MDS Testimony 2023 - Support - Senate Bill 515 - S

Uploaded by: Chesahna Kindred, MD, MBA, FAAD
Position: FAV

February 22, 2023

The Honorable Melony Ghee Griffith
Chair, Senate Finance Committee
11 Bladen Street
James Senate Office Building, Room 220
Annapolis, Maryland 21401

Re: Support for Senate Bill 515

Dear Chair Griffith,

On behalf of the nearly 150 physician members of the Maryland Dermatologic Society, we are writing to share our support for Senate Bill 515. This legislation would be a critical step to ensure patients have access to their prescription medicines. Pursuant to Senate Bill 515, health insurers would be required to expeditiously grant a step therapy override determination request if, in the professional judgment of the prescribing physician, the step therapy requirement would be medically inappropriate for that patient.

Step therapy protocols, a cost containment tool used by health insurance plans, require patients to try one or more prescription drugs before coverage is provided for a drug selected by the patient's health care provider. We understand the need to contain health care costs, but a 2022 survey of our membership found the following:

- 78% of respondents indicated their patients pay more out of pocket because of the Step Therapy process.
- 91% of respondents indicated that Step Therapy has INCREASED rates of non-adherence to treatment plans as compared to those not undergoing Step Therapy procedures.
- 74% of respondents indicated Step Therapy policies have resulted in forced drug switching, treatment gaps, and cessation of effective therapy "Always" (35%) and Usually (39%)

- 61% of respondents indicated that insurers invoke Step Therapy protocols between 5-20 times per month, with 62% indicating that this causes upwards of 5-30+ hours a month to respond to step therapy protocols.
- 36% of respondents indicate they have full time staff to work on Step Therapy and another 14% considering hiring staff dedicated to handling Step Therapy.

Requiring patients to try and fail treatments jeopardizes the health of patients, potentially resulting in dangerous consequences. In some instances, health plans force patients to return to the same treatments that have proven to be ineffective when tried previously under a different health plan. The decision to change plans may occur through no fault of the patients but rather an employer's decision to change plans.

We appreciate the opportunity to provide written comments on this important public health issue and urge your support for Senate Bill 515. As physicians, our number one priority is the health and welfare of our patients. The enactment of this legislation will improve access to prescription medications that are in the best interest of the patient. For further information, please contact Russ Kujan, executive director, Maryland Dermatologic Society at 410-539-0872.

Sincerely,

Chikoti Mibenge Wheat, MD, FAAD
President
Maryland Dermatologic Society

AADA Testimony 2023 - Support - Senate Bill 515 -
Uploaded by: Daniel Shattuck
Position: FAV

Mark D. Kaufmann, MD, FAAD President
Terrence A. Cronin Jr., MD, FAAD President-elect
Linda F. Stein Gold, MD, FAAD Vice President
Robert S. Kirsner, MD, PhD, FAAD Vice President-elect
Daniel D. Bennett, MD, FAAD Secretary-Treasurer
Keyvan Nouri, MD, MBA, FAAD Assistant Secretary-Treasurer
Elizabeth K. Usher, MBA Executive Director & CEO

February 21, 2023

The Honorable Melony Ghee Griffith
Chair, Senate Finance Committee
11 Bladen Street
James Senate Office Building, Room 220
Annapolis, Maryland 21401

Re: Support for Senate Bill 515

Dear Chair Griffith,

On behalf of the nearly 16,500 U.S. physician members of the American Academy of Dermatology Association, we are writing to share our support for Senate Bill 515. This legislation would be a critical step to ensure patients have access to their prescription medicines. Pursuant to Senate Bill 515, health insurers would be required to expeditiously grant a step therapy override determination request if, in the professional judgment of the prescribing physician, the step therapy requirement would be medically inappropriate for that patient. We urge members of the Senate Finance Committee to support Senate Bill 515.

Step therapy protocols, a cost containment tool used by health insurance plans, require patients to try one or more prescription drugs before coverage is provided for a drug selected by the patient's health care provider. We understand the need to contain health care costs, but we are concerned that step therapy strategies for medication and other treatment selection have the potential to impact patient outcomes and quality of life.

Requiring patients to try and fail treatments jeopardizes the health of patients, potentially resulting in dangerous consequences. In some instances, health plans force patients to return to the same treatments that have proven to be ineffective when tried previously under a different health plan. The decision to change plans may occur through no fault of the patients but rather an employer's decision to change plans.

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Further, step therapy interferes with the patient-physician relationship by preventing dermatologists from prescribing drugs they know will provide the best treatment results in the most effective manner. Senate Bill 515 would ensure that step therapy protocols used by health plans in Maryland will preserve the heath care provider's right to make treatment decisions in the best interest of the patient. Physicians know their patients' medical history, which enables them to identify potential contraindications and life-threatening adverse reactions. Retaining physicians' medical judgement in patients' treatment plans is a cost-effective way to prevent health care dollars from being used on medications that are not effective. It also prevents patients from enduring a prolonged course of treatment that includes scheduling multiple visits to their physician and spending money on prescription medications that are not effective.

We appreciate the opportunity to provide written comments on this important public health issue and urge your support for Senate Bill 515. As physicians, our number one priority is the health and welfare of our patients. The enactment of this legislation will improve access to prescription medications that are in the best interest of the patient. For further information, please contact Lisa Albany, director, state policy for the American Academy of Dermatology Association, at lalbany@aad.org or (202) 286-1041.

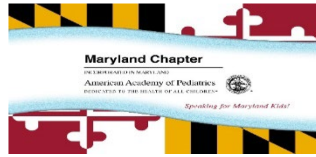
Sincerely,

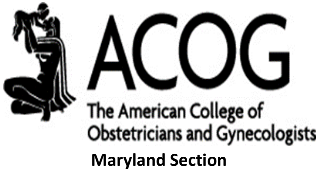
Mark D. Kaufmann, MD, FAAD
President
American Academy of Dermatology Association

SB0515_FAV_MedChi, MDAAP, MDAFP, MSEPS, MDACOG, MA

Uploaded by: Danna Kauffman

Position: FAV





TO: The Honorable Melony Griffith, Chair
Members, Senate Finance Committee
The Honorable Clarence K. Lam

FROM: Danna L. Kauffman
Pamela Metz Kasemeyer
J. Steven Wise
Andrew G. Vetter
Christine Krone
410-244-7000

DATE: February 22, 2023

RE: **SUPPORT** – Senate Bill 515 – *Health Insurance – Step Therapy or Fail-First Protocol – Revisions*

On behalf of the Maryland State Medical Society, the Maryland Chapter of the American Academy of Pediatrics, the Maryland Academy of Family Physicians, the Maryland Society of Eye Physicians and Surgeons, the Maryland Section of the American College of Obstetricians and Gynecologists, the Mid-Atlantic Association of Community Health Centers, and the Maryland Clinical Social Work Coalition, we submit this letter of **support** for Senate Bill 515.

Bill Rationale

Maryland has fallen behind other states in protecting patients from restrictive step-therapy or fail-first protocols ("step therapy"). Step therapy is a form of prior authorization where a health insurance carrier or pharmacy benefits manager (PBM) requires a patient to "fail-first" on certain medications, which are typically older and less-expensive, before the patient can take the medication recommended by the treating prescriber. While over two dozen states have added robust exemption policies into their laws, Maryland still only allows a patient to avoid an insurer's step therapy protocol if the patient has been on a drug for 180 days and the prescriber attests that the patient is doing well on the drug.[1] This typically occurs when a patient changes health insurers or health plans or there is a change to the patient's health plan.

[1] States with similar provisions of Senate Bill 515 are: North Dakota, Louisiana, Maine, New York, Pennsylvania (as of January 1, 2024), Kentucky, West Virginia, Virginia, Iowa, Minnesota, Kansas, Minnesota, Oklahoma, Colorado, New Mexico, Arizona, Oregon, Washington and California.

While carriers may have their own exemption process, it is not consistent or uniformly applied. The only exemption process in the law for requesting a drug outside of the carrier's requirements is when the carrier either does not have a drug on its' formulary, removes a drug from its' formulary, or moves the drug to a different cost tier (Section 15-831 of the Insurance Article). It does not address situations as outlined in Senate Bill 515 – when the carrier has a drug on its formulary but is requiring the patient to use another drug and the 180-day exception does not apply.

Step therapy prevents patients from accessing treatments recommended by their treating prescriber in a timely manner. When a patient is required to try what is often the "lesser" medication for treating his/her condition, patients suffer serious negative consequences, compromising treatment decisions and the patient's health. As pointed out by the Maryland/DC Society of Clinical Oncologists, "step therapy or fail first policies can be particularly problematic for patients with cancer because they can significantly delay a patient's access to the best treatment available for their condition. While waiting to complete a "step," a patient with cancer may experience disease progression and irreversible damage to their overall health." This is true for those also suffering from other chronic care diseases.

Bill Summary

Therefore, Senate Bill 515 makes the necessary changes to ensure that patients have access to the most appropriate and necessary drugs in a timely manner. While there may be times that a patient can handle a "step" medication, there needs to be safeguards built into the law to protect patients when the "step" medication may result in poor health outcomes.

Senate Bill 515 requires a health insurance carrier to establish a process for requesting an exception to a step therapy protocol if, based on the professional judgement of a prescriber:

- the prescription drug required to be used under a step therapy protocol is either:
    - contraindicated or will likely cause an adverse reaction, physical harm, or mental harm to the patient; or
    - is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or
- the patient is stable on a prescription drug selected by their health care provider; or
- the patient has already tried a prescription drug in the same pharmacologic class or has the same mechanism of action as the step therapy drug and was discontinued by the prescriber due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

This legislation also exempts from step therapy protocols a prescription drug that is used to treat the insured or enrollee's mental disorder or condition under certain conditions.

Lastly, the bill requires that the exemption process be clearly described, including the specific information and documentation that must be submitted by the prescriber to be considered a complete step therapy exception request; easily accessible to the prescriber; and posted on the entity's website.

On behalf of the above-referenced organizations and our patients, we urge a favorable vote on Senate Bill 515.

SB0515 Step Therapy - SUPPORT.pdf
Uploaded by: Emily Allen
Position: FAV

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MENTAL HEALTH ASSOCIATION OF MARYLAND

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Senate Bill 515 Health Insurance – Step Therapy or Fail-First Protocol - Revisions
Senate Finance Committee
February 22, 2023
Position: SUPPORT

The Mental Health Association of Maryland is a nonprofit education and advocacy organization that brings together consumers, families, clinicians, advocates, and concerned citizens for unified action in all aspects of mental health, mental illness, and substance use. We appreciate this opportunity to present testimony in support of Senate Bill 515.

SB 515 recognizes the clinical reasons why a patient cannot or should not be prescribed certain drugs and requires insurance carriers to establish a process for requesting an exception to a step therapy protocol in certain circumstances based on the professional judgement of a prescriber. Current law only allows for step therapy to be overridden in very limited circumstances.

Step therapy in its current form results in patients not having access to necessary treatment in a timely manner and can result in worsened symptoms for patients. It directly undermines decisions made between a patient and their provider, through multiple interactions and discussions of care, due to an insurance company's red tape. [1] A 2010 study found the number of antidepressant days supplied and medication costs decreased after step therapy was implemented, but overall and mental health-specific inpatient and emergency room utilization and costs increased.[2] Step therapy can be incredibly difficult to navigate, as requirements vary across carriers and plans. A 2021 study found that across 17 of the largest commercial health plans in the United States, plans applied step therapy in 38.9% of drug coverage policies, with 34% consistent with clinical guidelines and 55.6% being more stringent.[3]

Insurance policies should maintain access to provider-recommended medications, and SB 515 is a step in the right direction. It allows for step therapy to be overridden in cases where following the required steps could cause harm or negatively impact a person's well-being. For this reason, MHAMD supports SB 515 and urges a favorable report.

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[1] https://nami.org/Advocacy/Policy-Priorities/Improving-Health/Medications-Step-Therapy
[2] https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2010.09060877
[3] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.00822

For more information, please contact Emily Brandon at (443) 901-1588

NAMI MD - SB515 FAV.pdf
Uploaded by: Josh Howe
Position: FAV

NAMI Maryland
National Alliance on Mental Illness

February 22, 2023

Chair Griffith, Vice Chair Klausmeier, and distinguished members of the Senate Finance Committee,

The National Alliance on Mental Illness, Maryland and our 11 local affiliates across the state represent a statewide network of more than 45,000 families, individuals, community-based organizations, and service providers. NAMI Maryland is a non-profit that is dedicated to providing education, support, and advocacy for persons with mental illnesses, their families and the wider community.

NAMI believes that all people with mental health conditions deserve access to effective medication and treatment options. NAMI supports public policies and laws that prohibit step therapy for psychiatric medications.

Mental health medications affect people in different ways, and individuals need to be able to access the medication that works best for them and their individual health needs. It is important that medication decisions are carefully considered with a health care provider who has both extensive knowledge of the individual and available medication options.

Sometimes, health insurers may request or require patients to demonstrate unsuccessful treatment on one or more insurer-preferred medications before they receive coverage for the medication that their physician recommends. This practice is also known as “step therapy” or “fail first,” meaning that an individual must “fail” on one or more medications before they can try another that may be recommended by their health care provider. Step therapy results in patients not being able to access the treatments they need in a timely manner.

Step therapy can be a danger to the health and well-being of the person taking the medication, and result in a worsening of symptoms and undermining the decisions made between individuals and their health care providers. Instead, policies should maintain access to provider-recommended medications and should specifically prohibit step therapy for psychiatric medications, or, at a minimum, establish clear, rapid timelines for insurer responses to requests for exceptions and ensure that people who have previously used a medication do not have to switch.

- For many people with mental illness, medication is an essential part of their treatment and can be a valuable tool in overall well-being.
- For individuals who take medications for their mental health condition, one size does not fit all.
- Mental health medications affect people — even those with the same diagnosis — in different ways, including varying levels of effectiveness and different side effects. Because of this, it is important that a person can access the medication that works best for them.

Kathryn S. Farinholt
Executive Director
National Alliance on Mental Illness, Maryland

Contact: Morgan Mills
Compass Government Relations
mmills@compassadvocacy.com

- Some insurers may use “step therapy” (or “fail first”) policies that require a person try one or more insurer-preferred medications unsuccessfully before they receive coverage for the medication that their doctor recommends.
- For some health conditions, people can switch to a different drug without problems. However, for people with mental health conditions, step therapy has unintended — and sometimes dangerous — consequences.
- The use of mental health medications is a decision made between an individual and their health care provider based on their symptoms, treatment history and consideration of side effects.
- When a health insurer requires step therapy, it can pose serious risks to a person taking mental health medication.
- While step therapy is often promoted as a cost-savings strategy, policies that restrict access to medications can cause negative outcomes, sometimes leading to emergency department visits, hospitalizations, homelessness or criminal justice involvement.
- The cost to individuals, families and communities when a person must fail on a medication before getting what they need is too high.
- Mental health medications should be exempted from step therapy policies. At a bare minimum, policies should establish clear, rapid timelines to requests for exceptions and ensure that people who have previously used a medication do not have to switch.
- Step therapy risks the safety of people with mental health conditions. State and federal policies should protect — not jeopardize — access to mental health medications.

NAMI MD urges a favorable report on SB 515.
Thank you,

Kathryn S. Farinholt
Executive Director
National Alliance on Mental Illness, Maryland

Contact: Morgan Mills
Compass Government Relations
mmills@compassadvocacy.com

CancerCare_Testimony_SB 0515 Step Therapy_02.21.23
Uploaded by: Kim Czubaruk
Position: FAV

SB0515: "Health Insurance – Step Therapy or Fail-First Protocol – Revisions."
Submitted by Kim Czubaruk, Senior Director, Strategy and Policy, Cancer*Care*
February 21, 2023

Senator Lam and members of the Senate Finance Committee, I am Kim Czubaruk, Senior Director of Strategy and Policy for Cancer*Care*, the leading national organization providing free, professional support services and information to help people manage the emotional, practical, and financial challenges of cancer. In 2022, our staff answered more than 38,000 calls to our helpline and served clients with 90 different types of cancer, from all 50 states. Our comments are informed by the stories we hear from our clients as they navigate the confusing, expensive, and frustrating process of accessing and paying for vital – and sometimes life-saving – cancer care and treatment. I am writing in support of SB0515: Health Insurance – Step Therapy or Fail-First Protocol - Revisions.

Step therapy, sometimes called "fail-first, is a utilization management (UM) tool implemented by plans which requires patients to first try treatments that the plan prefers (often due to lower plan cost or larger PBM rebate) and have them fail before the plan will cover the treatment prescribed by the clinician.

When cancer patients don't get the right drug at the right time, the length and severity of illness can increase and major setbacks may occur in managing the disease. Delayed, disrupted, and denied treatment due to step therapy causes serious harm in the time-sensitive fight against cancer and other aggressive diseases. One study found that breast cancer patients who endured a three-month or more delay in treatment had a 12% lower five-year survival rate. The uncertain process of waiting for lesser drugs to fail can take weeks or months and step therapy has been shown to reduce the long-term effectiveness of a treatment. Step therapy policies often require patients to retry treatments that have already failed for them, such as when a patient switches plans or the formulary changes. People respond differently to treatments with regard to both effectiveness and adverse reactions. Despite payers' insistence on requiring step therapy, oncology drugs often do not have substitutes that are equally effective and less costly.

The revisions in SB0515 establish necessary and clearly defined requirements that protect patients from the potential serious consequences of step therapy. Current procedural ambiguities in the application of step therapy lead to harmful delays and barriers to patients receiving or maintaining effective treatment prescribed by their clinician. By requiring plans to establish an exceptions process to their step therapy protocol and describing the necessary steps for that process, SB0515 will prevent procedural ambiguity from being a catalyst for delay. Furthermore, delineating time parameters for plans to respond to an exception's request or an appeal of a denial, and including that such requests be granted by default if a plan fails to timely respond, ensures the process is timely and patient-centered.

SB0515 also restores respect for clinicians' expertise and knowledge and the importance of the patient-clinician shared decision-making process. For too long step therapy has allowed plans' financial interests to be prioritized over the professional judgment of clinicians on how best to efficaciously and safely

treat their patients' disease. Currently, Maryland law limits clinicians' use of their professional judgement to override step therapy protocol to situations when the effective drug has been prescribed within the past 180 days. This limitation negates the value of clinicians' medical knowledge and expertise and jeopardizes the health and safety of their patients. SB0515 reaffirms the knowledge and expertise of clinicians by requiring a step therapy exception request be granted if, based on the professional judgement of the prescriber, the expanded parameters established for an exception in SB0515 are met. Importantly, as described below, this requirement applies in some circumstances when the drug is covered under the current policy or contract or under a previous source of coverage. The expanded parameters of SB0515 on which prescribers may base their professional judgement to obtain a step therapy exception are:

- The step therapy drug is contraindicated or will likely cause an adverse reaction, physician harm, or mental harm to the patient; or
- The step therapy drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or
- The patient is stable on a prescription drug prescribed for the medical condition under consideration while covered under the entity's policy or contract or under a previous source of coverage; or
- While covered under the entity's policy or contract or a previous source of coverage, the patient has tried a prescription drug that:
    1. Is in the same pharmacological class or has the same mechanism of action as the step therapy drug; and
    2. Was discontinued by the prescriber due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

Approximately one in four individuals with cancer has clinical depression. SB0515 includes another important step therapy provision that prohibits the imposition of step therapy if the prescription drug is used to treat a patient's mental health (as defined in the source referenced in the bill) that results in a serious functional impairment that substantially interferes with or limits one or more major life activities. SB0515 will ensure that medication prescribed by a clinician to treat their patient's serious mental health condition will not be delayed or denied by a plan's imposition of step therapy.

Thank you for the opportunity to provide this written testimony and for your thoughtful consideration of this important legislation.

SB 515-CBH-FAV.pdf
Uploaded by: Lori Doyle
Position: FAV

Testimony on SB 515
Health Insurance – Step Therapy or Fail-First Protocol - Revisions
Senate Finance Committee
February 22, 2023
POSITION: SUPPORT

The Community Behavioral Health Association of Maryland (CBH) is the leading voice for community-based providers serving the mental health and addiction needs of vulnerable Marylanders. Our 110 members serve the majority of those accessing care through the public behavioral health system. CBH members provide outpatient and residential treatment for mental health and addiction-related disorders, day programs, case management, Assertive Community Treatment (ACT), employment supports, and crisis intervention.

There is a high correlation between non-adherence to drug regimens and utilization of high-cost care – such as emergency department visits or hospitalization - for individuals with serious mental health disorders treated with psychotropic medications. While various mental health drugs in a specific category may be equally efficacious, there is wide variability among those drugs as to their side effects, which may include liver damage, excessive weight gain, and sexual dysfunction. To the extent that consumers with serious mental health disorders do not have access to drugs whose side effects they can or will tolerate – due to step therapy or fail first protocols - there is a higher risk of non-adherence to the drug regimen.

SB 515 disallows the use of step therapy or fail-first protocols for prescription drugs used to treat an enrollee’s mental disorder or condition. The stakes are very high for those with serious mental illness who may rapidly decompensate if they don’t have access to medications that can stabilize their symptoms and improve their level of functioning. It can be very challenging to find the right mix and dosage of meds that work for any given individual. Requiring an enrollee to fail first on medications may result in hospitalization, job loss, and the loss of employer-based health insurance.

This is an important consumer protection bill. We urge a favorable report.

For more information contact Lori Doyle, Public Policy Director, at (410) 456-1127 or lori@mdcbh.org.

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SB515_SSAA_favorable (002).pdf
Uploaded by: Mary Moran
Position: FAV

Promoting support, research, treatment, and public policies that improve and save lives

SB 515, Health Insurance - Step Therapy or Fail-First Protocol - Revisions
Senate: Finance Committee
Date: February 22, 2023
From: Evelyn Burton, Maryland Advocacy Chair, Evelyn.Burton@sczaction.org
Position: SUPPORT

The consequences of delay in receiving effective treatment for numerous psychiatric illnesses can be costly and catastrophic. Especially for illnesses, such as schizophrenia, bi-polar disorder, and major depression, delay of effective treatment can result in hospitalization, suicide, homelessness, incarceration, and victimization, or violence.

In addition, the longer the period of untreated psychosis, the more brain cells are destroyed, which worsens the functional prognosis and chance of recovery.

Prescription drugs are an important part of treatment of individuals with mental disorders or conditions and it is important that prescribers be free to prescribe medication that will most benefit the patient in a timely manner and one which the patient will be most likely to tolerate.

Therefore, we support SB 515 which prohibits a step therapy or fail-first protocol for an insured or an enrollee for a prescription drug approved by the U.S. Food and Drug Administration that is used to treat a mental disorder or condition as defined in the current Diagnostic and Statistical Manual of Mental Disorders. It also prohibits an insurer, a nonprofit health service plan, or a health maintenance organization from requiring that a prescription drug or sequence of prescription drugs be used before the prescription drug ordered by a prescriber is covered.

Prescription drugs are a vital part of treatment of individuals with mental disorders or conditions and it is important that prescribers be free to prescribe medication that will most benefit the patient.

Enacting SB 515 would be of great benefit to patients with mental disorders or conditions by making it more likely the patient will recover and be able to live a normal life by getting effective treatment when it is needed.

Arthritis Foundation Written Testimony MD SB 515.p

Uploaded by: Melissa Horn

Position: FAV

Finance Committee
3 East
Miller Senate Office Building
Annapolis, Maryland 21401

February 22, 2023

Chairwoman Griffith and Members of the Finance Committee,

On behalf of the 1.4 million Maryland residents with doctor-diagnosed arthritis, thank you for the opportunity to submit testimony in support of Senate Bill 515, which addresses step therapy reform. The Arthritis Foundation understands utilization management tools such as step therapy can play a role in helping payers manage costs, but when these processes are overly burdensome, they can pose a significant hurdle for patients and impede patient-centered care.

Step therapy practices currently used by insurers require people with arthritis to try lower-cost medications before permitting more expensive treatments, despite a physician's recommendations for treatment. As a result, patients can often only access the drug their physician feels will be most effective after they have failed on the drug required by the payer. When a person changes insurance or a drug they are currently taking is moved to a non-preferred status, the person may be put through this step therapy process again. Some step therapy protocols also impose these requirements on patients remaining on stable treatments.

The complexity and length of these processes often leads to delays in treatment; these tools should be streamlined to allow for flexibility, including timely override of requirements, appeal of denials and in circumstances where a patient is changing plans, ensure the new plan does not need to repeat previously completed step therapy processes.

A survey of more than 1,400 patients conducted in 2016 by the Arthritis Foundation revealed that over half of all patients reported having to try two or more different drugs prior to getting the one their doctor had originally ordered. Step therapy was stopped in 39 percent of cases because the drugs were ineffective, and 20 percent of the time due to worsening conditions. Incredibly, nearly a quarter of patients who switched insurance providers were required to repeat step therapy with their new carrier.

This legislation will require a carrier to establish a process for requesting an exception to a step therapy protocol if, based on the professional judgement of a prescriber, the prescription drug required to be used by a step therapy protocol:

- is contraindicated or will likely cause an adverse reaction, physical harm, or mental harm to the patient; or
- is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or
- the patient is stable on a prescription drug selected by their health care provider; or
- the patient has already tried a prescription drug in the same pharmacologic class or has the same mechanism of action as the step therapy drug and was discontinued by the prescriber due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

For chronic patients living with arthritis, it can take months or even years to find the treatment that works best. Interruptions to ongoing treatment can result in negative health consequences and unnecessary delays and patients may miss work or become permanently disabled as a result. SB 515 reforms the step therapy process in Maryland to ensure patients living with arthritis can access the treatment that works best for their long-term care without having to navigate an overly burdensome process for drug approval.

The Arthritis Foundation thanks the committee for their consideration of SB 515 and urges all members to support this critical legislation.

Melissa Horn
Director of State Legislative Affairs
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2023 MCHS SB 515 Senate Side FAV.pdf

Uploaded by: Michael Paddy

Position: FAV

Maryland Community Health System

Committee: **Senate Finance Committee**

Bill Number: **Senate Bill 515 - Health Insurance – Step Therapy or Fail–First Protocol – Revisions**

Hearing Date: **February 22, 2023**

Position: **Support**

Maryland Community Health System (MCHS) is in strong support of *Senate Bill 515 – Health Insurance – Step Therapy or Fail–First Protocol – Revisions.* This bill requires a carrier to establish a process for requesting an exception to a step therapy protocol, and exempts from step therapy protocols a prescription drug that is used to treat the insured or enrollee's mental disorder or condition under certain conditions.

Step therapy is a policy implemented by insurance companies to require patients to try an initial course of inexpensive medications before moving on to more expensive treatments. The intent of the law on step therapy is to reduce the cost of healthcare, but it is not achieving this goal. Instead, it is causing delays in treatment, risking the health of the patient, and increasing the overall cost of healthcare. Our network of federally-qualified health centers focuses on providing care to underserved communities and consistently see delays in our patient's care because of certain step therapy protocols.

The current law does not provide adequate protections for patients who need specialty medications, especially for medication to treat mental disorders. It does not take into account the medical necessity of a particular treatment, nor does it require treatments to be approved in a timely manner. In addition, the bill would require insurance companies to provide an appeals process for patients who are denied a higher cost medication. This would ensure that patients can contest their denial and that their voices are heard in the process. This appeal process would be done in a timely manner, which would reduce delays in treatment and hopefully improve health outcomes. This legislation ultimately offers an opportunity to create a better system.

We ask for the Committee's full support of this legislation. We are committed to working with the Committee and other stakeholders as you review this bill. Thank you for your consideration of our testimony, and we urge a favorable vote. If we can provide any further information, please contact Michael Paddy at mpaddy@policypartners.net.

SB0515_FAV_MDCSO, ASCO_HI - Step Therapy - Revisio

Uploaded by: Pam Kasemeyer

Position: FAV

February 22, 2023

Senator Melony Griffith, Chair
Senate Committee on Finance
Room 3, East Wing, Miller Senate Office Building
11 Bladen St.
Annapolis, MD 21401

Dear Chair Griffith, Vice Chair Klausmeier, and Members of the Senate Finance Committee,

The Maryland/District of Columbia Society of Clinical Oncology (MDCSCO) and the Association for Clinical Oncology (ASCO) are pleased to support SB 515, which establishes guardrails around step therapy in the state.

MDCSCO is committed to improving the quality and delivery of care in medical oncology in the State of Maryland and the District of Columbia. ASCO is a national organization representing physicians who care for people with cancer. With nearly 45,000 members, our core mission is to ensure that cancer patients have meaningful access to high quality, equitable cancer care.

MDCSCO and ASCO are committed to supporting policies that reduce cost while preserving quality of cancer care; it is critical that such policies be developed and implemented in a way that does not undermine patient access. Payer utilization management approaches like step therapy protocols are of particular concern because they represent greater likelihood of raising barriers to appropriate care for individuals with cancer. While many treatments preferred by payers cost less, they may not be the best treatment available for the patient.

Step therapy or fail first policies can be particularly problematic for patients with cancer because they can significantly delay a patient's access to the best treatment available for their condition. While waiting to complete a "step," a patient with cancer may experience disease progression and irreversible damage to their overall health.

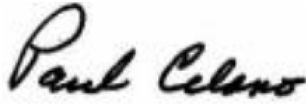
MDCSCO and ASCO are pleased that SB 515 would place guardrails around step therapy by requiring carriers to grant an exception to a step therapy protocol if:

- The drug required to be used is contraindicated or will cause an adverse reaction;
- The drug required to be used is expected to be ineffective based on the known clinical characteristics of the patient and the know characteristics of the prescription drug regimen;
- The patient is stable on a prescription drug selected by their clinician; or
- The patient has already tried a prescription drug in the same pharmacologic class or has the same mechanism of action as the step therapy drug and was discontinued by the prescriber due to lack of efficacy or an adverse event.

MDCSCO and ASCO are encouraged by the steps SB 515 takes toward improving step therapy in Maryland, and we welcome the opportunity to be a resource for you. For a more detailed understanding of our policy recommendations on this issue, we invite you to read the ASCO Position Statement:

Utilization Management. Please contact Sarah Lanford at ASCO at Sarah.Lanford@asco.org if you have any questions or if we can be of assistance.

Sincerely,



Paul Celano, MD, FACP
President
Maryland/DC Society of Clinical Oncology

Lori J. Pierce, MD, FASTRO, FASCO
Chair of the Board
Association for Clinical Oncology

SB 515 NMSS Testimony in Support S Wood .pdf
Uploaded by: Shannon Wood
Position: FAV

Maryland General Assembly – Senate Finance Committee

Testimony of Shannon Wood
Director of Advocacy and Policy: National Multiple Sclerosis Society
Support for SB 515: Health Insurance – Step Therapy or Fail First Protocol – Revisions

Chair Griffith, members of the Senate Finance Committee: thank you for the opportunity to provide testimony in support of SB 515, to provide important and necessary revisions to Maryland's step therapy protocols.

Multiple sclerosis, or MS, is an unpredictable disease of the central nervous system. Currently there is no cure. Symptoms vary from person to person and may include disabling fatigue, mobility challenges, cognitive changes and vision issues. An estimated 1 million people live with MS in the United States. Early diagnosis and treatment are critical to minimize disability. Significant progress is being made to achieve a world free of MS.

Step therapy or "fail first" policies are a form of utilization management that health plans may use as a mechanism to control the order in which patients take certain therapies. Step therapy protocols require that patients must try one or more medications selected by their insurer before the plan will grant coverage for the drug originally prescribed by the healthcare provider. Under step therapy protocols, for a given diagnosis, insurers cover specific drugs in a specific order, meaning an individual must be prescribed medications in the step order so that they are covered by the insurer. Insurers often defend the use of step therapy protocols as a method to ensure that safe, appropriate, and affordable drugs or other treatments are provided to patients. Plans rely on this process, among others, to help guide utilization of prescription drugs or other services and control the cost of treatment.

Patients (including people with MS) and healthcare providers have voiced concern regarding the potential adverse effects of step therapy, when it is not paired with protections for patients. Step therapy protocols transition medical decisions from a shared decision-making approach, between the provider and the patient, towards more standardized policies that focus on cost-effective care. These policies may not take into account detailed conversations between healthcare providers and patients, as they discuss the right medication for each person—factoring in things like efficacy, dosage, route of administration and side effects.

In addition, step therapy protocols may involve significant paperwork and documentation from healthcare providers and patients. Staff in provider offices must dedicate time to communicating with insurance companies to find out whether a prescribed drug will be covered—or appealing treatments that are denied. The time providers spend on these often-burdensome processes affects the office workflow and leaves them with less time to treat patients. This process is not only challenging for providers, but also a challenge for patients, who may spend many hours working with their provider's office to access the prescriptions they need.

When patients are required to cycle through and document a "step"—or in some cases, more than one step or medication—the process may result in substantial delays in treatment deemed appropriate by their healthcare provider. This process may affect patients' ability to immediately start treatment, or in some cases, their ability to continue a treatment that has been effective. Prolonging ineffective treatment (and delaying the medication initially prescribed by the healthcare provider) may result in disease progression for patients. For those with diseases such as multiple sclerosis, which may be severe or debilitating, delaying treatment can be a serious outcome. According to "The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence," a consensus paper by the Multiple Sclerosis Coalition, evidence supports the initiation of treatment with an FDA-approved disease-modifying therapy (DMT) as soon as possible following a diagnosis of relapsing MS. It can take years following an MS diagnosis to find the most effective course of treatment and when a patient does, they should remain on that drug uninterrupted. Considering the cost of MS medications, patients cannot afford to take drugs out of step order and without coverage. In 2022, the median annual price of the MS DMTs is close to $94,000, up nearly $25,000 from 2015. Six of the MS DMTs have increased in price more than 200% since they came on market, with nine now priced at over $100,000.

Although insurers utilize step therapy as a means to control cost, research has demonstrated that step therapy can in fact lead to higher spending over time. For example, while Georgia's Medicaid program initially saved $20 per person per month after introducing step therapy protocols for schizophrenia medications, the state ultimately ended up spending $32 per person per month on outpatient care, due to the use of ineffective medications by patients (Clinical Therapeutics, 2008, as cited in Health Affairs, 2016). The use of ineffective treatment has been associated with higher costs due to additional office visits, increased drug costs, and even the increased likelihood of needing additional treatment or hospitalization. Additionally, in the case of MS, effectiveness of the drug should not be the only factor considered. The risk profile of the medication as well as side effects and the ability for an individual to adhere to the medication must also be taken into account.

The National MS Society urges this committee – and the larger legislative body – to pass Senate Bill 515 this session. Allowing individuals, especially those with chronic diseases such as MS, access to step therapy protocol exceptions will not only improve their quality of life but may ultimately end up saving the state money. Protect the residents of Maryland and ensure that they receive the best care possible.

Please contact me if I can be of further assistance: shannon.wood@nmss.org.

FOR MD SB515- SDLong 02212023.pdf

Uploaded by: Sharon Long

Position: FAV

Greetings, Chair Griffith and members of the Senate Finance Committee! My name is Sharon D Long and I live in Fort Washington. I have MS, a chronic disease of the brain, optic nerves, and spinal cord. MS has significantly impacted my spine in that I have difficulty walking and standing. I am here to share my story as it relates to step therapy and urge this committee to FAVORABLY report SB 515.

I was officially diagnosed the day before Thanksgiving 2018. My family and I are daily processing MS' impact "on the fly", thinking "outside the box" to get things done. It's become a superpower for me as I continue contributing to society. **I work full-time, pay my taxes, go to church, and volunteer. I'm before you now for All of us with MS, especially those who can't speak for themselves.**

Picture it: You're at a doctor's visit, in the examination room. You and your doctor are wrapping up and he's writing a prescription for a med that's been successfully working for your MS symptoms. In comes an insurance representative, who doesn't know you, interrupting your doctor and setting aside the prescription saying you're required to try an alternative drug for 6 months to a year before you can go back to what you Already know works. (*Keep in mind your doctor's taken an oath **to do no harm**. Has that insurance representative or company? NO!*) Your preferred med is held "hostage" and you take this alternative drug getting sicker and sicker. Then, you're finally returned to the drug your doctor originally prescribed and was working for you. ***What's happening with your body?*** It's in "shock"- MS symptoms flaring, side effects from the alternative drug are manifesting, and the drug that had been working for you **NO LONGER WORKS**!

You were just treated like a "guinea pig" for the insurance company's bottom line profits!

Now what?! You and your doctor have to try to reverse the short-term and potentially long-term damage done to your body by starting all over, while your body suffers a "new Horrible MS normal". Guess what? The insurance company is getting paid TWICE at your expense- 1.) alternative drug and 2.) now you having to try other drugs to get, at least, your MS under control again. What about the non-MS side effects? Maybe you need more drugs for those too. ***It's $$$ going to the insurance company hand-over-fist while you suffer!***

While the topic **TODAY** is MS and Step Therapy, tomorrow it could easily be a drug **you** or a loved one are on for diabetes, high blood pressure, high cholesterol, asthma, or arthritis. Don't be naive and assume you won't be put in the same position in the future. For these insurers, it's about the $$$ Not your or my health and wellbeing! **Thank you for your time and I urge this committee to FAVORABLY report SB 515.**

Sharon D. Long

SB 515 - Step Therapy - Letter of Support (final).
Uploaded by: Steven Chen
Position: FAV

Maryland
Hospital Association

February 22, 2023

To: The Honorable Melony G. Griffith, Chair, Senate Finance Committee

Re: Letter of Support – Senate Bill 515- Health Insurance – Step Therapy or Fail-First Protocol – Revisions

Dear Chair Griffith:

On behalf of the Maryland Hospital Association's (MHA) 60 member hospitals and health systems, we appreciate the opportunity to comment in support of Senate Bill 515. Due to rising prescription drug costs, health insurance carriers increasingly require patients to undergo step therapy, which is a process where the patient must first try and fail on another drug—often a less expensive variation—before being allowed to step up to the more expensive medication. While the practice theoretically can control cost, improper use of step therapy delays access to necessary drugs and can lead to negative health outcomes. MHA supports proposals to reduce unnecessary delays and expedite patient access to lifesaving medication.

SB 515 would create two important protections against the undesirable effects of step therapy. First, the bill would exempt prescription drugs used to treat mental disorders from step therapy protocol. The United States is in the midst of a severe behavioral health crisis, which has been exacerbated by the COVID-19 pandemic.[1,2] While not the silver bullet, medications serve an important role in treating mental health disorders. Studies, however, show step therapy may inadvertently reduce antidepressant use and increase overall and mental health-specific inpatient and emergency room expenditure and utilization.[3] **Maryland should protect access to prescription drugs for patients afflicted with mental health disorders.**

Second, the bill would require health insurance carriers to establish a process for requesting a step therapy protocol exception. The bill outlines a number of exceptions, including if (1) the required drug is likely to cause harm to the patient; (2) is expected to be ineffective; (3) the patient is already stable on a different drug; or (4) the patient has already tried and failed using a drug in the same pharmacologic class.

These exceptions would help patients avoid unnecessary and potentially harmful delays. Carrier step therapy protocols are not always consistent with medical practice. A study of

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[1] "The US' growing mental health crisis, in 6 charts," Advisory Board, Oct. 7, 2022. www.advisory.com/daily-briefing/2022/10/07/mental-health-crisis

[2] "Increased need for mental health care strains capacity," American Psychological Association, Nov. 15, 2022. www.apa.org/news/press/releases/2022/11/mental-health-care-strains

[3] "The Effects of Antidepressant Step Therapy Protocols on Pharmaceutical and Medical Utilization and Expenditures," The American Journal of Psychiatry, Oct. 1, 2010. ajp.psychiatryonline.org/doi/full/10.1176/appi.ajp.2010.09060877

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commercial health plans found that 55.6% of the sampled step therapy protocols were more stringent than corresponding clinical guidelines.[4] More stringent protocols mean patients must try more drugs than clinical guidelines recommend, leading to more delays and potentially worsening the patient's health before they can access their preferred treatment. The proposed exceptions would help bypass delays and restore health care decision making to the patient and their providers.

For these reasons, we request a ***favorable*** report on SB 515.

For more information, please contact:
Steven Chen, Director, Policy
Schen@mhaonline.org

[4] "Variation in Use and Content of Prescription Drug Step Therapy Protocols, Within and Across Health Plans," Health Affairs, November 2021. www.healthaffairs.org/doi/10.1377/hlthaff.2021.00822

SB0515.LOSWA.pdf
Uploaded by: Heather Forsyth
Position: FWA

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February 21, 2023

TO: The Honorable Melony Griffith
Chair, Senate Finance Committee

FROM: Office of the Attorney General, Health Education and Advocacy Unit

RE: SB0515 – Health Insurance – Step Therapy or Fail-First Protocol – Revisions – **Support with Amendments**

The Office of the Attorney General's Health Education and Advocacy Unit (HEAU) supports the goal of curtailing the unjustifiably negative effects of step therapy by carriers that increasingly deny claims for prescribed drugs. The HEAU supports eliminating unnecessary step therapy requirements and streamlining the step therapy process when appropriately utilized. The changes this bill proposes should help eliminate dangerous delays in care, reduce inappropriate denials of medically necessary care, and reduce administrative costs.

The HEAU assists consumers in mediating and filing a grievance or appeal of carrier adverse decisions (denials based on medical necessity, appropriates or efficiency) or coverage decisions (other non-coverage decisions). In fiscal year 2022, the HEAU closed nearly 600 appeals and grievances cases, mediating 436 of those cases. Of the 436 cases, 26% were adverse decision cases, 56% were coverage decision cases, and 18% were eligibility cases. The HEAU mediation process resulted in 65% of the medical necessity cases and 56% of the coverage decision cases being overturned or modified. The HEAU mediation process resulted in 72% of pharmacy-related denials being overturned or modified. In the same fiscal year, 50% of grievances the MIA investigated were pharmacy-related grievances, and 84% of the denials were modified or overturned during the grievance process.

Over the years the HEAU has assisted many consumers impacted by step therapy protocols including:

200 Saint Paul Place ♦ Baltimore, Maryland, 21202-2021
Main Office (410) 576-6300 ♦ Main Office Toll Free (888) 743-0023
Consumer Complaints and Inquiries (410) 528-8662 ♦ Health Advocacy Unit/Billing Complaints (410) 528-1840
Health Advocacy Unit Toll Free (877) 261-8807 ♦ Home Builders Division Toll Free (877) 259-4525 ♦ Telephone for Deaf (410) 576-6372
www.marylandattorneygeneral.gov

- A 42-year-old woman diagnosed with psoriatic arthritis had been stable on Remicade infusions every 6 weeks with a dosage of 7 mg/kg since 2017. In July 2021, the carrier abruptly denied the Remicade claim, declaring "you will be held to FDA dosing guidelines not to exceed [6 mg/kg every 8 weeks]." In her internal appeal letter, the rheumatologist said "I have been made aware that the new policy at [the carrier] is to automatically deny any medication for a patient that is a higher dose or more frequent schedule than what the FDA product insert guide lists; even if it is a proven dose and schedule that has had significant benefit for a particular patient. This policy will jeopardize my patient's treatments and cause disease relapse, unnecessary pain, loss of income from not being able to work and irreversible damage to her joints." With the HEAU's intervention, the denial was overturned, and the prior dosage and frequency resumed. Several other patients filed complaints about the same carrier, which was denying medication claims notwithstanding each patient's established need for medically necessary treatments tailored to their disease progression and symptoms. The HEAU also obtained reversals of those denials.

- A 62-year-old consumer had been taking a brand name medication for a thyroid condition consistently since 2014. When she attempted to obtain a refill, her carrier denied coverage because the brand name drug was off-formulary and the plan required her to try and fail a generic drug first. The consumer's physician provided records stating that the consumer had tried the on-formulary generic drug prior to 2014 and that it was unsuccessful in controlling her TSH level. The carrier continued to deny coverage. The HEAU sought external review resulting in the carrier overturning the denial and approving the medication for one year.

- A 35-year-old resident suffered from psoriatic arthritis. After trying several medications without success, he was prescribed Enbrel which significantly improved his health. When he switched jobs and employer-based insurance, his new carrier denied coverage of Enbrel because it was off-formulary and required step-therapy. The consumer unsuccessfully appealed the denial twice with the carrier. The carrier's plan documents were unclear suggesting on the one hand that step therapy was required, but also suggesting that continuation of Enbrel therapy required proof of a positive clinical response. The HEAU obtained his medical records and appealed the denial, resulting in the carrier overturning the denial and approving the medication for one year.

These stories are not unique and highlight the problems faced by consumers and providers daily. The data shows that denials of coverage are overturned or modified at a high rate, so the current process only prevents or delays access to timely and appropriate care, jeopardizing patient health and well-being and burdening healthcare providers.

But the HEAU does have some technical concerns.

1. On page 4, line 22, the HEAU suggests substituting "THE" with "A" to account for any of the patient's providers having discontinued a drug due to lack of efficacy or effectiveness, diminished effect, or an abuse event.

2. On page 4, line 25, the term "appeal" is introduced without definition. It has long been the HEAU and the MIA's position that a carrier's denial of coverage based on step therapy is a medical necessity denial and subject to the appeals and grievances process under Title 15, Subtitle 10A. Introduction of the term "appeal" without definition or reference to 15-10A, which does not use the term "appeal," introduces unnecessary ambiguity regarding the process that is due.

It is possible the bill's step therapy exception denial process is intended to be a precursor to the carrier's internal grievance process given the real-time and one business day turnaround times, but this should be clarified.

In any event, to avoid confusion, we believe it would be appropriate to state that a decision by an entity subject to this section to deny a step therapy exception request constitutes an adverse decision as defined under Subtitle 10A of this title.

Lastly, the HEAU objects to Page 5, line 10, which appears to state that the step therapy exceptions process does not apply if the issuer mandates use of generics/biologics first; this exception could swallow the rule with respect to generics/biologics. Consumers who have previously tried and failed on generics/biologics, or for whom a generic/biologic is contraindicated, should not lose the protections afforded by this bill.

We support this well-intentioned bill and look forward to working with all stakeholders to strengthen consumer protections regarding step therapy without inadvertently reducing or hindering consumer rights under existing law.

cc: Senator Clarence Lam