NORD®
National Organization
for Rare Disorders

Alone we are rare. Together we are strong.®

January 27, 2025

The Honorable Roy Freiman
Chair
Assembly Committee on Financial Institutions and Insurance
390 Amwell Rd, Suite 301
Hillsborough, NJ 08844

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 creates exemptions from step therapy protocols, sets timeframes for health plan responses, and regulates step therapy practices.

NORD is a unique federation of over 350 non-profits and health organizations dedicated to improving the health and well-being of people living with rare diseases. NORD was founded more than 40 years ago, after the passage of the federal Orphan Drug Act (ODA), to formalize the coalition of patient advocacy groups that were instrumental in passing that landmark law. Our mission has always been, and continues to be, to improve the health and well-being of people with rare diseases by driving advances in care, research, and policy.

Step Therapy

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 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. 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 practice aims to control health care costs but is often applied without consideration for individual medical histories, leading to treatment delays and adverse reactions. Stepping through fail-first requirements is a test of endurance – requiring patients to cycle through ineffective treatments before finally granting them access to the medication their doctors knew they needed from the start. For rare disease patients, these delays can mean irreversible health damage and increased costs.

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.

Right now, there are no guardrails to ensure step therapy will be used with the care and discretion patients deserve. A1825 (Conaway) remedies that, providing crucial safeguards and ensuring step therapy protocols do not hinder timely access to life-saving treatments. By explicitly allowing exceptions, it protects patients who are stable on their current medication or who require alternatives due to contraindications or other valid clinical reasons.

Regulating Step Therapy Protocols & Establishing 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 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 guaranteed to patients.[1] An overall grade for step therapy is determined by taking the average of these four separate grades.

As of today, New Jersey's step therapy policies earn an "F" on NORD's State Report Card—a failing grade that reflects the frustration and hardship faced by patients across the state. **With the passage of A1825, New Jersey wouldn't just catch up to the 40 states already leading the way; it would go from failing to excelling—from an "F" to an "A."** Therefore, we respectfully urge you to bring step therapy reform to the state and vote "aye" on A1825. Please do not hesitate to reach out with any questions.

Sincerely,

C Sheridan

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

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[1] NORD's State Report Card® Step Therapy Grading Methodology

CC:
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