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H.46 (STONE) VT RARE DISEASE ADVISORY COUNCIL (RDAC)

NORD'S Project RDAC

East | *AL, CT, DE, FL, GA, IN, KY, ME, MD, MA, MI, MS, NH, NJ, NY, NC, OH, PA, RI, SC, TN, VT, VA, WV*

National Organization for Rare Disorders®

2025-2026 Session

NORD® National Organization for Rare Disorders

Alone we are rare. Together we are strong.®

Our Mission

Improving the health and well-being of people with rare diseases by driving advances in care, research, and policy.

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National Organization
for Rare Disorders

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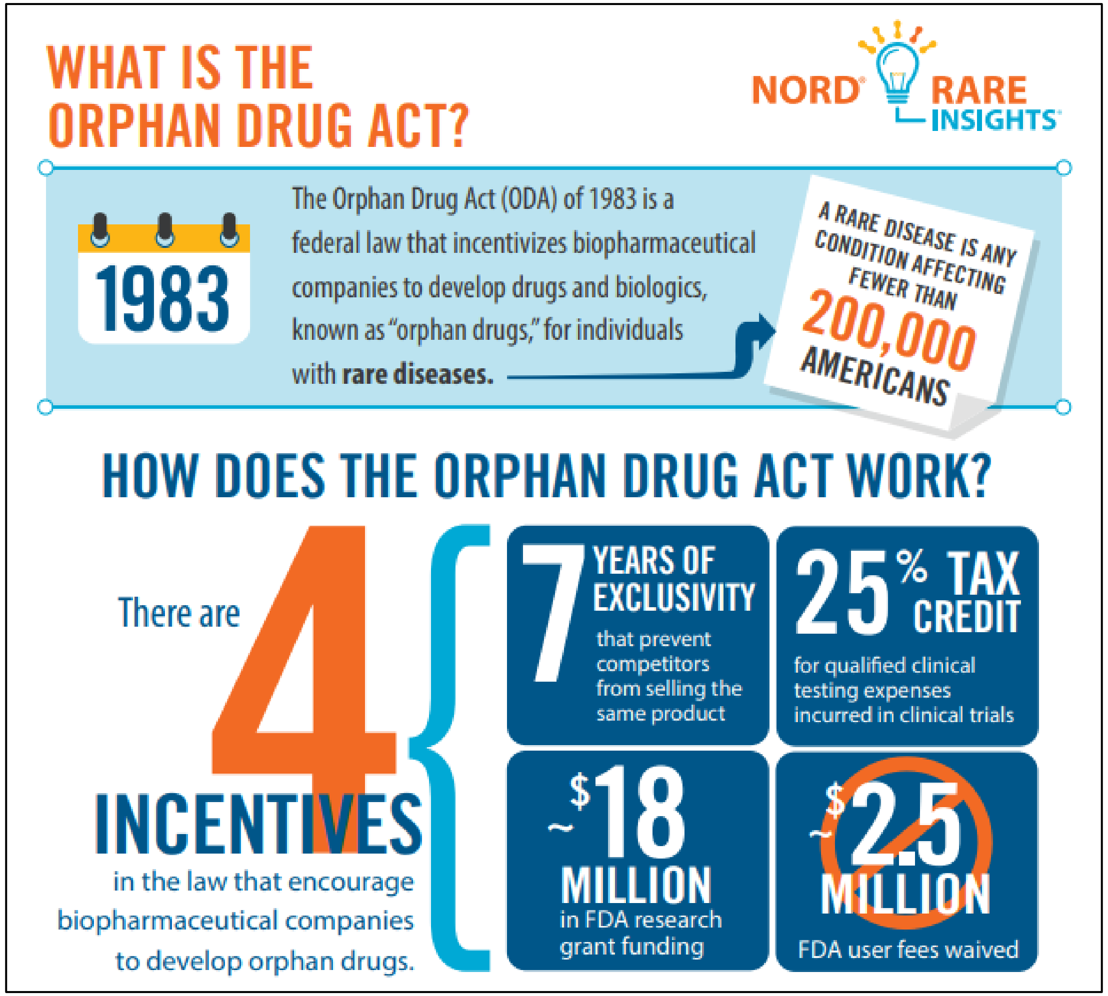
NORD, Rare Diseases and Disorders

NORD founder Abbey Meyers formed and led the coalition of advocates who successfully fought for the passage of the Orphan Drug Act of 1983.

NORD, is the only independent and nonpartisan U.S. organization working at the intersection of care, research, policy, and community for all rare diseases.

- One in ten in the U.S. have a rare disease. That's about 30 million of our loved ones, friends, colleagues or neighbors.



WHAT IS THE ORPHAN DRUG ACT?

NORD RARE INSIGHTS

1983

The Orphan Drug Act (ODA) of 1983 is a federal law that incentivizes biopharmaceutical companies to develop drugs and biologics, known as "orphan drugs," for individuals with **rare diseases.**

A RARE DISEASE IS ANY CONDITION AFFECTING FEWER THAN 200,000 AMERICANS

HOW DOES THE ORPHAN DRUG ACT WORK?

There are 4 INCENTIVES in the law that encourage biopharmaceutical companies to develop orphan drugs.

7 YEARS OF EXCLUSIVITY that prevent competitors from selling the same product

25% TAX CREDIT for qualified clinical testing expenses incurred in clinical trials

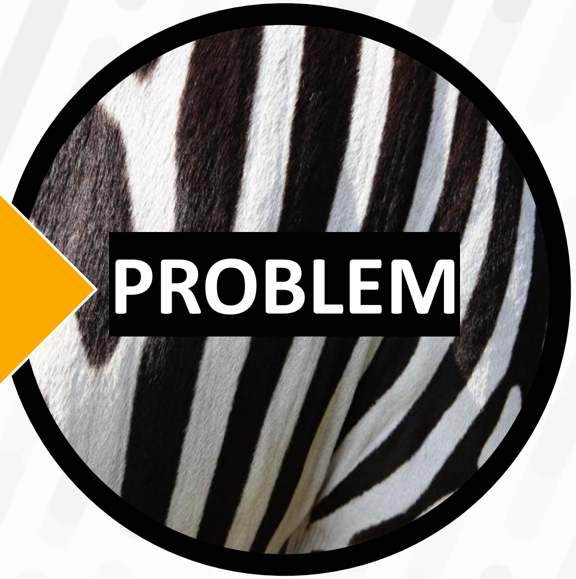
~$18 MILLION in FDA research grant funding

~$2.5 MILLION FDA user fees waived

+30M or approx. 1 in 10 Americans living with a rare disease

Over 10,000 known unique rare diseases

Limited awareness and knowledge of the impact of these conditions among decisionmakers

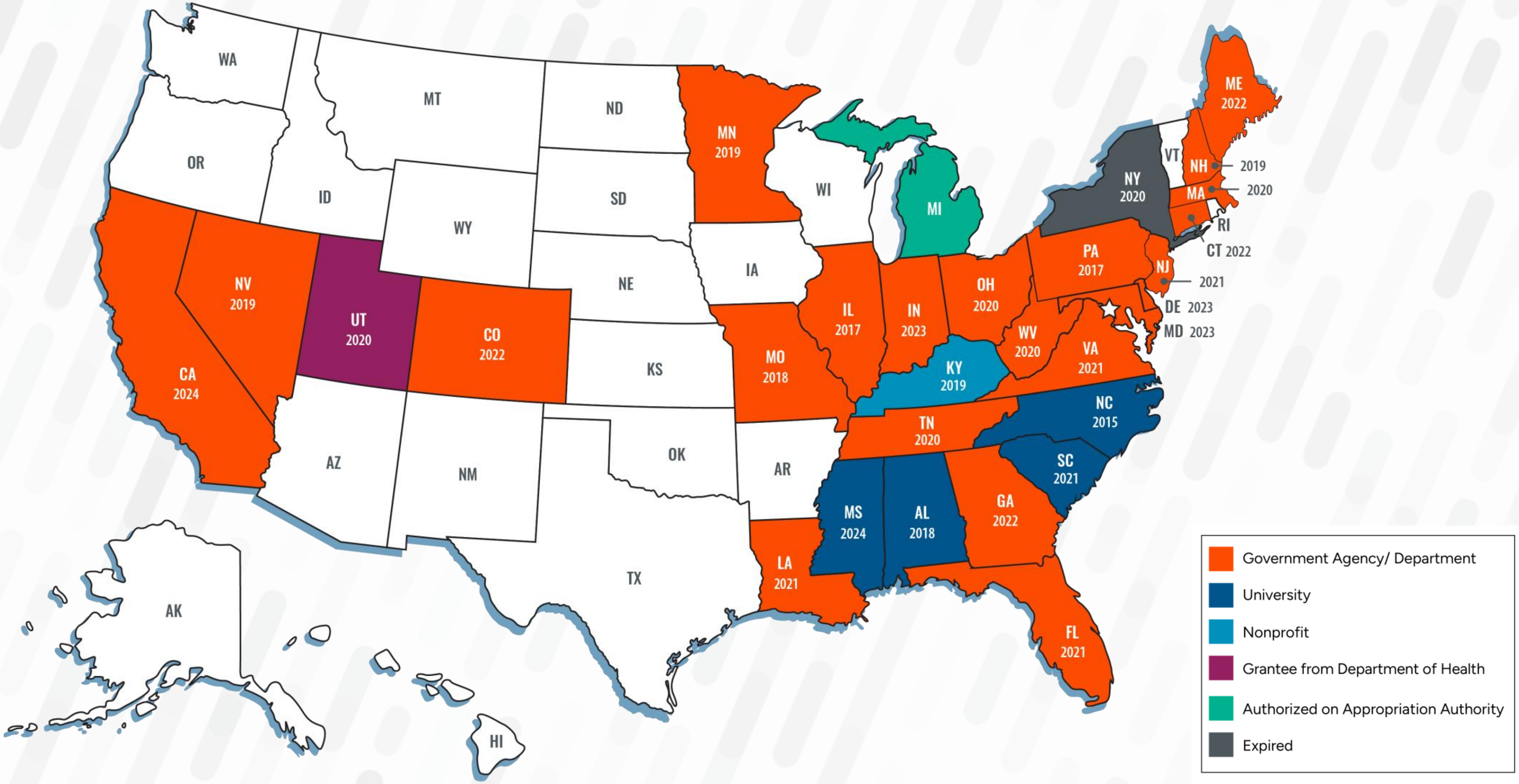


Solution: Rare Disease Advisory Councils (RDACs)

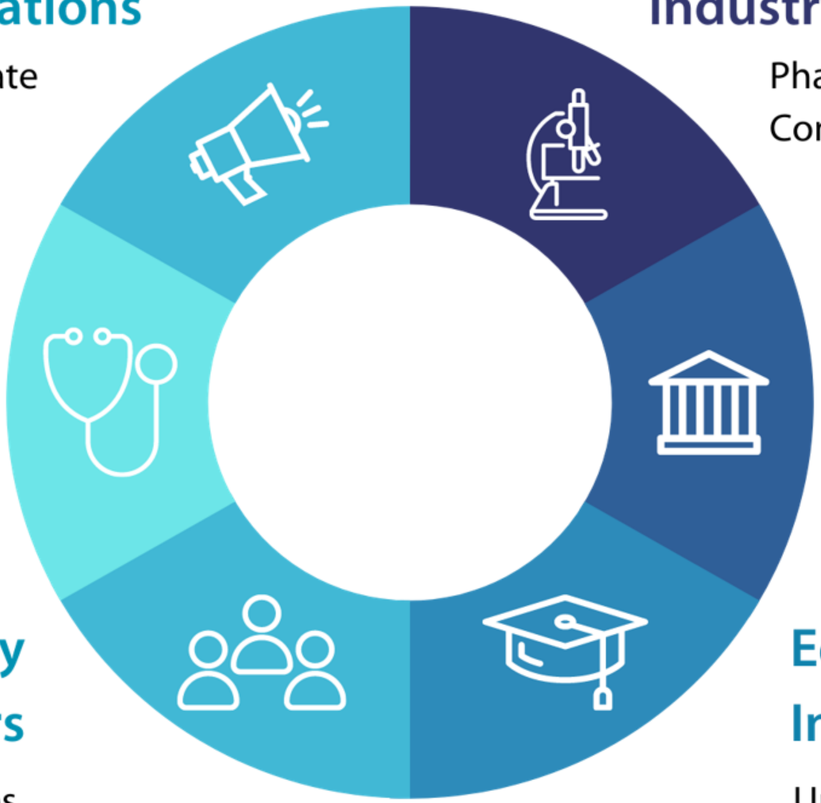
- A diverse body from the rare disease community that helps state officials understand and address their common challenges.
- Government officials and people with rare diseases work together to create resources that can help overcome obstacles in a smart and organized way.
- Customize the Rare Disease Advisory Council for each state based on factors like where the Council is run, how many members, and its responsibilities and rules.

Current Councils of the Union

30 states have created a Rare Disease Advisory Council (RDAC).



Who Serves On These Councils?



Patient Organizations

Non-profits that operate in the state

Health Care Partners

Doctors, Nurses, Geneticists, Hospital Administrators

Community Members

Patients, Advocates, Caregivers

Industry Partners

Pharmaceutical, Biotech Companies

State Agencies

Department of Health, Department of Insurance

Educational Institutions

Universities, Academic Research Institutions

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VERMONT'S RARE DISEASE ADVISORY COUNCIL

H.46 (STONE)

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Creation

§1 sub (a) & (b) and §2

The bill creates the **Rare Disease Advisory Council** within the Department of Health effective **July 1, 2025.**

- **PURPOSE:** To provide guidance and recommendations to the public, General Assembly, and other government agencies and departments, as necessary, regarding the needs of individuals living with rare diseases in Vermont.

What is a housing entity?

The Council shall have the administrative, technical and legal assistance of the Department of Health.

Council Membership

§1 sub (b)

Government Agencies
Commissioner of Health* *Chair, per sub (f) sub (2)* Commissioner of Vermont Health Access Commissioner of Financial Regulation Director of the Office of Racial Equity

Appointed Individuals Membership Role	Appointing Authority
Individual with a Rare Disease	Speaker of the House
Individual with a Rare Disease	Senate Committee on Committees
Representative of an Academic Research Institution, Grant Funded for Rare Disease Research	Speaker of the House
Caregiver of a person with a Rare Disease	Senate Committee on Committees
Physician Practicing in Vermont with Experience Treating a Rare Disease	Vermont Medical Society
Nurse Practicing in Vermont with Experience Treating a Rare Disease	Vermont Chapter of the American Nurses Association
Geneticist or Genetic Counselor	Senate Committee on Committees
Representative of Health Insurance Companies Serving Vermonters	Blue Cross Blue Shield of Vermont & MVP Health Care
Representative of Biopharma Industry Doing Business in Vermont	Speaker of the House
Representative of a **Rare Disease Patient Organization** Operating in Vermont	Governor

Membership Considerations

§1 sub (b)(1) and (b)(2)

- Members may potentially fill multiple roles if that member meets the qualifications for more than one membership role.

- **In the event the membership roster is an even number:**
  - The **Governor** may appoint one additional member.
    - That appointment must align with the Council's purpose and prioritize the representation of patients and caregivers.

Council Duties

§ 1 sub (c)

The Council must conduct the following activities for the benefit of individuals impacted by rare diseases in Vermont:

(1) Convene public hearings, make inquiries, and solicit comments from the general public to assist the Council with an initial **needs assessment** of the needs of individuals with a rare disease in Vermont and the needs of their caregivers and providers.

(2) Provide **testimony & comments** on pending legislation & rules that impact Vermont's rare disease community before the General Assembly and other State agencies.

(3) Consult with experts on rare disease to **develop policy recommendations** that:

  a) Improve patient access to and quality of services provided by rare disease specialists.
  b) Advance affordable and comprehensive health care coverage.
  c) Provide relevant diagnostic services and improve programs such as the States's Newborn Screening Program; and
  d) Ensure timely treatment and other needed services.

(4) **Publish a list of existing, publicly accessible resources** on research, diagnosis, treatment, and education, including education resources for healthcare providers, relating to rare diseases on the Advisory Council's website.

(5) Review the **Department of Health's January 2025 presentation** describing the public health impact of rare diseases in Vermont and the Department's role in addressing rare diseases Statewide as required by 2024 Acts and Resolved No. 164, Sec.2

(6) Any **other priorities as identified** by the Department or a majority of the Council.

Reporting Requirements

§1 sub (e)

Each year, on or before December 15th the Council must submit a written report to the House Committees on Health Care and on Human Services and the Senate Committee on Health and Welfare on the following:

- A description of the activities and progress of the Council during the previous year.
- An update on the status of the Council's funding needs.

The report must also include its findings and recommendations for legislative actions.

Meeting Requirements

§1 sub(f)

As Chair, the Commissioner of Health must call the first meeting. A majority of members present constitutes a quorum.

During the first year, the Council must meet at least monthly. After its first year, meetings will be at the call of the Chair.

Meetings may be held in person or remotely on an electronic platform as determined by the Chair.

The Advisory Council shall maintain a webpage on the Department of Health's website containing notices of upcoming meetings, meeting minutes, public comments, and previous annual reports.

Council Funds & Reimbursement

§1 sub (g)

Members of the Council will not be compensated for their role on the Council.

- However, they are entitled to per diem compensation and reimbursement of expenses.
  - For not more than 12 meetings annually.
  - In accordance with existing Vermont law.

- Funds for reimbursement comes from money appropriated to the Department of Health.

RESOURCES

2025 Bill Updates from 2024 Bill

Contextualizing Vermont within New England

RDACs by the Numbers

FAQ: How Do RDACs Work in Other States?

FAQ: What Have RDACs Achieved in Other States?

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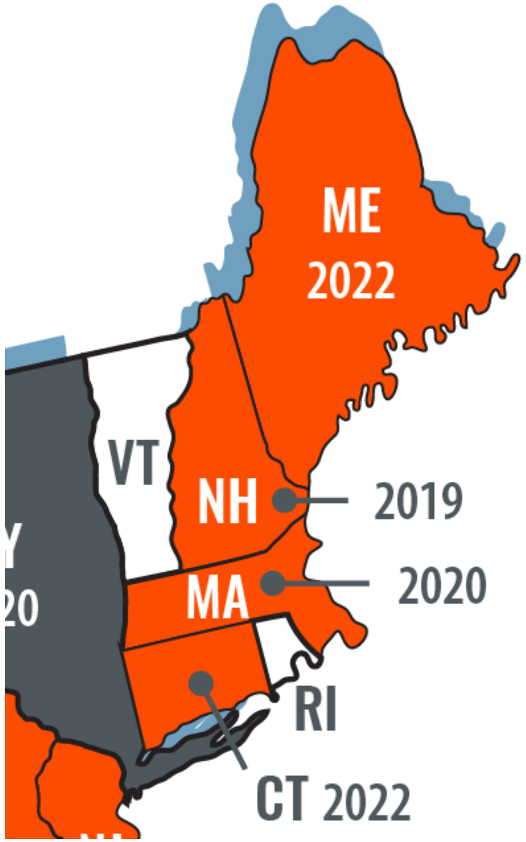
Changes from Last Year’s (2024) Bill H.573 to H.46 (2025)

1. A new provision allows members to fulfill multiple roles if qualified.
2. Added a seat on the Council for a Geneticist or Genetic Counselor.
3. Removed the membership slot for a scientific community member (covered under academic research representative role).
4. A new provision authorizes the Governor to appoint one additional member if the council roster has an even number of members. The patient and caregiver voice must be prioritized.
5. Reduced the Council’s duties from nine to six while incorporating a review of the Department’s presentation on rare disease impact and the authority for the Council to set additional priorities upon a majority vote.

Contextualizing Vermont within New England



How Vermont's RDAC is Similar	How Vermont's RDAC Stands Out
Public Health Integration Resides within the Department of Health, as in CT, ME, MA, and NH.	Includes the **Director of the Office of Racial Equity** to prioritize health equity.
Mission Alignment Provides **guidance to policymakers,** improves **awareness,** and addresses **care barriers.**	**Actionable Focus** • Strengthens VT **Newborn Screening Program** • Offers **expert testimony** for legislative decision-making.
Diverse Membership Includes patients, caregivers, healthcare providers, researchers, and state agency Reps.	**Structural Flexibility** • Members may **fulfill multiple roles** • Governor may appoint an additional member for a **voting majority.**

RDACs By-the-Numbers

- 30 Councils Nationwide – 25 active, 2 expired – remainder in appointments process
    - (1) Grantee from Department of Health | *UT*
    - (1) Nonprofit | *KY*
    - (4) University System | *AL, MS, NC, SC*
    - (24) Gov. Agency or Department

Average Number of Members = 16
(low:high; 11:28)

- **Funding** (9) Councils have language that authorize them to seek and utilize outside funding. | *CO, FL, GA, KY, MD, MA, PA, VA, WV*

CT → $50,000 (in committee)
MI → $70,000 (available)
MN → $314,000 (operates as State Agency)
MS → $100,000 (via university)
SC → $250,000 (restrictive)

FAQ: How Do RDACs Work in Other States?

They way NORD's model language works allows each RDAC to be tailored to its state.

- RDACs across the country vary in size, membership structure, and duties but they all share the core function of giving the rare disease community a voice in state government policy making.
- They serve as formal advisory bodies bringing together patients, caregivers, providers, insurers, researchers and state officials to develop actionable policy recommendations.

FAQ: What Have RDACs Achieved in Other States?

RDACs across the country have successfully expanded healthcare access, influenced policy, raised awareness, empowered patients, and gathered critical data to inform decision-making. For ex:

- **Expanding Access to Care and Driving Policy Initiatives** – Network Access Bill (Minnesota) and Pediatric Research Grants (Florida)
- **Raising Awareness** – Rare Disease Day Billboard (Tennessee), Events (South Carolina's Symposium, CT Town Halls, MA Town Hall)
- **Empowering Patients to Self Advocate** – Policy Guide (Utah)
- **Assessing Population Needs** – Statewide Prevalence Studies and Patient Needs Assessments (Massachusetts, Pennsylvania, South Carolina, Tennessee, Michigan)

Beyond these individual state achievements, RDAC members have build a unique, collaborative network across state lines. Unlike most advisory bodies, RDACs are unified and supported by NORD, which facilitates cross-state collaboration.

Through in-person gatherings at NORD-sponsored events and an exclusive online portal, RDAC members exchange resources, share best practices, and seek guidance from fellow council members across the country.

Thank You!

Carolyn G. Sheridan, MPH
State Policy Manager, East

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