NORD®
National Organization for Rare Disorders

Alone we are rare. Together we are strong.®

March 27, 2024

The Honorable Virginia "Ginny" Lyons
Chair
Senate Committee on Health and Welfare
115 State St.
Montpelier, VT 05633

The Honorable David Weeks
Vice-Chair
Senate Committee on Health and Welfare
115 State St.
Montpelier, VT 05633

Re: NORD Supports Provisions of H.766 (Black) Relating to Step Therapy Requirements

The National Organization for Rare Disorders (NORD) would like to thank you for giving House Bill 766 (Black) the opportunity to be heard before your Committee and to express our support for provisions the legislation. Specifically, NORD is supportive of provisions which establish categories of exemptions from step therapy protocols §1, modify timelines within which health plans must respond to prior authorization requests§4, and make responses to requests for a step therapy protocol exemption subject to the same timelines. §4

NORD is a federation of non-profits and health organizations dedicated to improving the health and wellbeing of people living with rare diseases. We have over 330 member organizations which represent patients and caregivers living with one of the over 10,000 known rare diseases. For forty years, NORD has been at the forefront of advocacy for policies and programs that improve the health and well-being of people living with rare diseases, including step therapy reform.

Step Therapy
Step therapy, also known as step protocols or fail first requirements, is a process by which insurers (public or private) require patients to take one or more alternative medications before they can access the medicine initially prescribed by their provider. This is a utilization management practice intended to control health care costs, but step therapy has been increasingly applied to patients with little regard for their medical situation or treatment history. When used inappropriately, step therapy protocols can delay necessary treatment and lead to adverse reactions that ultimately increase health care costs, not lower them. For rare disease patients, the use of step therapy protocols is particularly concerning, as it can take years to find a diagnosis and a treatment that works.

Expanding Categories for Exemptions (§1)
For rare disease patients, it can take years to find the right diagnosis and a treatment that works. To avoid disruptions in care, delays in necessary treatment, increased risk for adverse reactions, and potentially higher out-of-pocket costs to patients, NORD supports the adoption of five automatic exceptions from step therapy protocols.

Under existing law, the only exemption from requiring a step protocol applies to patients who have tried and failed the same alternative medication on one or more prior occasions. This legislation (H766) would expand the circumstances when patients or providers can request an exception from step protocols to include situations when the alternative medication is contraindicated, is expected to be ineffective, the patient is stable on the initially prescribed drug, or when it is not in the patient's best interest.

Many rare disease patients face years of a difficult "diagnostic odyssey" before receiving their correct diagnosis and more than 95% of rare diseases lack an FDA approved treatment. Lengthy additional delays before access to a prescribed treatment harm rare disease patients.

Modifications to the Timeline for a Response to a Prior Authorization Request, Step Therapy Exemption Subject (§4)
For rare disease patients, delayed responses to step therapy exceptions may lead to more unnecessary tests and procedures and, in some cases, mean a greater risk of experiencing irreversible damage as the disease progresses.

Current law requires plans to respond within 48 hours of receipt for a prior authorization request in urgent situations and two business days in nonurgent circumstances. This legislation (H. 766) would shorten that timeline such that plans must respond within 24-hours after receipt in urgent situations and in two business days in nonurgent circumstances, provided they notify the enrollee of receipt of the request within 24-hours. Additionally, these timelines would also apply to a step therapy exemption request brought by a patient or provider. In situations where additional information is required for the insurer to reach a decision, urgent or not, the plan is granted 24 hours to approve or deny the request upon receipt of the necessary additional information.

Such clear and expedited timelines, for both emergency and non-emergency situations, are important for patient care. This ensures patients have access to the prescription drugs they need without experiencing lengthy delays in treatment. To shorten the diagnostic and treatment odyssey, prevent waste of a patient's precious time & the health care system's resources, and mitigate the risk of irreversible damage, NORD® supports establishing a clear and expedited timeline for decisions for both emergency and non-emergency situations.

NORD's State Report Card
Since 2015, on an annual basis, NORD has evaluated how effectively states are serving people with rare diseases across nine issue areas that impact the rare disease community through the publication of NORD's State Report Card. In the area of step therapy, NORD's State Report Card grades States separately across four separate categories: regulation of step therapy protocols, timelines for responses to exemption requests, clarity of the exemption process, and the categories of exceptions guarantee to patients. An overall grade for step therapy is determined by taking the average of these four separate grades.

In the most recent publication of NORD's State Report Card, based upon law in force as of December 2023, Vermont received an overall grade of "F" in the step therapy issue area. Enacting the changes in H.766 would raise Vermont's overall grade on step therapy from an "F" to a "B" and align the patient protection with those that have been successful in many other states. We hope you consider NORD a resource for you as this bill moves through the legislative process.

Sincerely,

Carolyn G. Sheridan, MPH
State Policy Manager, Eastern Region

CC:
Jennifer Carbee, Director and Chief Counsel, Office of Legislative Counsel
Kiki Carasi-Schwartz, Senate Health Committee Assistant