it is paramount that continuity of care for patients with rare disease be maintained.

    b. The council recommends that Medicaid Service Regulations be updated to include the following requirement:

    > All payers currently providing managed Medicaid services or exchange based plans to Nevada beneficiaries must include, at a minimum, the same provider network as fee-for-service Medicaid. There has been no movement in this regard despite ongoing conversations with Medicaid in 2021.

**Objective #5:**

*Objective # 5 - Determine the effect of delayed or inappropriate treatment on the quality of life for patients suffering from rare disease and the economy of Nevada*

1. Activities: As with all such committees, the exact monetary impact cannot be determined without appropriate funding. Current national research has historically been shared, but does not include the impact on local policies.

2. Recommendations:

    a. Without a mechanism to register patients with rare disease, the Council is unable to determine data which is specific to patients in Nevada. While barriers remain for ERISA specific plans, the Nevada Division of Insurance should require all payers seeking to provide rare disease care maintain an open network which at minimum aligns with fee-for-service Medicaid. This will prevent the significant delays that patients with rare disease currently face when having to move between plans and reduce the disruption in therapy access. The Council has not received feedback from the Department of Insurance regarding this recommendation

### Objective #6, #8, & #10:

*Objective # 6 - Study the effect of early treatment for rare disease on the quality of life for patients suffering from rare disease; the provision of services to such patients and reimbursement for such services*

*Objective #8 - Evaluate the systems for delivery of treatment for rare diseases in place in Nevada and develop recommendations to increase the survival rates and quality of life of patients with rare disease.*

*Objective #10 - Establish a comprehensive plan for the management of rare diseases in Nevada which must include recommendations for the state and local health authorities, public and private organizations, businesses and potential sources of funding, and update the comprehensive plan as necessary.*

1. Activities: The Council appreciates Governor Sisolak’s support of this important goal. The Council has discussed the various systems and services currently in place through experiential dialogue.

2. Recommendations:

    a. The Council is requesting assistance from DHHS to provide grant writing and submission assistance to community partners who otherwise may not have the resources to do so, to improve state funding for such programming and provide grant administration assistance with accounting and reporting. This remains unaddressed and unchanged from 2021.

    b. The Council is requesting assistance from DHHS to develop a state disease specific reimbursement model to reduce administrative burdens and properly reimburse the complexity of the level of care. The current mechanisms for reimbursement which, for example, limit the use of the code 99215, increase the patient burden of having to come back for multiple lower-level visits and does not fully cover the complexity of the care provided. The council was notified that providers can request prior authorization for 99215 in advance but that the limitations of this administrative burden would remain. Requests by individual council members to ascertain the history and creation of this particular policy and the Nevada specific need for its implementation remain unanswered beyond the "potential for clinician abuse." Objective reports to substantiate this occurs in Nevada have not been received per individual council members.

    c. The Council is requesting assistance from DHHS to develop an additional statewide reimbursement model to provide incentives for providers to provide rural care. DHHS presented three possible models but as of November 1, 2022 no further updates have been received as to whether this will proceed.

e. The Council requests funding for a patient navigator who can assist Nevadans with accessing rare disease specific care. The Council could develop road map and transition and continuity of care algorithms, and this role could be shared with the Patient Protection Commission patient navigator.

f. The Council requests the funding of a study which would evaluate the development of a new specialty designation and curricula for physician residency programs, advanced nurse, and nursing programs with a specific focus on rare disease.

g. The Council also requests a legislative modification to provide authority to speak on and provide recommendations such as Silver State Formulary decisions as they relate to rare disease.

## Conclusion

As noted above, the Council's activities continue to be hindered by both a lack of adequate funding and a lack of authority of the Council to provide advisement beyond an annual recommendation. Limited or varying insurance coverage of rare disease providers, as well as differences in reimbursement for services continue to be a significant barrier in making meaningful comparisons or data analysis in rare disease policies.

The Council members remain committed to assisting rare disease in Nevada, however, the lack of resources, inability to provide legislative input via BDR, and lack of department communication continues to provide immense barriers to make meaningful change. The Council recognized the devastating budgetary impacts that COVID-19 has had on Nevada's budget and the reality that not all legislatively implemented councils could be funded. We recommended in 2021 to be integrated into the well-funded Patient Protection Commission. The Council felt that many of the objectives of the Council and the Commission overlap and would serve both rare disease and non-rare disease patients alike in the progression of patient centered initiatives and policies. This integration would have created a more centralized place for patients to seek assistance. When asked about this in Medicaid follow-up regarding this recommendations with DuAne Young the council was notified that to level set our expectations this would never happen as the PPCs focus is cost growth targets.

The Council expresses their sincere gratitude to Governor Sisolak and the 2019 Legislature for the acknowledgement of the need to update and improve rare disease policies in Nevada. The Council has been honored to seek a path forward on behalf of patients, families, caregivers, and others who have fought to bring about this public body. We also wish to express gratitude for the tireless efforts of the DHHS staff with agenda, meeting, and minute recording support.

We look forward to having DHHS, the governor's office, and legislative authors review these recommendations for consideration and feedback. As always, the Council remains committed to progressing the care of Nevadans with rare disease in any way we can.

Respectfully submitted.

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