



Alone we are rare. Together we are strong.®

March 13, 2024

The Honorable Herb Conaway Jr.  
Chair  
Assembly Committee on Health  
Delran Professional Center  
Delran, NJ 08075

The Honorable Pamela R. Lampitt  
Vice-Chair  
Assembly Committee on Health  
1101 Laurel Oak Rd., Suite 150  
Voorhees, NJ 08043

**Re: NORD Supports A1825 (Conaway) An Act Establishing Certain Guidelines for Health Insurance Carriers Concerning Step Therapy Protocols**

The National Organization for Rare Disorders (NORD) supports [Assembly Bill 1825 \(Conaway\)](#), which establishes categories of exemptions from step therapy protocols, establishes timelines within which health plans must respond to step therapy exception requests, and provides a framework for the regulation of step therapy protocols.

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.

**Establishing Categories for Exemptions from Step Therapy Protocols**

For rare disease patients, it can take years to find a 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.

Currently, there are no patient protections in place that would provide a basic framework for when it is most appropriate to exempt patients from step therapy. This legislation establishes circumstances where patients or providers can request an exception including if the medication is contraindicated, is expected to be ineffective, the patient is stable on the initially prescribed drug, or if it's 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. Patients living with a rare

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condition that does have a safe and effective therapy need access to that therapy to achieve their optimal health and usually have few, if any, alternative treatment options.

### **Regulating Step Therapy Protocols & Establishing a Timelines for a Response to a Step Therapy Exemption Request**

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. To shorten the diagnostic and treatment odyssey, prevent waste of a patient's precious time and 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 and ensuring step therapy protocols are based on medical criteria and clinical guidelines developed by independent experts.

This legislation establishes a timeline within which health plans must respond to a patient or provider's request for an exemption from a step protocol and requires step protocols be based upon clinical practice guidelines developed and endorsed by a multidisciplinary panel of experts.

A clear and expedited timeline, for both emergency and non-emergency situations, is important. This ensures patients have access to the prescription drugs they need without experiencing any delays in treatment. Additionally, rare diseases are complex and often require intervention by specialists. It is important that rare disease patients are not subject to a one-size-fits-all standard for prescription drug coverage and that protocols are developed based upon high-quality studies, research, and medical practice and consider the needs of atypical populations, like the rare disease community.

### **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.<sup>1</sup> 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, New Jersey received an overall grade of "F" in the step therapy issue area. Should A1825 be enacted, New Jersey's overall grade in the issue area of step therapy of the NORD State Report Card would be elevated from an "F" to a "A." We hope you consider NORD a resource for you as this bill moves through the legislative process.

Sincerely,



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<sup>1</sup> NORD's State Report Card® Step Therapy [Grading Methodology](#)