MINNESOTA
RARE DISEASE
ADVISORY COUNCIL

Rare is not rare.

PATIENT ADVOCACY GROUP LISTENING SESSION: *INSIGHTS REPORT*

2024

The Minnesota Rare Disease Advisory Council (RDAC) Community Legislative Debrief

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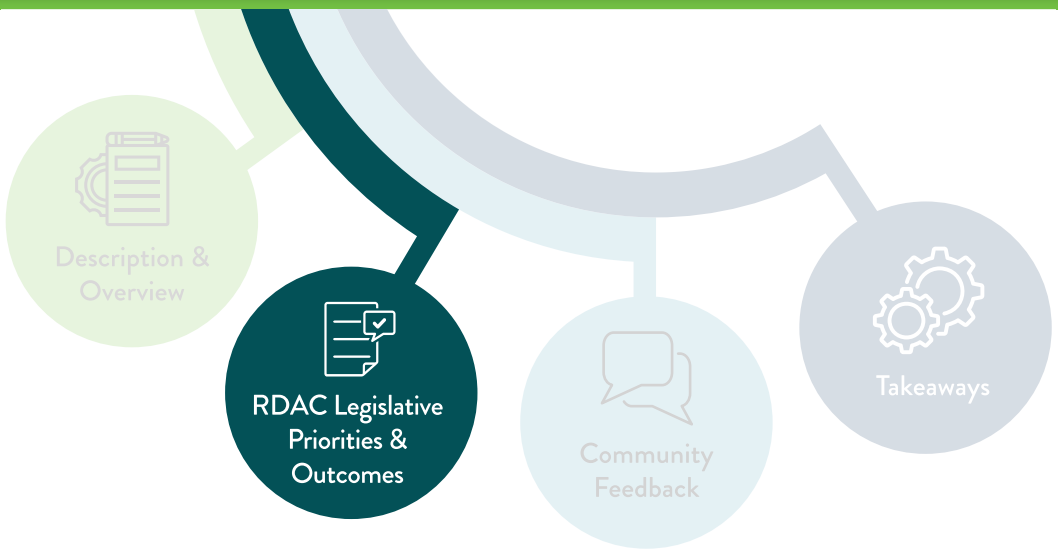
The purpose of this document is to summarize the 2024 Community Legislative Debrief and to outline the Minnesota Rare Disease Advisory Council's (RDAC) legislative priorities and involvement related to the rare disease (and disability) community.

DESCRIPTION AND OVERVIEW

The Minnesota Rare Disease Advisory Council (RDAC) hosted a Community Legislative Debrief following the 2024 legislative session. The debrief, which was a hybrid of virtual and in-person, had two primary objectives. The first objective was to provide a summary of the 2024 Minnesota legislative session and cover all the legislation that passed which would benefit the rare disease (and disability) communities and included the Minnesota Council of Disability priority updates presented by Trevor Turner, Public Policy Director. The second objective was to provide a forum for members of the rare disease community to share any concerns they are experiencing in accessing quality care and for patient communities to share any priority policies they might have. About 55 individuals attended the debrief. This included patient advocacy group representatives, racially/ethnically diverse organization representatives, state agency staff, state lawmakers, industry partners, physicians, and individual members of the rare disease community.

Patient advocacy groups that were represented (click organization to visit their website):

- The Minnesota Indian Affairs Council (MIAC)
- The Prader-Willi Syndrome Association of Minnesota
- The Coalition of Asian American Leaders (CAAL)
- The Minnesota Council on Disability (MCD)
- The Minnesota Department of Human Services (DHS)
- The Minnesota Department of Health (MDH)
- The PACER Center
- The ALS Association
- The Sickle Cell Foundation of Minnesota
- The Minnesota Consortium of Citizens with Disabilities (MNCCD)
- The Minnesota Medical Association (MMA)
- The Midwest Rhett Syndrome Foundation



OVERVIEW OF RDAC LEGISLATIVE PRIORITIES AND OUTCOMES PRESENTED

Background provided to attendees

The Minnesota State Legislature operates on a two-year cycle with odd years being budget years and even years being policy years. The 2024 legislative session was a policy year. Compared to a budget year where legislation with a lot of funding attached to it is heard by lawmakers, in policy year lawmakers are more inclined to consider legislation with policy changes that have no cost to them or legislation that has a minimal financial impact. This was one of the important contexts that RDAC had to consider when deciding legislative priorities and the overall advocacy strategy heading into the 2024 legislative session. RDAC used its four pillars to determine priority legislation.

1. Deepening our understanding of the collective needs of the rare disease community
2. Reducing the time to diagnosis
3. Increasing coordination of care/improving transition of care
4. Accelerating rare disease research

2024 Legislative Priorities for RDAC

RDAC had the following priorities during this legislative session (click bill numbers to see the online version):

- Implementation of the Network Access Bill (HF384/SF1029)
- Unbundling gene products from current reimbursements to hospitals (HF3664/SF4058)
- Expanded coverage for Rapid Whole Genome Sequencing (rWGS) for critically ill children with suspected rare diseases (HF3330/SF2445)
- Prior Authorization Reform (HF3578/SF3532)
- Increasing RDAC base operating budget (HF3841/SF3927)
- Copay accumulator ban included in Medical Debt Bill (HF4100/SF4065)
- Disability legislation

OVERVIEW OF RDAC LEGISLATIVE PRIORITIES AND OUTCOMES PRESENTED *continued...*

Policy Summary 2024 -Legislative Priorities & Outcomes

NETWORK ACCESS BILL (HF384/SF1029)

The HHS Omnibus included this landmark legislation that allows individuals with a diagnosed rare disease (or a suspected rare disease defined by specific criteria) to receive care from a specialist with expertise in their rare disease without being assessed an out-of-network fee by health plans.

PASSED: Currently in effect

UNBUNDLING GENE PRODUCTS FOR RARE DISEASES FROM CURRENT REIMBURSEMENTS TO HOSPITALS (SF4058/HF3664)

This bill provides separate reimbursement for biological products provided in the inpatient hospital setting as part of cell or gene therapy to treat rare diseases separate from the associated DRG. This increases access to emerging and innovative treatments, allows hospitals to provide gene therapy without significant financial loss, and allows payers to enter into value-based arrangements with manufacturers.

PASSED: Effective July 1st, 2025

EXPANDED COVERAGE OF RWGS FOR CRITICALLY ILL INFANTS WITH SUSPECTED RARE DISEASE (SF2445/ HF3330)

This bill requires commercial payers (including managed care organizations contracted with the State) to cover rapid whole genome sequencing (rWGS) for children under the age of 21 in the ICU, reducing time to diagnosis. Reimbursement must be separate from the DRG/capitated payment.

PASSED: Effective January 1, 2025

PRIOR AUTHORIZATION REFORM (SF3532/ HF3578)

This bill streamlines prior authorization and requires reporting related to how and when prior authorization is being used by payers. This improves timely access to treatments by reducing some prior authorization requirements, including treatment of a chronic condition.* This authorization does not expire unless the standard of treatment for that health condition changes.

PASSED: Effective January 1st, 2026

**A chronic health condition is defined as: a condition that is expected to last one year or more and: (1) requires ongoing medical attention to effectively manage the condition or prevent an adverse health event; or (2) limits one or more activities of daily living.*

OVERVIEW OF RDAC LEGISLATIVE PRIORITIES AND OUTCOMES PRESENTED *continued...*

Policy Summary 2024 -Legislative Priorities & Outcomes

RDAC FUNDING (HF3841/SF3927)

As a new state agency, RDAC wanted to ensure that the base operating budget was fully funded. This additional funding would enable RDAC to carry out its duties prescribed by state statutes and better serve the rare disease community.

PASSED: Effective July 2024

COPAY ACCUMULATOR (HF4100/SF4065)

Copay accumulator programs are coupons issued by drug manufacturers for expensive specialty medications to reduce deductibles and coinsurance rates for individuals. Unfortunately, these coupons do not end up going towards patient cost sharing. Payers argue that cost sharing is necessary to push people to find less expensive alternatives. However, for patients with rare diseases there are usually no other options. While the ban on copay accumulators was taken out of the medical debt bill, the bill was introduced as a standalone bill with the option to be reintroduced in 2025.

Did not pass

DISABILITY LEGISLATION

Due to the significant overlap between the disability and the rare disease community, RDAC followed several disability policies that were being considered in the legislature. Trevor Turner of the Minnesota Council on Disability (MCD) provided an overview of the legislative priorities that passed this session which benefits the broader disability community.
This included:

- The passage of a bill to increase wages for drivers of transportation network companies. This bill also included pay incentives for drivers who make their vehicles wheelchair accessible.
- The passage of the Minnesota Rise, Innovate, Succeed and Empower (RISE) Act which would create standards for how universities and institutions of higher education communicate with students about disability services and their rights to reasonable accommodations.
- The passage of a bill to include episodic disabilities in the Minnesota Human Rights Act.
- The passage of a bill to clarify requirements for service animals to apply to all people with disabilities.
- Other bills that MCD supported included bankruptcy protections for individuals with disabilities who have modified their homes, adding disability rights to social studies curriculum, and enabling PCA's to continue serving clients even when they are in the hospital.

COMMUNITY FEEDBACK

The remainder of the debrief focused on listening to the needs of the rare disease community. This included discussions about:

- Outreach to racially/ethnically diverse communities
- Copay accumulator programs
- Use of cannabis and other alternative medications to treat rare diseases
- Having homecare nurses present at schools
- Access to medical foods
- What happens after medications are approved by the FDA?
- Expanding prior authorization reform to include durable medical equipment such as wheelchairs

Outreach to racially/ethnically diverse communities

One of the participants from the Coalition of Asian American Leaders brought up the need for agencies like RDAC and MCD to do more outreach particularly for immigrant families to help them understand the disability services that are available in Minnesota. Outreach to racially/ethnically diverse communities is a priority for RDAC to ensure that all people with rare diseases are part of the decision-making process and are aware of important policy changes that affect them and their families.

Copay Accumulator Programs

The ALS Association identified a ban on copay accumulator programs as a particular priority for their patient community. Copay accumulator programs are coupons issued by drug manufacturers for expensive specialty medications to reduce deductibles and coinsurance rates for individuals. Unfortunately, these coupons do not end up going towards patient cost sharing. Payers argue that cost sharing is necessary to push people to find less expensive alternatives. However, for patients with rare diseases there are usually no other options. While the ban on copay accumulators was taken out of the medical debt bill, the bill was introduced as a standalone bill with the option to be reintroduced in 2025.

COMMUNITY FEEDBACK, *continued*

Use of cannabis and alternative medications to treat rare diseases

Patient advocacy groups like PACER and the Sickle Cell Foundation, brought up issues concerning the use of cannabis to treat certain rare diseases. Two primary issues were discussed. The first issue was that schools are requiring students with seizure disorders to be picked up by their parents and driven off campus to receive their medication. This is harmful for students who are prone to emotional dysregulation when their routine is disrupted. It is also the case, that sometimes individuals have only responded to cannabis to treat their seizure disorders and no other medications. Right now, school nurses are not required to administer over the counter medications to students if they feel uncomfortable. Even in instances where students have received the medication from regulated medical marijuana dispensaries, or the drug has been approved by the FDA, schools are still reluctant to administer the medication at school. The second issue is that for members of the pain community, physicians will deny them their opioids for pain management if cannabis is detected. Research has shown that this community is less likely to abuse pain killers and using cannabis reduces reliance on pain killers. Some of the community members at the debrief wondered if a federal reclassification of marijuana from Schedule 1 (no medical use) to Schedule 3 (medical use) would address this issue. Advocates noted that part of the problem is medical bias and hospitals not following guidance on treating Sickle Cell.

Homecare nurses in schools

Advocates from the PACER center and even MCD routinely get complaints from parents who are being told by schools that their child cannot have their homecare nurse present with them during school hours. This sometimes leads to parents deciding not to send their child with a disability to school because they are unsure whether the school can adequately meet the child's needs.

COMMUNITY FEEDBACK, *continued*

Medical Foods

For many patients with rare diseases, a primary source of treatments are medical foods. One of the participants at the debrief noted that many of the patients cannot access formula due to lack of insurance coverage for medical foods. This is an issue that has been raised to RDAC in the past.

What happens after FDA approval?

The Prader-Willi Syndrome Association of Minnesota does a lot of advocating for rare disease funding. The challenge is that once a drug is approved by the FDA many advocates do know where to start to ensure that community members can access these drugs. Erica Barnes, RDAC's Executive Director, responded that the state drug formulary committee meets to decide the prior authorization criteria and state formulary decisions. For that to happen, drug companies must first participate in the Medicaid drug rebate program for their drugs to be on the state formulary. Commercial insurance companies have a different calculus for determining what drugs to cover. Erica noted that the Drug Formulary Committee provides opportunities for public comment and public testimonies. RDAC will continue to inform the rare disease communities about these opportunities for public input.

Expanding prior authorization reform to include durable medical equipment like wheelchairs

The issue of prior authorization requirements for durable medical equipment was raised. Prior authorization is required for not just the wheelchair but for any adjustments, new parts, or subsequent wheelchairs which adds significant burden and delayed access to necessary equipment.

TAKE AWAYS

Key takeaways for RDAC staff following the community debrief:

- The forum was an invaluable opportunity for patient advocacy group representatives to connect with one another across rare diseases and suggest ways to collaborate further after the event.
- Accessing alternative treatments such as cannabis and medical foods remains a challenge for the rare disease community.
    - A lack of treatments and chronic pain are unique to the rare disease community. Since this community does not have too many options there is an urgent need to make it easier to access these alternative therapies such as cannabis. In fact, of the 7,000 rare diseases only 5% have known treatments.
- There is a need for increased care in the schools for students with rare diseases.
- Many of the issues discussed cut across rare disease communities.
- It is important for the rare disease community to participate in opportunities such as offering public comment/testimony at the Drug Formulary Committee and Newborn Screening Committee to ensure the patient voice is heard.
- Prior authorization reform is a significant milestone towards improving access to quality healthcare for the rare disease community.