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# Annual Report on Establishing a Rare Disease Advisory Council

**December 15, 2022**



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## Letter from the Chair

December 15, 2022

On behalf of the members of the Massachusetts Rare Disease Advisory Council (RDAC), it is my pleasure to submit the first annual legislative report in compliance with the Massachusetts Acts of 2020, Chapter 260. This inaugural report summarizes the collaborative efforts of the RDAC members over the past year. The council members are steadfast in their commitment to improving the lives of those impacted by a rare disease in Massachusetts.

While each rare disease is different, the obstacles faced by individuals and families impacted by a rare disease are common. These obstacles include difficulties in diagnosis and treatment, limited access to high-quality chronic care for poorly understood conditions, and lack of adequate social supports for patients and their caregivers as they try to cope with the intense challenges of living with a rare disease. Over the past year, the RDAC has focused on establishing the organizational foundations for our work. We have developed a mission statement, strategic priorities, goals for the council and operating procedures, all focused on achieving tangible improvements in the lives of people with rare diseases.

Most recent discussions have centered on the challenge of quantifying the burden of rare diseases in Massachusetts. To this end, the council will focus on three tasks in the coming year.

1. Determining the prevalence of rare diseases in Massachusetts.
2. Identifying the social supports and services available to those with a rare disease in Massachusetts.
3. Identifying the stakeholders with interest in rare diseases in Massachusetts.

Our efforts will provide the Commonwealth with a better understanding of the rare disease community and its needs. I look forward to leading the council in the next year as we embark on this important work.

Sincerely,

*Dylan Tierney*

Dylan Tierney, MD MPH
Chair, Rare Disease Advisory Council
Associate Medical Director
Bureau of Infectious Disease and Laboratory Sciences
Massachusetts Department of Public Health

## Executive Summary

The Massachusetts Rare Disease Advisory Council (RDAC) is pleased to present its inaugural annual legislative report in accordance with the Acts of 2020 Chapter 260. The RDAC was established as part of Senate Bill 2984, *An Act promoting a resilient healthcare system that puts patients first.* The legislature enacted the bill in December 2020, signed into law by Governor Charlie Baker on January 1, 2021 (https://malegislature.gov/Laws/SessionLaws/Acts/2020/Chapter260). This inaugural report describes the accomplishments of the RDAC over the past year.

The RDAC is composed of representatives from the legislature, state agencies, healthcare providers, researchers, advocacy groups, the life sciences industry, individuals living with a rare disease, and caregivers of individuals with a rare disease. Council members have been selected and appointed according to the legislative mandates. The council members all hold a shared vision: to improve the lives of those Massachusetts residents impacted by a rare disease.

The council has met bimonthly over the past year. Each council meeting starts with a presentation from a person impacted by a rare disease, helping to ground meeting proceeding. Additionally, the council hosts speakers from national, regional, and local advocacy organizations develop a deeper understanding of the complexity of issues at play in the lives of people with rare diseases.

One of the council's first accomplishments was the drafting of a mission statement.

*"The Massachusetts Rare Disease Advisory Council's mission is to provide guidance and recommendations on rare disease incidence and the status and needs of the rare disease community to the governor, the legislature, and the department of public health with the goal of improving the lives of people impacted by a rare disease in the Commonwealth."*

The council established a steering committee subcommittee whose primary goal is to provide guidance to the larger council about its direction and priorities. The steering committee meets bimonthly (alternating months relative to the full council meetings) to provide leadership and guidance for the council's work. Additional subcommittees and workgroups have more recently been established to survey the burden of the rare disease in Massachusetts. Once this survey is conducted, the council will develop recommendations related to strategic priorities that have also been developed by the council. Each recommendation will be linked to a legislative charge and will have time-specific achievable goals and objectives to guide its implementation.

## Background

The Orphan Drug Act defines a rare disease as a disease or condition that affects fewer than 200,000 individuals in the United States.[1] According to the National Institutes of Health (NIH), the total number of Americans living with a rare disease is estimated to be between 25 and 30 million individuals or approximately 10 percent of the total population.[2] This estimate has been used by the rare disease community for several decades to highlight that while the individual disease may be rare, the total number of individuals living with a rare disease is large.

Rare diseases have many causes. It is believed that 80 percent or more of rare diseases are genetic.[3] For

[1] H.R.5238 - 97th Congress (1981-1982): Orphan Drug Act. (1983, January 4). Retrieved from https://www.congress.gov/bill/97th-congress/house-bill/5238

[2] U.S. Department of Health and Human Services. (2021, January 26). FAQ About Rare Diseases. Genetic and Rare Diseases Information Center. Retrieved from https://rarediseases.info.nih.gov/about

[3] Rare Genetic Diseases. Genome.gov. (2018, April 13). Retrieved from https://www.genome.gov/dna-day/15-ways/rare-genetic-diseases

rare genetic diseases, genetic testing is often the only way to obtain a definitive diagnosis. There are also many rare diseases with no known genetic cause. These include some types of infections, autoimmune diseases, some forms of cancer, or disease caused by exposure to toxins or environmental factors.[4] Some rare diseases have multiple causes, and although some rare diseases have been named and researched for decades, investigators are still not able to determine a cause.

Rare diseases often present fundamentally different challenges than those of other common diseases. Individuals often face uncertainty and an unpredictable future as they go through a "diagnostic odyssey" to find a definitive diagnosis for their condition. For almost one-third of individuals with a rare disease, getting an accurate diagnosis can take up to five years.[5] Individuals with a rare disease often seek treatment in a healthcare setting that has never seen their condition. Many healthcare providers are unfamiliar with the multitude of symptoms that can be associated with a specific rare disease. Additionally, misunderstood and confusing symptoms can contribute to delayed diagnosis and incorrect treatment, jeopardizing a patient's condition. No matter the cause or origin, many rare diseases still lack effective treatments or preventive strategies.

Clinical management of a rare disease often presents many challenges for the person with the disease and the caregivers who help them coordinate their care. People with rare diseases often seek care from many different types of providers. Coordinating care across healthcare systems can be challenging, time-consuming and frustrating for the patient, the patient's family, and the patient's caregivers.

The financial impact of rare diseases is also significant—collectively and individually. In 2014, the average cost in the US for Orphan drug development for a rare disease was $137,782 per patient.[6] Direct medical costs are large, due to longer lengths of stays and frequent readmissions. Additionally, people with rare diseases and their care givers may experience higher insurance premiums and co-pays plus costs associated with the diagnostic odyssey and consultation with diseases specialists. There are also out of pocket costs associated with ancillary services, including education, transportation, home modifications and lost earnings through unpaid caregiver work.

Rare diseases can affect anyone at any point in their life. Rare diseases can be acute or chronic. The features and symptoms of rare diseases may vary in a myriad of ways; however, the effects on the individual's quality of life and ability to function productively in society are often similar. Individuals impacted by rare diseases may face significant challenges in maintaining autonomy caused by often chronic, progressive, degenerative, and life-altering aspects of their disease.

**The Council's Purpose**

To achieve its purpose, the council's legislative charges include:

i. Coordinating the performance of the rare disease advisory council duties with those of other rare disease advisory bodies, community-based organizations, and other public and private organizations with the Commonwealth for the purpose of ensuring greater cooperation regarding the research, diagnosis, and treatment of rare diseases. This coordination may require:

    a. Disseminating the outcomes of the advisory council's research and identifying best practices

[4] Field, M. J., & Boat, T. F. (2010). Profile of Rare Diseases. In Rare Diseases and Orphan Products: Accelerating Research and Development. essay, National Academies Press. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK56184/?msclkid=6d5bce28d07c11ec85146bea249c2fa3

[5] FDA.(2018, March 1). Orphan Products: Hope for People with Rare Diseases. U.S. Food and Drug Administration. Retrieved from https://www.fda.gov/drugs/information-consumers-and-patients-drugs/orphan-products-hope-people-rare-diseases

[6] Hadjivasiliou A. EvaluatePharma. Orphan Drug Report 2014. *http://info.evaluategroup.com/rs/evaluatepharmaltd/ images/2014OD.pdf* (accessed July 27, 2018)

and policy recommendations

b. Utilizing common research collection and dissemination procedures

ii. Using existing publicly available records and information to undertake a statistical and qualitative examination of the prevalence and causes of rare diseases in order to develop a profile of the social and economic burden of rare diseases in the Commonwealth.

iii. Receive and consider reports and testimony from expert individuals, the Department of Public Health, community-based organizations, voluntary health organizations, healthcare providers, and other public and private organizations recognized as having expertise in rare disease care to learn about their contributions to rare disease care and the possibility to improve rare disease care in the Commonwealth.

iv. Develop methods to publicize the profile of the social and economic burden of rare diseases in the Commonwealth to ensure that the public and health care providers are sufficiently informed of the most effective strategies for recognizing and treating rare diseases.

v. Determine the human impact and economic implications of early treatment of rare diseases versus delayed or inappropriate treatment of rare diseases as it pertains to the quality of care, the quality of patient's and family's lives, and the economic burdens, including insurance reimbursements, rehabilitation, hospitalization, and related services, on patients, families, and the Commonwealth.

vi. Evaluate the current system of rare disease treatment and available public resources to develop recommendations to increase rare disease survival rates, improve quality of life and prevent and control risks of co-morbidities for rare diseases based on the available evidence.

vii. Research and determine the most appropriate method for the Commonwealth to collect rare disease data, including a database of all rare diseases identified in the Commonwealth along with known best practices for the care of said diseases and such additional information concerning these cases as the advisory council deems necessary and appropriate to conduct thorough and complete epidemiological surveys of rare diseases, subject to all applicable privacy laws and protections.

viii. Examine the feasibility of developing a rare disease information and patient support network in the Commonwealth to aid in determining any genetic or environmental contributors to rare diseases.

ix. Develop and maintain a comprehensive rare disease plan for the Commonwealth utilizing any information and materials received or developed by the advisory council pursuant to the law, and shall include information specifically directed toward the general public, state and local officials, state agencies, private organizations, and associations, businesses, and industries.

The legislative language allows the advisory council to accept and solicit funds, including any gifts, donations, grants, bequests, or federal funds, for the purpose of carrying out the above charges.

**Council Membership**

The Commissioner of Public Health appointed Dr. Dylan Tierney as chair of the council. Dr. Dylan B. Tierney is an infectious disease physician and the Associate Medical Director for the Bureau of Infectious Disease and Laboratory Sciences at the Department of Public Health.

***Rare Disease Advisory Council Members***

| Seat | Member | Appointed By |
|---|---|---|
| Commissioner, DPH or designee | Dylan Tierney, MD, MPH | Commissioner, DPH |
| Executive Director, Health Policy Commission, or designee | Celia Segel, MPP | Executive Director, Health Policy Commission |
| Senate Member 1 | Vacant | Senate President |
| Senate Member 2 (Minority Leader) | Senator Bruce Tarr (Ms. Tai Pasquini, MPA, PhD) | Senate Minority Leader |
| House Member 1 | Representative Jay Livingstone | Speaker of the House |
| House Member 2 (Minority Leader) | Rep. Hannah Kane | House Minority Leader |
| Pharmacist – Experience with Rare Disease Drugs | Shivang Patel, Pharm.D. | Senate President |
| Geneticist | Diane Lucente, MS, LCGC | Senate President |
| Nurse with Experience Treating Rare Disease | Lena Joseph, RN, CPN | Senate President |
| Senate President 4 | Michele Rhee, MBA, MPH | Senate President |
| Representative of a Health Plan | Michael Sherman, MD, MBA, MS | Speaker of the House |
| Genetic Counselor with Rare Disease Experience | Asma Rashid, MS, CGC | Speaker of the House |
| Representative of a Rehab Facility | Ross Zafonte, DO | Speaker of the House |
| House Speaker 4 | Janis Creedon | Speaker of the House |
| Academic Research Institution 1 | Michael Green, MD, PhD | Governor |
| Academic Research Institution2 | Andrew Dwyer, PhD, FNP-BC, FNAP, FAAN | Governor |
| Physician with Rare Disease Experience 1 | Andrew Lane, MD, PhD | Governor |
| Physician with Rare Disease Experience 2 | David Miller, MD, PhD | Governor |
| Hospital Administrator 1 | Ryan Thompson, MD | Governor |
| Hospital Administrator 2 - Pediatric | Charlotte Boney, MD | Governor |
| Representative of Rare Disease Organization 1 | Julie Gortze, RN | Governor |
| Representative of Rare Disease Organization 2 | Lisa Deck | Governor |
| Representative of Rare Disease Organization 3 | Jenn McNary | Governor |
| Biotechnology and Scientific Community 1 | Jeff R. Livingstone, PhD | Governor |
| Biotechnology and Scientific Community 2 | Robert E. Schultz, MBA | Governor |

| | | |
|---|---|---|
| Dietician -experience with Rare Disease | Ann Wessel, MS, RD, LDN | Governor |
| 18 or older with Rare Disease 1 | Glenda Thomas | Governor |
| 18 or older with Rare Disease 2 | Guadalupe Hayes-Mota, MBA, MS, MPA | Governor |
| Rare Disease Caregiver | Alexsandra Mahady | Governor |

**Summary of RDAC Meetings**

Below is a summary of the meeting dates

September 16, 2021, Full Council Meeting
The RDAC held its first meeting on September 16, 2021. The first meeting consisted of a review of the statutory authority and law regarding open meeting law, public records, and conflict of interest. Member introductions and future scheduling were also included in the first meeting.

December 9, 2021, Full Council Meeting
The second meeting included an informational presentation from the National Organization of Rare Disorders (NORD). The RDAC also voted to have a speaker impacted by a rare disease at the beginning of each full council meeting. This will support the council in staying grounded in its mission.

The council also voted to form a seven-member steering committee to guide the council's work. This steering committee would consist of; the chair, Dr. Dylan Tierney, a person living with a rare disease, a caregiver or parent of a patient with a rare disease, a legislator, a hospital administrator, a clinician, and a researcher.

March 28, 2022, Full Council Meeting
The steering committee nominees were appointed:
Dr. Dylan Tierney – Chair
Michele Rhee – a person living with a rare disease
Jenn McNary – a caregiver or parent
Representative Hannah Kane – legislator
Dr. Ryan Thompson – hospital administrator
Dr. David Miller – clinical
Dr. Jeff Livingstone – researcher

May 27, 2022, Steering Committee Meeting
The steering committee's first meeting was scheduled for May 27, 2022. During this meeting, the committee received a presentation from Kevin Cranston, Assistant Commissioner and Director of the Bureau of Infectious Disease and Laboratory Sciences (BIDLS) at the Department of Public Health. Mr. Cranston discussed how BIDLS could support the work of the RDAC.

The committee discussed the scope of the RDAC and how the steering committee could help guide the council's work by setting agendas and helping to prioritize activities to meet the legislative charges. The committee discussed the expansive nature of the charges and that subcommittees may be a helpful way to meet the specific charges laid out in the legislation.

July 14, 2022, Steering Committee Meeting
The committee drafted a mission statement and suggested three additional subcommittees: Research, Advocacy, and Fundraising.

July 28, 2022, Full Council Meeting
The council accepted a mission statement for the RDAC by unanimous vote.

**Mission Statement**
***"The Massachusetts Rare Disease Advisory Council's mission is to provide guidance and recommendations on the rare disease incidence, the status, and the needs of the rare disease***

***community to the governor, the legislature, and the department of public health with the goal of improving the lives of people impacted by a rare disease in the commonwealth."***

The council voted to approve the addition of three new subcommittees:
- Research
- Advocacy and Policy
- Fundraising

August 25, 2022, Steering Committee Meeting
The committee voted to approve standard operating procedures for the council (Appendix A).

The committee also approved a set of priorities for the council's initial work.
1. Improving healthcare access and quality for people with rare diseases
2. Establishing social supports for people impacted by rare diseases
3. Strengthening the rare disease community in Massachusetts

September 15, 2022, Full Council Meeting
The full council voted to approve the standard operating procedures approved by the steering committee on 8.25.22. The full council also voted to approve the set of priorities as approved by the steering committee on 8.25.22

November 3, 2022, Steering Committee Meeting
The committee voted to establish subcommittee workgroups to complete this initial work. They agreed to establish workgroups based on the priorities of the council. Each workgroup would have one primary goal in this initial phase.

**Workgroup 1 - *Improve healthcare access and quality of care for people with rare diseases.***
GOAL: Determine the prevalence of rare diseases in Massachusetts.

**Workgroup 2 - *Advocate for and improve access to social supports and services for people impacted by rare diseases.***
GOAL: Develop a profile of rare disease social supports and services in Massachusetts

**Workgroup 3 - *Foster communication and collaboration to empower the rare disease community in Massachusetts.***
GOAL: Develop a profile of rare disease expert individuals, community-based organizations, voluntary organizations, healthcare providers, and any other public or private organizations interested in rare diseases in Massachusetts.

November 17, 2022, Full Council Meeting
The council voted to prioritize the goals as presented by the steering committee.
The council also voted to establish subcommittee workgroups as presented and approved by the steering committee. Subcommittee workgroups will appoint a chair and begin their work in 2023. They will meet regularly and report their progress at each full council meeting.

The RDAC and the Steering Committee have an alternating, bimonthly meeting schedule. All meetings are open to the public, and additional information detailing the discussions held, including the minutes of the meetings as well as any meeting materials, can be found here (https://www.mass.gov/orgs/rare-disease-advisory-council) on the RDAC webpage.

## Rare Disease Advisory Council Accomplishments

The RDAC was established to provide guidance and recommendations on rare disease incidence and the status and needs of the rare disease community to the governor, the legislature, and the department of public health with the goal of improving the lives of people impacted by a rare disease in the Commonwealth.

The RDAC has identified activities that will help to establish a better understanding of the burden of rare diseases in Massachusetts:

- to determine the prevalence of rare diseases in Massachusetts,
- to identify the supports and services available to the rare disease community in Massachusetts,
- to identify the stakeholders with interest in the rare disease community in Massachusetts.

With these activities, the RDAC will be better positioned to summarize the current state of the rare disease community in the Commonwealth and provide guidance and recommendations as legislated.

**Actions taken and progress made toward implementing the comprehensive rare disease plan**

Progress toward the development of a comprehensive rare disease plan includes

- Assembly of the council (28 members appointed),
- Establishment of RDAC standard operating procedures,
- Formation of steering committee to guide the RDAC agenda,
- Identification of RDAC mission, strategic priorities, and goals,
- Formation of three subcommittees focus on research, advocacy, and fundraising,
- Formation of three subcommittee workgroups focused on achieving RDAC goals,
- Consultation with state and federal experts on rare diseases, including presentations from the National Organization for Rare Disorders, Rare New England, and individuals impacted by a rare disease.

**An accounting of all funds received by the council and the source of those funds**

No account has been set up for the RDAC to accept funds. No funds have been accepted.

**An accounting of all funds expended by the council.**

No account has been set up for the RDAC to expend funds. No funds have been expended.

**To the extent practicable, an estimate of any cost savings on the part of individuals and the commonwealth will occur upon full implementation of the comprehensive rare disease plan and accompanying programs.**

At this time, it is not possible to estimate any cost savings on the part of individuals or the commonwealth once the comprehensive rare disease plan is implemented.

**Conclusion**

In conclusion, the Massachusetts Rare Disease Advisory Council (RDAC) was convened to provide guidance and recommendations on rare disease incidence and the status and needs of the rare disease community to the governor, the legislature, and the department of public health with the goal of improving the lives of people impacted by a rare disease in the Commonwealth.

To date, the council has focused on establishing a foundation for its work in the future, including the establishment of standard operating procedures, a mission statement, and strategic priorities. The council has established a steering committee to guide the work of the larger council. More recently, the council established three subcommittee workgroups to begin collecting and analyzing data with the goal of developing a profile of rare diseases in Massachusetts. The council will create an account with the

treasurer to begin collecting and expanding funds as needed to complete its work.

Over the next year, the council looks forward to performing the foundational analyses required to underpin the development of meaningful recommendations on how to improve the lives of people with rare diseases in the Commonwealth. The council plans to explore opportunities to hear from the public and those impacted by a rare disease.

The council plans to focus on summarizing the prevalence of rare diseases in Massachusetts, identifying the supports and services available for individuals and families in Massachusetts, and identifying the stakeholders interested in the rare disease community. As the council looks to complete its foundational work over the next year, it is mindful of finding ways to improve the lives of those impacted by a rare disease in a meaningful way.

**Appendix A**

Massachusetts Rare Disease Advisory Council (MA RDAC)
Standard Operating Procedures (SOP)
August 2022

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## Council Mission

The purpose of this Advisory Council is to provide guidance and recommendations on rare disease incidence, the status, and the needs of the rare disease community to the governor, the legislature, and the department of public health with the goal of improving the lives of people impacted by a rare disease in the Commonwealth.

## Purpose

To establish general procedures for the Council meetings and administrative matters.

## Membership

Membership shall consist of 29 voting members, which shall consist of;

- the commissioner, or a designee, who shall serve as chair
- the executive director, or a designee, of the health policy commission
- Two members of the senate or a designee
    - 1 of whom shall be appointed by the minority leader of the senate
- Two members of the house of representatives or a designee
    - 1 of whom shall be appointed by the minority leader of the house
- Four persons appointed by the senate president
    - 1 of whom shall be a pharmacist with experience with drugs used to treat rare diseases
    - 1 of whom shall be a geneticist licensed and practicing in the commonwealth
    - 1 of whom shall be a registered nurse or advanced practice registered nurse licensed and practicing in the commonwealth with experience treating rare diseases
- Four persons appointed by the speaker of the house
    - 1 of whom shall be a representative of a health plan or accountable care organization certified by the health policy commission
    - 1 of whom shall be a genetic counselor with experience providing services to persons diagnosed with a rare disease
    - 1 of whom shall be a representative from a rehabilitation facility that provides rare disease care
- 15 persons to be appointed by the governor
    - 2 of whom shall be from academic research institutions that receive grant funding for rare diseases research
    - 2 of whom shall be physicians licensed and practicing in the commonwealth with experience researching, diagnosing, or treating rare diseases
    - 1 of whom shall be a hospital administrator, or a designee, from a hospital in the commonwealth that provides care to persons diagnosed with a rare disease
    - 1 of whom shall be a hospital administrator, or a designee, from a hospital in the commonwealth that provides care to persons diagnosed with a rare disease and in which the scope of service focuses on rare diseases of pediatric patients
    - 3 of whom shall be representatives of rare disease patient organizations that operate in the commonwealth
    - 2 of whom shall be representatives of the biotechnology and scientific community who are engaged in rare disease research, including, but not limited to, a medical researcher with experience conducting research on rare diseases
    - 1 of whom shall be a dietician licensed and practicing in the commonwealth with experience administering dietary therapies to those with rare diseases
    - 2 of whom shall be persons age 18 or older who have a rare disease

- 1 of whom shall be a caregiver of a person with a rare disease

## Membership Term

Each member of the rare disease advisory council shall serve for a term of 3 years and shall serve until their successors have been appointed. Members may be reappointed to serve consecutive terms indefinitely.

All members shall be appointed/reappointed as directed by legislation.

## Replacement of a Council Member

Upon receipt of a letter of resignation or completion of the three-year term, the council chair shall reach out to the appointing authority, as stated in the legislative language, for the reappointment of an existing council member or the appointment of a replacement council member. The existing council member shall continue to serve on the council until a replacement is appointed.

## Membership Compensation

The members of the advisory council shall serve without compensation.

**Meetings**

## Number of Meetings

The advisory council shall meet periodically, not fewer than four times annually, with members able to participate in any meeting by teleconference.

## Agendas

Meeting agendas will be developed by the Council Chair based on legislative charges and council discussions. According to Open Meeting Law requirements, agendas will be posted on the webpage: https://www.mass.gov/orgs/rare-disease-advisory-council.
Agendas will also be sent to all members in advance of the meeting.

## Public

All meetings will be open to the public.

## Meeting Materials

Meeting materials will be posted on the webpage:
https://www.mass.gov/orgs/rare-disease-advisory-council Meeting materials will be sent to all members before the meeting.

## Role of the Council Chair

The council chair will ensure the goals and duties of the council are carried out as planned and will facilitate meetings to discuss and plan the council's activities.

## Role of the Council Coordinator

The council coordinator's primary responsibility includes supporting the chair in facilitating and coordinating all council meetings.
Specifically:

1. Develop and maintain agendas, minutes, and meeting materials in collaboration with the council chair
2. Develop and maintain operating procedures in collaboration with the council chair
3. Organize and maintain all documents as required by Open Meeting Law
4. Email the Department of Public Health Web Liaison, Secretary of State, and Accounting and Finance representative to meet the Open Meeting Law Requirements
5. Maintain a member contact list
6. Maintain meeting schedule for the council
7. Contact and schedule speakers as directed by the council chair
8. Maintain speaker bureau list
9. Collaborate with other rare disease organizations as directed by the chair
10. Attend all meetings and draft minutes for council review
11. Maintain approved minutes
12. Draft and coordinate review of any council reports

## Roles of Members

The member's primary duty is to carry out the intent of the legislative charges. This duty includes actively contributing to efforts to achieve deliverables prioritized by the council about the council's mission. These contributions include participation in Council subcommittees by providing services and expertise towards subcommittee goals.

## Voting Procedures

Robert's Rules of Order will be enforced.

Motions: The motion maker must clearly and concisely state and explain the motion. After discussion, the motion shall be restated clearly and concisely by the council chair before a vote is taken. The motion must be recorded in written form, as voted on, and must be part of the record or minutes of the meeting, including the exact vote of each council member.

In the case of a virtual meeting environment, the council chair shall conduct a roll call vote for all votes taken by the council.

A voting member of the council may not vote on any council matter that would have a conflict of interest. The affected member who may not vote may still participate in deliberations relating to the decision after letting the council know of their voting recusal and stating the reason for the recusal.

## Meeting Procedures

### Facilitation of Meetings

The council chair shall be the facilitator of all full council meetings.

## Quorum

Fifteen members of the council members must be present for a quorum. The chair is counted in determining whether a quorum is present. Each council member is asked to notify the council coordinator or council chair at least 24 hrs. before the meeting time if they will not be present.

## Member Participation

The council chair may call upon members from time to time to provide background or expertise related to the topic to be discussed.

1. Members should strive to attend all meetings and arrive on time. A member who cannot participate in a meeting should notify the council coordinator in advance of the meeting to ensure a quorum can be met. Members can send a person to represent their views when they cannot attend. The member representative will not have voting rights unless sworn explicitly in as a representative member of the council.
2. Members should come to meetings prepared for discussion by reviewing any information sent by the council chair and/or coordinator and be prepared to participate.
3. Members shall recognize the legitimacy of the concerns and interests of others, whether or not they agree with them. Members shall participate in the spirit of collaboration and consensus.
4. Members shall share discussion time and encourage everyone to participate fully. Members will attempt to present their views succinctly and cooperate with the chair to ensure that everyone is given equitable time to state their ideas.
5. Members shall avoid interrupting and will listen respectfully to others.
6. Only one person will speak at a time. Members will not participate in side conversations.
7. Members are encouraged to share individual experiences, perspectives, and interests and recommend ways to achieve the council priorities within the limitations and opportunities of the legislation.
8. Members shall work together to identify where there is common ground and where there are key differences between perspectives.
9. Members are encouraged to inform and solicit the opinions of others in the rare disease community and organizations that are interested in the rare disease community.
10. All members take responsibility for the success of the meeting and are respectful of others' views and opinions.
11. Innovation is encouraged by listening to all ideas and creating strategies and recommendations that build on differing and common perspectives and interests.
12. Recognize that the council must operate in an open and public manner.

## Discussion

The council chair may bring various agenda items to the council for discussion. The chair will inform the council members when the discussion becomes circular and will subsequently summarize the discussion sentiments. During a council discussion, members are to be mindful of waiting to speak and allowing everyone to speak. All members wishing to discuss the matter under consideration should be given the opportunity to do so.

## Public Participation

From time to time, the council may elicit public participation. When the agenda calls for public participation, the council chair will call on individuals who wish to provide comments. When individuals are recognized to speak, they will have 3 minutes to speak. The council chair may adjust this time as needed.

## Council Subcommittees

From time to time, the council may establish subcommittees made up of council members.

### Subcommittee Membership

Subcommittee membership shall consist of an odd number of members.

No subcommittee shall have more than 15 council members.

Members within a subcommittee cannot work together outside of the official posted meeting times unless the number of members is less than the subcommittee quorum. For example, a subcommittee with five members cannot have an external meeting of 3 or more members. A subcommittee with seven members cannot have an external meeting of 4 or more.

Subcommittees may have external participants. External participants can bring expertise or information pertinent to the discussion.

External participants will not have voting rights.

### Facilitation of Subcommittee Meetings

Each subcommittee shall have a chair to coordinate and lead the group. The council chair shall appoint the subcommittee chair.

Each subcommittee shall meet as directed by the subcommittee chair in collaboration with the council coordinator and the council chair.

### Subcommittee Rules

Subcommittees shall meet as directed by the subcommittee chair in collaboration with the council coordinator and the council chair.

Subcommittees must follow the same open meeting law procedures as the larger council. For example, posting meeting times and agendas, taking attendance, meeting quorum, taking meeting minutes, including voting and external discussion.

Subcommittees can meet in person or virtually, but all meetings must be accessible to the public, and notices must be posted as required by open meeting law.

Subcommittees will present their discussions, activities, and votes to the full council as directed by the council chair.

Subcommittees can meet jointly to enhance coordination between the subcommittees in achieving Council priorities. Similarly, representatives from one subcommittee may be invited to participate in another subcommittee's meeting to facilitate communication and collaboration between subcommittees. No joint meeting may exceed 15 members.

Subcommittees can be disbanded if the subcommittee or larger council votes to do so.

### Subcommittee Chair Responsibilities

Set a meeting time and location/virtual in collaboration with the council coordinator

Set an agenda in collaboration with the council coordinator.

Facilitate subcommittee meetings.

Take attendance roll call at subcommittee meetings to ensure a quorum. (if a quorum is not met, the meeting must be adjourned and rescheduled)

Call the meeting to order, facilitate the discussion according to the agenda, conduct a roll call vote to approve the minutes from the previous meeting, take deliberation votes by roll call as directed by the agenda, and call a vote to adjourn.

### Council Coordinator's Responsibilities to Subcommittees

Work collaboratively with the subcommittee chair to coordinate activities.

Set meeting date and time in collaboration with the subcommittee chair. If virtual, create a link for a meeting in coordination with DPH IT Facilitator.

Coordinate with the DPH IT Facilitator to ensure organized storage of all meeting notices, agendas, documents, and minutes.

Email the Attorney General, Secretary of State, and Accounting and Finance Office of Public Meeting Notices as required by Open Meeting Law.

Ensure that all notices are posted as required by Open Meeting Law.

### DPH IT Facilitator Responsibilities

Work collaboratively with the council coordinator to create meeting links for all council and subcommittee meetings.

Facilitate all virtual meetings ensuring the proper recording of audio, visual, and transcript files.

Shall share all recordings of audio, visual, and transcript files with the council coordinator, subcommittee chair, and council chair.

Store and maintain all records of the council and subcommittees, including meeting notices, meeting agendas, meeting minutes, meeting discussion documents, and presentations as required by open meeting law.

## Financing the Work of the Council

The legislative language allows for the collection and distribution of funds to carry out the activities and goals of the council.
“The advisory council may accept and solicit funds, including any gifts, donations, grants or bequests or any federal funds, for any of the purposes of this section. Such funds shall be deposited in a separate account with the state treasurer, be received by the treasurer on behalf of the Commonwealth, and be expended by the advisory council in accordance with the law.”