

SusanBehen_FAV_SB0952

Uploaded by: Behen, Susan

Position: FAV

Susan L. Behen, MD, FACS
1612 Park Grove Ave
Catonsville, MD 21228

February 25, 2020

Written testimony in support of Senate Bill 952

Dear Senators of the Committee:

I am a constituent from District 12 with Psoriatic Arthritis who benefitted from being started on biologic therapy without having to go on "fail first" protocol.

The diagnosis of my Psoriatic Arthritis took about 2 years of worsening symptoms. I am a General Surgeon and I trained at the Johns Hopkins Hospital. I had a busy private practice, and the pain and weakness was significantly affecting the ability to clamp instruments, use staplers, lift and maneuver organs and tissue. This affected the ability to perform surgery safely, to be a full partner in my business, and support my family.

When my Rheumatologist came to the diagnosis of Psoriatic Arthritis, it was a relief to have a diagnosis. As we discussed the right treatment for me, she recommended starting a biologic in my particular situation. In 2009, biologics were not as well know, but I was quite desperate for a solution. I did not realize at the time how fortunate I was, as my insurance company did not require a "fail first " Step Therapy protocol.

Starting on biologic therapy first, had a quick and significant effect. I was able to return to full Surgery practice for several years, and then transition to teaching medical students when the timing was right for me.

Thank you for considering my testimony.

Susan L. Behen

MonicaBertagnolli_FAV_SB0952

Uploaded by: Bertagnolli, Monica

Position: FAV

February 26, 2020

Chair, Senator Delores Kelley
Senate Committee on Finance
Maryland State Senate
11 Bladen Street
Annapolis, MD 21401



Honorable Chair Kelley and Members of the Senate Committee,

The Association for Clinical Oncology (ASCO) is pleased to **support SB 952: Health Insurance – Requirement for Establishing Step Therapy Protocol and Requesting Exceptions**. 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 cancer care.

ASCO is committed to supporting policies that reduce cost while preserving quality of cancer care; however, 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.

Step therapy or fail first policies can be problematic for patients with cancer because they can severely 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. For patients with advanced cancer, a delay in care is a matter of life and death. For that reason, step therapy policies are generally inappropriate in oncology due to the individualized nature of modern cancer treatment and the general lack of interchangeable clinical options. With all of this in mind, **we are encouraged to see that SB 952 improves step therapy protocols in the state by:**

- **Enhancing clinical validity** by requiring insurers to incorporate evidence-based, peer-reviewed clinical guidelines into the development of their step therapy protocols;
- **Accommodating the needs of special patient populations** by requiring insurers to take atypical patient populations and diagnoses like cancer into account in their clinical review criteria;
- **Creating a step therapy exemption process** that is clear, convenient, and easily accessible; **and**
- **Ensuring timely access to care** by determining that a step therapy exemption request must be answered within 72 hours under normal circumstances and within 24 hours under exigent circumstances.

ASCO is encouraged by the steps that SB 952 takes toward improving step therapy protocols in Maryland. **We therefore urge the committee to pass the measure.** For a more detailed understanding of our policy recommendations on this issue, we invite you to read the [ASCO Position Statement: Utilization Management](#) by our affiliate, the American Society of Clinical Oncology. Please contact Allison Rollins at ASCO at allison.rollins@asco.org if you have any questions or if we can be of assistance.

Sincerely,

A handwritten signature in black ink that reads "Monica Bertagnolli, MD". The signature is written in a cursive style.

Monica Bertagnolli, MD, FACS, FASCO
Chair of the Board
Association for Clinical Oncology

BenjaminChandhok_FAV_SB0952

Uploaded by: Chandhok, Benjamin

Position: FAV



February 26, 2020

Chair Delores G. Kelley
Senate Finance Committee
Legislative Services Building
90 State Circle
Annapolis, MD 21401

Dear Chair Kelley and Senate Finance Committee Members,

On behalf of the 1.1 Million Maryland residents living with doctor-diagnosed arthritis, the Arthritis Foundation asks for your support of SB 952, legislation that would reform health insurance step therapy protocols. This important legislation will provide patients timely access to the medications they need to maintain their health.

While step therapy can be an appropriate way to control costs, for some patients this “one-size-fits-all” process can produce adverse health outcomes. For Maryland children and adults with chronic, debilitating and sometimes life-threatening diseases like arthritis, delaying access to the appropriate treatment, or requiring them to “fail-first” on a medication an insurer chooses rather than one originally prescribed by their physician can have a significant negative impact on a patient’s continuity of care. This can result in progression of their condition, loss of function or mobility, or other devastating consequences as well as increased overall healthcare costs.

A survey of over 1,400 patients completed by the Arthritis Foundation in 2016 found that over 50% of all patients surveyed reported having to try two or more different drugs prior to getting the medication their doctor had initially prescribed. Step therapy was stopped in 39% of cases because the drugs were ineffective, and 20% of the time due to worsening conditions. A majority of respondents experienced negative health effects from delays in receiving their prescriber’s preferred treatment.

SB 952 creates common-sense reforms for all Maryland patients by guaranteeing access to a clear process to request a step therapy exception when it is medically appropriate. This successfully balances protecting patients while still allowing the use of step therapy.

Your support will help ensure a healthier Maryland patient population. For more information, please contact Ben Chandhok, Senior Director of State Legislative Affairs with the Arthritis Foundation, at bchandhok@arthritis.org or 513-484-7623.

Sincerely,

Benjamin Chandhok

Ben Chandhok
Senior Director of State Legislative Affairs
Arthritis Foundation

ACS CAN_FAV_SB 952

Uploaded by: Collins, Jocelyn

Position: FAV



American Cancer Society
Cancer Action Network
555 11th St., Suite 300
Washington, DC 20004
202.661.5700
www.fightcancer.org

February 26, 2020

TO: The Honorable Delores G. Kelley, Chair
The Honorable Brian J. Feldman, Vice Chair
Members of the Senate Finance Committee
3 East
Miller Senate Office Building
Annapolis, MD 21401

FROM: Jocelyn Collins, Maryland and DC Government Relations Director
American Cancer Society Cancer Action Network
555 11th St. NW, Suite 300
Washington, DC 20004
jocelyn.collins@cancer.org
(301) 254-0072 (cell)

SUBJECT: SB 952 Health Insurance—Requirements for Establishing Step Therapy Protocol and Requesting Exceptions

POSITION: SUPPORT

The American Cancer Society Cancer Action Network (ACS CAN) is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society. We support legislation that balances protecting patients when a step therapy protocol would produce an adverse health outcome, with allowing for the use of step therapy when it is appropriate for controlling costs. On behalf of our constituents, many of whom have been personally affected by cancer, we stand in support of SB 952.

Step therapy is a tool insurers use to limit how much they spend covering patients' medications. Under a step therapy protocol, a patient must try one or more drugs chosen by their insurer—usually based on financial, not medical, considerations—before coverage is granted for the drug prescribed by the patient's health care provider.

Patients may be required to try one or more alternative prescription drugs that are of lower cost to the insurer, but may not be the best therapy for some patients.

Scientific breakthroughs mean that, in many cases, a cancer diagnosis now can be managed and treated. Patients need the ability to quickly assess their condition with their doctors and find the best course of treatment for their individual medical needs. Delays in access to the best treatment available, that could be experienced as a result of patients having to go through a step therapy protocol, can pose significant risk to the treatment of disease.

Step therapy can undermine physicians' ability to effectively treat patients, can lower quality of care, and lead to setbacks and disease progression for patients.

Exemptions from step therapy do not prohibit insurers from using step therapy but seek to balance cost containment with patient needs. ACS CAN supports SB 952/HB 1359 because it protects patients by: ensuring that step therapy programs are based on clinical guidelines developed by independent experts; by ensuring that the exceptions process for step therapy is transparent and accessible to patients and health care providers; and by establishing a basic framework for when it is medically appropriate to exempt patients from step therapy.

JosieCooper_FAV_SB0952

Uploaded by: Cooper, Josie

Position: FAV



**Alliance for
Patient Access**

February 25, 2020

The Honorable Delores G. Kelley
Chair
Senate Finance Committee
Legislative Services Building
90 State Circle
Annapolis, MD 21401

The Honorable Shane E. Pendergrass
Chair
Health and Government Operations Committee
Legislative Services Building
90 State Circle
Annapolis, MD 21401

The Honorable Brian J. Feldman
Vice Chair
Senate Finance Committee
Legislative Services Building
90 State Circle
Annapolis, MD 21401

The Honorable Joseline A. Pena-Melnyk
Vice Chair
Health and Government Operations Committee
Legislative Services Building
90 State Circle
Annapolis, MD 21401

Re: Support for SB 0952 and HB 1359 - Health Insurance - Requirements for Establishing Step Therapy Protocol and Requesting Exceptions

Dear Senators and Delegates,

On behalf of the Alliance for Patient Access (AfPA), I am writing in support of SB 0952 and HB 1359, companion bills that will protect the physician-patient relationship by providing clear guidelines on the use of step therapy, one of the most common utilization management tools.

Founded in 2006, AfPA is a nonprofit, national network of physicians and other health care providers dedicated to patient-centered care. AfPA advocates for health policies that support clinical decision making, protect the physician-patient relationship, and ensure patients' access to approved therapies and appropriate clinical care.

SB 0952 and HB 1359 would protect patients' access to care by establishing guidelines around health insurers' use of step therapy protocols, helping to ensure patient-centered care and preserving physician-patient decision making in health care treatment.

Step therapy is a utilization management tool used by insurers to dictate a specific course of care, often as a way to contain health care costs. Sometimes referred to as "fail first", step therapy protocols require patients to try and fail on one or more medications, usually lower cost medications, before the patient can access the medication as prescribed by their health care provider. This leads to delays in accessing treatment for many patients.

The bills provide commonsense reforms that give the health care provider and patient a path to satisfy step therapy protocols by providing clear exception criteria and an approval timeline. While step therapy rooted in clinical guidelines would be permitted, this legislation would help protect patient access by requiring a clearly described and accessible exemption process. Further, exception requests must be granted in a timely manner when the preferred medicine is contraindicated, expected to be ineffectual based on a specific patient, has already been tried and found ineffective or the patient is stable on another medicine. Importantly, the legislation does not prevent insurance companies from using step therapy, nor does it limit the number of steps required by the insurer. However, it serves as an important step toward protecting the provider-patient relationship that is critical to successful care by providing clear guidelines, improved accessibility, and faster response times to step therapy appeals.

We thank the sponsors for introducing legislation that incorporates the patient-physician relationship ideals outlined in AfPA's step therapy [position paper](#):

- Step therapy must be rooted in clinical evidence.
- Insurers must offer a straightforward exemption process.
- Insurers' communication must be timely and clear.

On behalf of Maryland patients and the Alliance for Patient Access, I urge your support for SB 0952 and HB 1359 throughout the legislative process to reform step therapy protocols.

Sincerely,



Josie Cooper
Executive Director
Alliance for Patient Access

CBH_FAV_SB952

Uploaded by: Doyle, Lori

Position: FAV



Testimony on SB 952
Health Insurance – Requirements for Establishing Step Therapy Protocol
And Requesting Exceptions

Senate Finance Committee

February 26, 2020

POSITION: SUPPORT

The Community Behavioral Health Association of Maryland is the professional organization for providers of community-based mental health and substance use disorder treatment services. Our members serve the majority of the almost-300,000 children and adults who access care through the public behavioral health system. We provide outpatient treatment, residential and day programs, case management and 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 952 requires step protocols to be based on clinical practice guidelines versus strictly cost considerations and includes numerous consumer education and protection provisions, such as requiring clearly described processes for an exception to the step therapy protocol that must be accessible and understandable to patients and prescribers.

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

RyanGough_FAV_SB0952

Uploaded by: Gough, Ryan

Position: FAV



PARTNERSHIP TO ADVANCE
**Cardiovascular
Health**

February 25, 2020

The Honorable Delores G. Kelley
Chair
Senate Finance Committee
Legislative Services Building
90 State Circle
Annapolis, MD 21401

The Honorable Shane E. Pendergrass
Chair
Health and Government Operations Committee
Legislative Services Building
90 State Circle
Annapolis, MD 21401

The Honorable Brian J. Feldman
Vice Chair
Senate Finance Committee
Legislative Services Building
90 State Circle
Annapolis, MD 21401

The Honorable Joseline A. Pena-Melnyk
Vice Chair
Health and Government Operations Committee
Legislative Services Building
90 State Circle
Annapolis, MD 21401

Re: Support for SB 0952 and HB 1359 – Health Insurance – Requirements for Establishing Step Therapy Protocol and Requesting Exceptions

Dear Senators and Delegates,

On behalf of the Partnership to Advance Cardiovascular Health (PACH), I am writing in support of SB 0952 and HB 1359. These bills that will help patients access appropriate and timely treatment by providing clear guidelines on health care plans' use of step therapy, a common utilization management tool.

PACH is a 501(c)(4) nonprofit advocacy coalition of stakeholder groups that represent patients, patient advocates, health care providers and medical researchers in the cardiovascular space. On behalf of its members, PACH advocates for patient access to FDA-approved therapies and promotes innovation in cardiovascular health care for the millions of Americans who are at high risk for heart disease. SB 0952 and HB 1359 would protect patients' access to care by establishing guidelines around health insurers' use of step therapy protocols, helping to ensure patient-centered care and preserving physician-patient decision making health care treatment.

Step therapy is a utilization management tool known as “fail first” that requires patients to follow an insurance dictated treatment path that favors low cost medicines over other treatment options. It is used by insurers as a way to contain health care cost but does not recognize that that treatment may not be appropriate for a patient, may have already been tried and failed or is contraindicated to other

medications being taken. Patients are prevented from accessing the medication prescribed by their health care provider, leading to delays in accessing treatment for many patients.

Limits on step therapy protocols are especially important to patients with cardiovascular disease, the number one killer in the state of Maryland, the United States, and around the world. Our nation is currently in a health crisis and today's CVD patient is drastically different from those of previous decades. Patients are younger and have comorbidities such as diabetes, high blood pressure, and obesity. The window for prevention has become much smaller and optimal treatment for patients must begin as soon as possible.

More and more patients are being considered high-risk by health care providers, and delays in appropriate treatment for them are life-threatening. One of the most egregious examples where market access has been systemically restricted for consumers is the PCSK9 inhibitor (PCSK9i) drug class. These medications have come to market in the last five years and have proven to significantly reduce the rates of heart attack, stroke and even death. More recently, data has shown that PCSK9is can also reverse atherosclerosis. This medication is very effective for those with severely elevated LDL-cholesterol, who have familial hypercholesterolemia (FH), and who are unable to tolerate first-line LDL lowering therapies. For some patients, other medicines have proven to be ineffective.

SB 0952 and HB 1359 provide guardrail reforms that give the health care provider and patient a path to satisfy step therapy protocols by outlining clear exception criteria and an exception request approval timeline. PCSK9is are not for every patient, but when it is deemed necessary by a physician to save their patients' lives, timely access is important. This legislation does not prevent insurance companies from using step therapy, nor does it limit the number of steps required by the insurer. However, it serves as an important step toward protecting the provider-patient relationship that is critical to successful care by providing clear guidelines, improved accessibility, and faster response times to step therapy appeals.

Health care innovations, like PCSK9is, have revolutionized the management of CVD. Going forward [patients can expect more and new therapies that aim to reduce and, in the long term, eliminate CVD altogether.. If insurers are allowed to install barriers to accessing these therapies, we will never reach our population health goals to ensure citizens live long, healthy lives. Access to these important treatments now, along with primary prevention measures for our future generations, is crucial to tackling our nation's CV health crisis.

On behalf of the Partnership to Advance Cardiovascular Health and its coalition members, we ask that you support SB 0952 and HB 1359 to create patient access protections in the use step therapy procedures.

Sincerely,

A handwritten signature in blue ink, appearing to read "Ryan Gough". The signature is fluid and cursive, with the first name "Ryan" and last name "Gough" clearly distinguishable.

Ryan Gough
Executive Director

TonyMartelli_FAV_SB0952

Uploaded by: Martelli, Tony

Position: FAV

February 26, 2020

Greetings Chair Kelley and members of the Senate Finance Committee. Thank you for your service to our communities and our state and for the opportunity to write to you today.

My name is Tony Martelli, and I am writing on behalf of my wife, Debbie Martelli, who lives with rheumatoid arthritis, psoriatic arthritis, and osteoarthritis. I am writing to advocate for SB 952 on behalf my wife Debbie and the many thousands of Maryland residents who suffer from these diseases.

Debbie has been battling increasingly severe pain for about 10 years and immobilizing pain in the last couple of years. After a couple years of many doctor visits, much testing, and several potential diagnoses, a new test confirmed that much of her pain was caused by severe rheumatoid arthritis (RA), as well as psoriatic arthritis, and osteoarthritis. A number of standard treatments were used, but none significantly controlled the disease.

When the common RA drugs did not work, immune system blockers had to be considered. Due to Debbie's damaged immune system, resulting from radiation and many years of oral chemotherapy following cancer as well as a couple serious allergies, her doctor had to carefully select and monitor new drugs for adverse reactions and serious infections. Due to Debbie's latex allergy, her doctor ruled out a couple of the most common immune system blockers and selected a newer drug that was covered through our insurance plan. However, when the prescription was submitted to the insurance company for prior approval, it was declined.

The insurance company stated that Debbie could not access the prescribed treatment because the common options had not been tried first. In other words, step therapy was required, even though the doctor had explained the latex allergy in the original request. It was not until the doctor then submitted an appeal explaining that the required first step therapy drug could cause a serious reaction and possible death, and also sent a letter detailing the situation to the State Attorney General's office, that the insurance company finally yielded and approved the drug.

During this period of waiting, Debbie was in crying pain, so I contacted the insurance company to see if I could expedite the process in any fashion. I received the two denial letters which included the Medical Director's name and phone number for questions. I called the number multiple times and explained the situation, but I was never connected with the Medical Director, I was only

provided excuses. It appeared to me that I was speaking with administrative personnel who were following hard and fast processes that were business driven to eliminate or defer costs, rather than trained medical staff making sound medical decisions in the best interests of their subscribers.

Thankfully, through the persistence of Debbie's doctor and our multi-front approach, we received approval after "only" a few weeks of waiting. I expect that this process could have taken many months had the doctor and their staff not been so dedicated to Debbie's case. However, this approval was not the end of Debbie's journey with step therapy. When our plan year started over, we had to jump through all of these hoops again. The insurance company required us to resubmit for approval of Debbie's treatment, even though they already had her full medical history on file. Step therapy delayed my wife's access to treatment to control her arthritis and reduce her crying pain.

Debbie's case does not fit into the one-size-fits-all approach of step therapy, which is why we need SB 952, to improve the step therapy process with clear exceptions for patients like Debbie. You may recall that I noted my wife's damaged immune system. That meant that the doctor, while beginning with much research and closely monitoring after administering a new immune system blocker, was subject to trial and error at best to identify a drug that reduced the RA affects for my wife without causing an adverse reaction. In a 12-month period during 2017 and 2018, the process required 3 failures before success in finding a drug that worked and my wife's immune system would tolerate. The first drug caused a severe lung infection requiring hospitalization and ongoing oxygen. The second drug caused a debilitating UTI requiring hospitalization. The third drug ONLY caused a burning skin rash that ONLY required strong antibiotics (that drug had a \$103,000 monthly prescription price). On top of this complex trial and error process to find a treatment that would work for Debbie, we had to go through step therapy – including lengthy denials and appeals – for many of these drugs. As you can imagine, there was great deal of crying in our home.

Although the final RA drug has controlled/limited the RA effects, the previously uncontrolled diseases have completely damaged two joints, and possibly a third. That means 3 replacement surgeries. The last thing we need as we go forward with surgeries and potential complications would be another lengthy step therapy process that again delays critical medications and mandates unnecessary pain and suffering.

Maryland must provide step therapy protections for situations like Debbie's. It is inhumane to make people suffer the way my wife and I did because of step therapy protocols that do not take individual's medical circumstances into account. This is why I encourage the committee to vote yes on SB 952.

Again, thank you for this time and your service.

Tony and Debbie Martelli
Millersville Residents

ErinnMaury_FAV_SB0952

Uploaded by: Maury, Dr. Erinn

Position: FAV

February 26, 2020
Dr. Erinn Maury
Baltimore, MD – District 46

Good afternoon. I'm Dr. Maury. I'm a solo practitioner rheumatologist in Glen Burnie Maryland. As you know, in 2014, Maryland was one of the first states to enact step therapy protections, which have benefited many Marylanders. I'm here today in support of SB 952 which would strengthen Maryland's step therapy protections to cover cases that are not addressed in the current law. I have many examples of such cases but will only cover a few in my remarks today.

First, step therapy has required my patients to try treatments that would cause an adverse reaction. For example, I have a few patients with severe latex allergies. Typically, I submit an authorization request to get a latex-free option for self-injectable medication covered by their health insurance, but my requests are routinely denied. The responses state that the patient must first fail the LATEX-containing treatment required by the step therapy protocol. After many appeals, I get the latex-free option covered. In one case, I had to get the State Attorney General's office involved to get approval.

Step therapy also requires patients to try treatments that have the same mechanism of action as a treatment they have failed. For example, I have a patient with Ankylosing Spondylitis. The PBM wanted him to try infliximab before going to Cosentyx even though he had failed a drug in the same class as infliximab. Based on my knowledge of the patient, the medications he had tried and the behavior of his disease, my clinical judgement told me he would be better off on Cosentyx, a different class of drug. They forced me to put him on infliximab which did not control his disease. After he went through many months of suffering, Cosentyx was finally approved. Within 6 weeks of starting it, he was dramatically better. The PBM could have SAVED money and prevented suffering of my patient had they listened to my clinical judgement. SB 952 would allow a patient like this to go straight to Cosentyx instead of trying another drug in a class he had already failed.

Lastly, there is only 1 rheumatoid arthritis medication considered safe in pregnancy and breast feeding. For my young women who want to start families, the only medically appropriate option is the one that is SAFE during pregnancy, but step therapy prevents them from accessing it even though it is covered by their insurance. I had a PBM deny this medication to a woman with very active rheumatoid arthritis who was still breastfeeding her infant. After many appeals, it was finally approved but her treatment was delayed by 3 months which significantly increased her risk of long-term disability.

I spend a lot of my personal time after hours dealing with arbitrary denials and writing appeal letters. I have one employee whose main job is dealing with authorizations and appeals. This is a complete waste of time and money. I could have her dealing with other patient care issues, instead she spends hours on hold for each appeal. It's an administrative nightmare. My staff and I suffer, my business suffers, and most importantly, my patients suffer. SB 952 would alleviate many barriers to timely and appropriate therapy for patients in the state of Maryland.

KatieRoberts_FAV_SB0952

Uploaded by: Roberts, Katie

Position: FAV

Step Therapy Testimony – Katie Roberts
Odenton, MD – District 32

Good afternoon Chairperson and committee members.

My name is Katie Roberts and I've lived with a severe and debilitating form of psoriatic arthritis for nearly 40 years, and psoriasis, a painful skin condition, for nearly 30 years. I'm here today as a patient advocate representing the National Psoriasis Foundation & the Arthritis Foundation. I'd like to share with you my experience with step therapy so you can better understand why **SB-952** is a "makes sense" bill.

For the majority of my 43 year life, I've lived with psoriatic arthritis, a debilitating form of autoimmune arthritis, and psoriasis a skin condition also triggered by the immune system.

I went undiagnosed and misdiagnosed for many years, despite knowing something was wrong with my body. My diagnoses for psoriasis came first in middle school, then arthritis a while later. My psoriasis popped up, quite literally, overnight following chicken pox strep throat combo, followed by pneumonia. I went from having chicken pox one morning to having close to 75% body coverage of psoriasis within 48 hours.

At age 17, I was struggling to function – I was in constant pain at all hours of the day, could not walk without an assisted device, and barely had enough energy to take care of basic life needs. I had been an active youth participating in dance, volleyball, outward bound, and many other adventures despite some arthritic pain. And then my arthritis rapidly worsened while in high school.

After an appointment with a Rheumatologist at age 17, I was told I would likely not live long enough to see my 21st birthday – my body was slowly shutting down from years of living with an autoimmune disease. It was more than the arthritis and psoriasis. The autoimmune disease had started to affect my digestive system, bladder, liver, kidneys, heart, and lungs.

In 1994, there were few drugs available to treat my illness. After pain medications quickly failed, my doctor and I agreed to a methotrexate and steroid combination, even after recognizing the many very serious side effects of both drugs. This medication combination has historically been used to treat my autoimmune disease, however it's efficacy, at least for me, was limited.

My disease continued to progress over the coming years despite this drug cocktail, ending up in the hospital at least every few months, and having had medical procedures or surgeries to try to remedy the effect of comorbidities that many patients like me face when their disease is not stable. Just about every week, sometimes every day, was filled with thoughts of suicide, and I questioned why this was happening to me.

At 26, I was spending more time in hospitals than out of them. I had been on countless drugs to try and treat the disease and even participated in several experimental drugs protocols at NIH. I had made it past my death date of 21 years of age, but my doctors had encouraged me to make the most of the days I had left, convinced I was nearing the end. My body was failing, and time was not on my side.

Then, a biologic drug was made available. Within 3-4 weeks of starting this medication, I was out of a wheelchair, and within about 6-8 weeks was walking mostly unassisted. My psoriasis went from 80%

body coverage to less than 5% body coverage within 8 weeks. I had hope for the first time in a long time. The medication was giving me my life back.

It was my miracle drug. It literally saved my life. I was able to join the workforce again and go on to have a very successful professional career for many years.

Until step therapy.

My insurance at the time had been covering my biologic injections for more than a year. Mid-plan, they sent me a letter informing me my biologic would no longer be covered under my plan. They indicated they needed me to prove a less-costly drug wouldn't work and to create medical necessity for my miracle drug. This practice is better known today as Step Therapy.

This was devastating to both me and my family. My loved ones saw me at my worst, and they cheered me on as I fought to win back my life while on the biologic. It was as if everything positive and hopeful we had experienced together for those successful years was slipping through our hands again. Fearful of what life would be like without my treatment, suicide once again entered my thoughts.

My doctors vowed to fight and help appeal the insurance decision to no avail.

There were no stipulations on how long I had to be on any particular step medication. My doctor had lost total control of my health care. We didn't know at what point the insurance company would allow me to advance through the various steps of medications, nor was it clear what medications were permitted for my disease in particular.

The decision by the insurance provider did not take into consideration my previous medical history, the length of time I had been stable on the biologic. It also didn't have clear expectations to what my health care treatment future looked like. The step therapy decision also didn't factor in my disease activity as a whole, or that the biologic was helping stabilize more than my arthritis. It was also controlling my psoriasis and associated comorbidities I had developed over years of being on ineffective drugs, including endocarditis (a heart condition), pleurisy (a lung condition), and Crohn's disease. Despite proven medical research that indicated drugs like methotrexate were not effective for advanced and severe psoriatic arthritis and psoriasis, the insurance company forced me to return to previously ineffective drugs.

During the 10 months I was forced through Step Therapy as a patient, I had 14 procedures/surgeries to address other disease activity that had been dormant for the years I was stable on a biologic, including intestinal surgery, a permanent implant in my bladder to prevent it from collapsing, and routine liver biopsies & partial removal of my liver since I had previously experienced liver problems and blood disorders often associated with long-term/high-dose methotrexate (chemotherapy drug) treatments.

Within 4 weeks of going off the biologic, I was back in a wheelchair – that's four weeks to go from a fully functioning active adult to wheelchair. That's how fast this disease can progress if not stabilized.

The costs associated with additional drugs I had not needed while on the biologic, doctor visits, surgeries, and the missed time from work because I was not strong enough or well enough to work, were staggering.

In the end, the total cost of all of the additional medications I had to take to curb full disease activity, the purchase of assisted devices, counseling services to address mental health and anguish, and surgeries exponentially exceeded the cost of the biologic – a drug that I had been stable on for many years and had been scientifically proven to effectively treat my disease.

I was able to return to my miracle drug after the 10 months of failed Step Therapy. I was able to regain my quality of life, but not without permanent health issues that will continue to need attention for the duration of my life. I did not respond to it as quickly as I did the first time – my body was stressed by the additional damage caused in my time without the biologic. It took about 8 months for me to return to a similar quality of life once enjoyed prior to Step Therapy.

I am able to sit here today and share my story because I'm one of the lucky ones. A biologic drug saved my life not just once, but twice. These drugs are powerful, and they work for many other patients like me.

But the real reason I'm able to sit here today and share my story is because of the relationship and trust I have with my team of doctors. I know they will do everything within their power to ensure I have the best quality of life my disease and available medications affords me. I trust them to guide me on the best course of action for my health care.

Step Therapy seemingly sounds like the right thing to do to help curb medical costs, however it falls short in universal application for many of the patients step therapy targets. I encourage you to remember my 10-month fight for my life while on step therapy, the accelerated costs incurred by both patient and insurance company during that time, and to ensure appropriate patient-centered protections are in place so no other person has to experience what I went through. There needs to be a clearly defined path that takes into consideration previous medical history, disease stability, doctor expertise, and scientific research. Physicians must be able to override step therapy when medically appropriate. Patients like me need a policy that reinforces the exceptions process and requires insurance providers to create step therapy protocols that are based on clinical guidelines. A standard appeals process for granting or denying submissions on step therapy can mean the difference between life and, in some cases, death. Non-exigent cases should be reviewed within 72 hours and 24 hours for exigent cases.

I ask that in your role as a representative of the people, that together, we can make sure health care quality and decision making are between the doctor and patient, and trust that our physicians can abide by the first rule of medicine, "do no harm," for their patients.

When reviewing policy, I encourage you to replace the word "Beneficiary" and "Patient" with the name of your child, parent, other family member or loved one to remember that phrases like beneficiary and patient are simply other words to define people. People like me. People like you and your family.

Please make an informed decision about the step therapy reform bill. Say yes to **SB-952**.

Thank you for allowing me the time to share my story with you today.

Senator Benson_FAV_SB952

Uploaded by: Senator Benson, Senator Benson

Position: FAV

JOANNE C. BENSON
Legislative District 24
Prince George's County

Finance Committee
Chair, Rules Committee

Joint Committees

Children, Youth, and Families
Ending Homelessness
Fair Practices and State Personnel Oversight
Management of Public Funds

Chair, Prince George's County
Senate Delegation



James Senate Office Building
11 Bladen Street, Room 214
Annapolis, Maryland 21401
301-858-3148 · 410-841-3148
800-492-7122 Ext. 3148
Fax 301-858-3149 · 410-841-3149
Joanne.Benson@senate.state.md.us

THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401

Testimony of Senator Joanne C. Benson

**SB 952: Health Insurance- Requirements for Establishing Step Therapy
Protocol and Requesting Exceptions**

Good afternoon Madam Chair and esteemed members of the Finance Committee. Senate Bill 952: Requirements for Establishing Step Therapy Protocol and Requesting Exceptions, reinforces exceptions for step therapy to protect patients from the harmful effects of being forced to fail first. Step therapy is an insurance protocol requiring patients to try and fail on a sequence of medications before being granted access to covered treatment prescribed by a patients' doctor. This causes a delay in access to necessary treatments and at times results in irreversible progression of disease and adverse effects for many with chronic diseases. It interferes with the doctor-patient relationship by placing prescribing power in the hands of the insurance company, rather than the doctor. It also increases an administrative burden for providers and their staff.

Senate Bill 952 **does not ban** step therapy. Instead, it offers a moderate, compromised solution by placing reasonable regulatory restraints on step therapy. In 2014, this committee passed legislation directing the Maryland Health Care Commission to create benchmarks for establishing an online process for overriding step therapy protocols and timelines for processing requests. This bill builds upon that success to strengthen those protections and bring Maryland's step therapy law in line with dozens of other states, including New York, Texas, Virginia, Ohio, Wisconsin, Georgia, and Maine.

Senate Bill 952 seeks to:

- Establish an exceptions process for patients if trying or staying on a medication that would create a significant barrier to compliance, worsen a comorbid situation, be contraindicated, or decrease a patient's ability to achieve or maintain reasonable function;
- Ensure step therapy protocols are based on widely accepted clinical guidelines so that medical expertise, not the rebate system, dictates utilization management;
- Unify timelines for granting or denying requests to override step therapy protocols;

- And protect patients whose conditions are well-controlled on a prescription from being required to try a new medication if step therapy protocols are added to the formulary at contract renewal.

We need to be about the business of helping and healing our Marylanders. Of providing them with the immediate access to medications that will allow our State to continue to sustain a healthy workforce, build loving families, and grant individuals the opportunity to have a long, fulfilling life. We should not subject people to jump through unnecessary hoops by trying numerous medications that are ineffective and that contradicts with their doctor's original prescribed medication for their patients.

You will hear from a number of advocates and physicians in support of this legislation today. In collaboration with many of the partners you worked with in 2014 to pass the first step therapy bill, we will be submitting amendments to preserve parts of existing law which are already protecting patients and to define utilization review. Those amendments will also make timelines for considering step therapy requests consistent with existing law for preauthorization requests. My fellow panel members are here to testify and answer any questions you may have.

Thank you and I respectfully request a favorable report on Senate Bill 952.

AADA_FWA_SB952

Uploaded by: Albany, Lisa

Position: FWA



February 26, 2020

The Honorable Delores Kelley
Chair, Senate Finance Committee
11 Bladen Street
Annapolis, MD 21401

RE: Senate Bill 952 – Support as Amended

Dear Chairperson Kelley,

On behalf of the nearly 14,000 U.S. members of the American Academy of Dermatology Association (“Academy”), we write in strong support of the amended version of SB 952. Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases and many genetic disorders. As physicians who are on the front lines fighting skin cancer and treating numerous skin diseases, we believe this legislation would be a critical step to ensuring that patients can access the therapies prescribed by their physician. Pursuant to SB 952, 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 amended SB 952.

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.

Further, step therapy interferes with the patient-physician relationship by preventing dermatologists from prescribing drugs they know will provide the best treatment results in

George J. Hruza, MD, MBA, FAAD
President

Bruce H. Thiers, MD, FAAD
President-Elect

Jane M. Grant-Kels, MD, FAAD
Vice President

Susan C. Taylor, MD, FAAD
Vice President-Elect

Marta J. Van Beek, MD, MPH, FAAD
Secretary-Treasurer

Daniel D. Bennett, MD, FAAD
Assistant Secretary-Treasurer

Support for SB 952

02/26/2020

Page 2 of 2

the most effective manner. SB 952 would ensure that step therapy protocols used by health plans in Maryland will preserve the health 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 a prolonged 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 SB 952 as amended. 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 Academy at lalbany@aad.org (202) 842-3555.

Sincerely,

A handwritten signature in black ink that reads "George Hruza". The signature is written in a cursive style with a large, sweeping initial "G".

George J. Hruza, MD, MBA
President

American Academy of Dermatology Association