

Thank you members of the Assembly Committee on Health and Senate Committee on Health for allowing me the opportunity to speak on this important bill today.

This common-sense, bipartisan legislation aims to provide exceptions to step-therapy protocols. I first was introduced to this issue through my work on substance abuse and the HOPE Agenda. Someone with an addiction is in a fragile state medically, and often, different forms of treatment may not work for many of them. In a life and death situation like substance abuse, affording flexibility to a physician is not only necessary, it's the right thing to do.

When a physician prescribes a particular drug treatment for a patient, the patient's insurance company may require them to try a less expensive treatment, or series of treatments, before they can have access to the drug originally prescribed by their physician. The patient is not able to try the second treatment until the first one is proven to "fail." This protocol is known as "step therapy" and is deployed by insurance companies as they strive to control costs while maintaining high-quality care. As an insurance agent, I understand and am sympathetic to these goals, but at the same time, I believe there needs to be logical, common-sense exceptions to this process.

Step therapy protocols often ignore a patient's medical history, such as whether they have already tried certain drugs under a different health insurance plan, or if they have other medical conditions that might interfere with the drug's effect. It may also not take into account whether a certain drug's side effects will affect the patient's ability to perform their job, or if the patient would benefit from a drug that has a different ingestion method or dosage form. Each of these aspects can have a profound influence on a patient's compliance and responsiveness to treatment.

After discussions with the Alliance of Health Insurers, the Wisconsin Association of Health Plans, and several patient advocacy groups, we created a substitute amendment that keeps the spirit, integrity, and patient protections of the original bill, while still ensuring the health plans have the ability to meaningfully utilize step therapy protocols in order to keep costs down.

This substitute amendment creates transparency for patients in how step therapy protocols are created. It also creates a clear exceptions process for patients, and will ensure that patients are able to access the healthcare their doctor is prescribing for them. At the same time, the amendment provides more flexibility for health plans and will ensure they are still able to use step therapy protocols in a meaningful way to keep costs down.

The many stories you'll hear following my testimony will illustrate the importance of this bill. It's rare that we can pass bills that will have a direct immediate impact on the lives of Wisconsinites, but this bill does just that.



Odds are, you have been or know someone who has suffered at the hand of step therapy protocols. The outpouring of support and personal stories that I have heard is unprecedented when compared to any other bill I have worked on.

I would like to extend a sincere thank you to the Alliance of Health Insurers and the Wisconsin Association of Health Plans for the involvement in helping craft a bill that works for Wisconsin.

I appreciate the opportunity to testify before the joint committee today on this important piece of legislation and welcome any questions you may have at this time.

Alberta Darling Wisconsin State Senator

Senate Bill 26 and Assembly Bill 24

Wednesday, April 17, 2019

Thank you Chairs Testin and Sanfelippo, and committee members for hearing Senate Bill 26 and Assembly Bill 24. I'd like to begin today by thanking the health plans and patient groups who worked with myself and Representative Nygren in crafting the sub amendment before the committee today. The language in the sub amendment is truly a compromise amongst all parties who worked to ensure that Wisconsin's patients are receiving the best healthcare available for them. As a result, the bill before the committee today is crucial to better connecting patients with the healthcare their doctors prescribed, while still ensuring our insurance plans have the flexibility to keep consumer prices low.

Step therapy is a process used by health plans that determines the order in which prescription drugs should be given to a patient. Each health plan's step therapy protocol is different, and for good reason. The goal of step therapy is to lower healthcare costs while maintaining access to quality medicine. However, there are clear instances when step therapy protocols need to be overridden for the health of the patient.

SB 26/ AB 24 lay out a clear exception process for step therapy protocols. Under the bill, patients may request exceptions to a step therapy protocol if the drug is contraindicated and will likely cause the patient harm, if the drug is expected to be ineffective, if the patient has already tried that drug and failed, or if the patient is already stable on a prescription drug. The exceptions laid out in the bill provide clarity for patients and doctors as they try to find a treatment plan that best suits the patient. Once a doctor requests an exception, under the bill, the health plan must respond within three business days for non-emergent cases, or by the end of the next business day for an emergency situation. This will re-ensure that patients are accessing the best treatment for them in a timely manner.

SB 26/ AB 24 create transparency in health care for patients and doctors. The bills expedite the process for patients to receive the drug that is right for them and ensure that step therapy protocols are created with the current medical practices in mind. This bill reaffirms patient centered care at the forefront in Wisconsin.

Again, I would like to thank Representative Nygren, the Wisconsin Association of Health Plans, the Alliance of Health Insurers, and the strong coalition of patient advocacy groups for their amazing work on this issue. It is because of their dedication to providing the best care for patients in Wisconsin that this sub amendment is before you today. Thank you all for taking the time to listen to the testimony on Senate Bill 26 and Assembly Bill 24. I hope the personal stories of those speaking after me can shine more light on this critical issue.



WISCONSIN ACADEMY of FAMILY PHYSICIANS

April 17, 2019

Senator Patrick Testin & Representative Joe Sanfelippo Senate Committee on Health and Human Services, Assembly Committee on Health

Re: Assembly Bill 24 and Senate Bill 26

Chairman Testin, Chairman Sanfelippo, Senate and Assembly Committee Members:

My name is Dr. Joanna Bisgrove. I am a family physician from Oregon, Wisconsin. I am also a member of the Wisconsin Academy of Family Physicians, and co-chair of the Academy's legislative committee.

The Wisconsin Academy of Family Physicians has been an engaged member of the Wisconsin Step Therapy coalition representing providers and patients throughout Wisconsin. I'm here today on behalf of the coalition, the Academy, and as a physician to urge you to support Assembly Bill 24 and Senate Bill 26.

This important, bipartisan legislation authored by State Rep. John Nygren and State Sen. Alberta. Darling aims to provide patients with timely access to the medications their physicians prescribe.

Step therapy is a tool commonly used by insurers to govern the order in which patients utilize certain therapies approved for a diagnosed condition. Step therapy processes are implemented for pharmaceutical therapies to treat a variety of diseases and chronic conditions, including Alzheimer's, Cancer, Diabetes, HIV/AIDS and Mental Health. Under step therapy protocols, patients may be required to try one or more alternative prescription drugs chosen by their health plan before coverage is granted for the drug prescribed by that patient's health care provider.

While it may be appropriate to follow step therapy protocols in some cases, there are instances where step therapy requirements work against the wellbeing of patients. For example, not long ago, I had a patient who is a mother of two young sons. She was having trouble breathing, and in our evaluation we discovered she had a rare condition where her throat had closed down to the size of a pinhole. Luckily, we have an expert on this condition at the University of Wisconsin. And even better luck, this expert had recently completed a study which showed that a particular inhaler already on the market was far better than all of the others at preventing her throat from reclosing once it was surgically reopened.

So I ordered the inhaler. And then got the denial letter. She had to try a different inhaler first. So I got on the phone with a pharmacist from the insurance company, and discussed the situation. The pharmacist insisted that, per the protocol, the patient had to try and fail the preferred inhaler first. I found myself saying. "You do realize that failing the first inhaler means she could die? This isn't like asthma. This is a rare, life threatening condition."

This story provides a perfect example of how fast medical knowledge and medical therapies evolve, and how difficult it can be for step therapy protocols to keep up. We need a better way. Assembly Bill 24 and Senate Bill 26 works towards that better way by striking the right balance between maintaining protocols and recognizing the necessity to override the protocols in certain circumstances not unlike what happened with my patient.

Specifically, the bill allows physicians to request exceptions to step therapy protocols when:

- 1. A drug required under a protocol is contraindicated
- 2. A drug required under a protocol is expected to be ineffective based on various criteria
- 3. The patient has already tried a drug required under a protocol and it was found to be ineffective.
- 4. The patient is already stable on a provider-prescribed drug while covered under the current or previous policy or plan.

These bills place some controls back into the hands of providers and patients to decide the best course of action in addressing a medical condition.

The Wisconsin Academy of Family Physicians is strongly supportive of these pro-patient bills and we urge your support for them too.

Wisconsin Association of Health Plans

The Voice of Wisconsin's Community-Based Health Plans

Testimony Presented to the Joint Hearing of the Assembly Committee on Health Senate Committee on Health and Human Services Assembly Bill 24/Senate Bill 26 April 17, 2019

Chairman Sanfelippo, Chairman Testin, and Members of the Assembly and Senate Committees, thank you for the opportunity to testify today on step therapy.

My name is Tim Lundquist and I am the Director of Government and Public Affairs at the Wisconsin Association of Health Plans.

I am here today to publicly thank Representative John Nygren and Senator Alberta Darling and their staff for working with health insurance providers to draft a substitute amendment to their step therapy proposal that responds to industry concerns and best practices in prescription drug coverage. Because of their hard work and collaboration, the Wisconsin Association of Health Plans will be neutral on Assembly Bill 24/Senate Bill 26 with the adoption of the authors' substitute amendment.

The Wisconsin Association of Health Plans is the voice of 11 Wisconsin community-based health plans that serve employers and individuals across Wisconsin in a variety of commercial health insurance markets. Our members are also proud to partner with the state to serve Wisconsin's Medicaid Managed Care Programs and the State Group Health Insurance Program.

Across all lines of business, Wisconsin's community-based health plans provide value to their members by creating access to the safest, most-effective health care, at a more affordable cost. Step therapy is an evidence-based process to help guide physicians and patients to safe, cost-effective drugs.

Dr. Chris Kastman, Chief Medical Officer at Group Health Cooperative of South Central Wisconsin, has joined me today to discuss how step therapy works at his health plan and is used on behalf of patients to achieve better health outcomes at lower costs.

We are also happy to answer any questions committee members may have.



WISCONSIN BOARD FOR PEOPLE WITH DEVELOPMENTAL DISABILITIES

April 17, 2019

Senator Testin Senate Committee on Health and Human Services Wisconsin State Capitol, Rm 131 S Madison, WI 53707 Representative Sanfelippo Chair, Assembly Committee on Health Wisconsin State Capitol, RM 314N Madison, WI 53708

Dear Senator Testin, Rep. Sanfelippo and Committee members:

The Wisconsin Board for People with Developmental Disabilities (BPDD) thanks the committee for the opportunity to provide testimony in support of Assembly Bill 24 and Senate Bill 26.

Step therapy requirements have detrimentally impacted people with intellectual and developmental disabilities (I/DD), especially those that have neurological disorders including epilepsy and other conditions that may result in seizures. Finding the right combination of medications and other techniques, including dietary changes or surgery, to manage symptoms often involves a time-consuming process of trial and error. Even small variations to medications or protocols may lead to loss of control over seizures.

Many people with epilepsy have described seizure control going awry when switching to generics or even between generic drugs. While the active ingredients are the same, any deviation of active or inactive ingredients can prove destabilizing for people whose seizure control is tenuous.

We recently heard from one parent who spent many years trying dozens of medications to control the hundreds of seizures their daughter was having each day. They found one drug that worked and had successfully controlled their daughter's seizures for many years when their HMO decided they wanted to switch to a generic version. In this case, the neurologist intervened, and the HMO respected the medical opinion that any variation would have devastating effects so that the patient could continue on the brand name drug that had already proven to be effective.

Step therapy also impacts people with I/DD who may be on multiple medications. The interaction between multiple drugs can be a delicate balance and changes to any one drug may trigger changes in control of symptoms, management of reoccurring or chronic conditions, and overall well being of the individual. Individuals do respond to the same medication differently.

Deciding what drug(s) and protocol are best able to manage the patient's health and quality of life should be between doctor and patient; it should not be determined by an insurer.

BPDD is charged under the federal Developmental Disabilities Assistance and Bill of Rights Act with advocacy, capacity building, and systems change to improve self-determination, independence, productivity, and integration and inclusion in all facets of community life for people with developmental disabilities (more about BPDD <u>https://wi-bpdd.org/wp-content/uploads/2018/08/Legislative_Overview_BPDD.pdf</u>).

Our role is to seek continuous improvement across all systems—education, transportation, health care, employment, etc.—that touch the lives of people with disabilities. Our work requires us to have a long-term vision of public policy that not only sees current systems as they are, but how these systems could be made better for current and future generations of people with disabilities.

Thank you for your consideration,

Bet Sweden

Beth Swedeen, Executive Director Wisconsin Board for People with Developmental Disabilities



WAG Coalition of Wisconsin Aging & Health Groups

Financial Empowerment – Personal Advocacy – Victim Rights

"Advocating for all Generations"

The Coalition of Wisconsin Aging and Health Groups is a nonprofit, nonpartisan, statewide membership organization that was founded in 1977.

4/17/19

Testimony in support of AB 24 and SB 26

Good morning Chair Testin, Chair Sanfelippo, and members of the Committees. Thank you for the opportunity to speak today, I'm Rob Gundermann, Executive Director of the Coalition of Wisconsin Aging and Health Groups speaking in favor of AB 24 and SB 26.

The provision in the bills that means the most to my organization is the one creating a timeframe for the appeals process. I'm referring to the language that provides an answer to an exemption request within three business days or in exigent circumstances, one day. This is important to us because many of the people we represent are taking multiple medications to address a variety of ailments and illnesses and this provision will mean a great deal to them.

Often, when we look at Step Therapy or other types of prior authorizations, we are looking at one specific medication because the request for an exception is usually for one specific medication but it's often much more complicated.

Let me just give you an example: Patient John Doe has lived with epilepsy for his whole life but has been successfully medicated and hasn't had an event for many years. A few years ago, he was diagnosed with arthritis and most recently he was diagnosed as having moderate dementia. Like many people diagnosed with dementia, John develops depression and begins having bouts of delirium and has to be medicated for this as well. His blood pressure is high so he's on medication to lower that and his cholesterol is high so he's on a medication to lower his cholesterol too. At this point John Doe is taking prescription medications to treat seven conditions and that doesn't include any over the counter medications he's taking. Now John gets something new, he develops pneumonia, or shingles, or something else and the physician needs to introduce a new medication. This is one of those times when an exemption to the Step Therapy protocol can be critical, when the physician is adding a new medication to a cocktail of drugs already cycling through the patient.

When someone is on a host of different medications to treat different ailments, managing the interactions between drugs can become very tricky and when a physician is adding in a new medication to this drug cocktail they have a lot to consider in terms of how that new medication interacts with what the patient is already taking. These bills will help patients in situations like this by speeding up the exemption process and preventing delays in obtaining the medications they need.

Thank you for your time and consideration. I'm happy to try to answer any questions.

My name is Dr. Joanna Bisgrove. I am a family physician from Oregon, Wisconsin. I am also a member of the Wisconsin Academy of Family Physicians, and co-chair of the Academy's legislative committee.

The Wisconsin Academy of Family Physicians has been an engaged member of the Wisconsin Step Therapy coalition representing providers and patients throughout Wisconsin. I'm here today on behalf of the coalition, the Academy, and as a physician to urge you to support Assembly Bill 24 and Senate Bill 26.

This important, bipartisan legislation authored by State Rep. John Nygren and State Sen. Alberta Darling and aims to provide patients with timely access to the medications their physicians prescribe.

Step therapy is a tool commonly used by insurers to govern the order in which patients utilize certain therapies approved for a diagnosed condition. Step therapy processes are implemented for pharmaceutical therapies to treat a variety of diseases and chronic conditions, including Alzheimer's, Cancer, Diabetes, HIV/AIDS and Mental Health. Under step therapy protocols, patients may be required to try one or more alternative prescription drugs chosen by their health plan before coverage is granted for the drug prescribed by that patient's health care provider.

While it may be appropriate to follow step therapy protocols in some cases, there are instances where step therapy requirements work against the wellbeing of patients. For example, not long ago, I had a patient who is a mother of two young sons. She was having trouble breathing, and in our evaluation we discovered she had a rare condition where her throat had closed down to the size of a pinhole. Luckily, we have an expert on this condition at the University of Wisconsin. And even better luck, this expert had recently completed a study which showed that a particular inhaler already on the market was far better than all of the others at preventing her throat from reclosing once it was surgically reopened.

So I ordered the inhaler. And then got the denial letter. She had to try a different inhaler first. So I got on the phone with a pharmacist from the insurance company, and discussed the situation. The pharmacist insisted that, per the protocol, the patient had to try and fail the preferred inhaler first. I found myself saying. "You do realize that failing the first inhaler means she could die? This isn't like asthma. This is a rare, life threatening condition."

This story provides a perfect example of how fast medical knowledge and medical therapies evolve, and how difficult it can be for step therapy protocols to keep up. We need a better way. Assembly Bill 24 and Senate Bill 26 works towards that better way by striking the right balance between maintaining protocols and recognizing the necessity to override the protocols in certain circumstances not unlike what happened with my patient.

Specifically, the bill allows physicians to request exceptions to step therapy protocols when:

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These bills place some controls back into the hands of providers and patients to decide the best course of action in addressing a medical condition.

The Wisconsin Academy of Family Physicians is strongly supportive of these pro-patient bills and we urge your support for them too.

Good Morning Chairman Testin, Chairman Sanfelippo and members of the committees, my name is **Jocelyn Wilke** and I am the nurse practitioner who works in the Multiple Sclerosis Clinic for UW Health. I am here today as a representative for the National Multiple Sclerosis Society, not as a representative of UW Health. I am here to testify in support of Assembly Bill 24 and Senate Bill 26 on behalf of the National Multiple Sclerosis Society.

As you may be aware, Multiple Sclerosis is an often-devastating disease that affects the central nervous system. Multiple Sclerosis causes both inflammatory lesions and degenerative changes in the brain and spinal cord. This means that our patients can go from walking, talking and seeing normally one day to being unable to function the next. Integral in treating this disease are our fifteen disease modifying therapies. With these medications many of our patients are able to achieve the goals of being free from relapses, having no new lesions develop in their brain or spinal cord and slowing brain atrophy. The acronym that we use to reflect our goals for therapy is NEDA - no evidence of disease activity. Effectively treating patients to NEDA is attainable with the right individualized treatment.

The current step therapy requirements utilized by most insurance companies limit our ability to provide the care to patients that we would all like to deliver. Often, the providers in our clinic see patient and know which disease modifying therapy is best for them. This decision is very personal for every patient as the available treatments do not work in the same way and have contraindications that make them less than ideal for certain patients. Unfortunately, many of these medications require an individual to step through other medications, before they are approved, causing dangerous delays in treatment. Many of our patients spend hours of their time attending appeals, filling out paperwork and communicating with our office about these appeals. In the field of MS all of the highly effective therapies are considered "second line." This means that people who we know are at high risk for disability are forced to try the less effective options first, resulting for many in severe and irreversible consequences. In addition, presently, there aren't set guidelines for receiving a response from insurers. In some of the worst cases I've experienced, it can take a patient up to three months to receive a response. Requiring a decision within 3 business days will help avoid treatment delays, which in turn will help our patients start these lifesaving therapies sooner.

In addition to the timeline language, I'd like to thank legislators for outlining circumstances in which an exception request can be sought, particularly the provisions that allow an individual who is stable to stay on their medication and the provision which states that if a person has tried and failed a medication before, they do not have to try and fail it again to get access to the medication that will work for them. As a health professional, I work very hard every day to make sure that we help our patients find a medication that will help them achieve NEDA status. It is so heart wrenching to watch someone deteriorate because of an insurance change or insurance denial of a medication that we truly feel is best for them.

Again, I'd like to thank the sponsors, cosponsors and supporters of this legislation for recognizing the needs of the patients in Wisconsin and for urging that all stakeholders, including the patient advocacy organizations, provider community and insurers work together on legislation that will benefit those facing MS and other conditions in Wisconsin. I urge your support of AB 24 and SB 26 and ask that you expeditiously act on this important legislation as we believe this is in the best interests of our patients, and for everyone in the community.

Good morning Chairman Sanfelippo, Chairman Testin and members of the Senate Health and Human Services committee. My name is **Kristie Berna**, I live in Cudahy with my husband and children. I am here to speak in support of AB 24 and SB 26 for my daughter Nora.

Nora has been sick since she was 1-year old, we went to doctors in and out of state and it took years for a diagnosis; systemic-onset juvenile rheumatoid arthritis. She tried countless medications before becoming stable on her current therapy.

We are currently insured through my husband's employer. Each year our health insurance is renewed; there is no guarantee we will have the same company or even plan. Past insurers have notified us that in the event we are insured with them once again-we would be required to go through complete step therapy.

While my husband and I understand the concern over cost, it would be detrimental if Nora has to go back on those failed medications – she could lose movement and suffer organ damage. Not to mention the mental and physical agony she goes through when not on the right medication.

AB 24/SB 26 would help Nora because it allows the patient to override the step therapy protocol when the drug required was previously tried and discontinued due to lack of efficacy or effectiveness, diminished effect, or a serious, adverse event. If this bill was passed, Nora could stay on her current therapy.

We are thankful that over the past few months, stakeholders across the health care system, including health insurers, health care providers and patient advocacy organizations, worked together on a strong bill that will help people like my Nora. As a parent of child who will gain so much from this bill, I respectfully urge you to prioritize the passage of AB 24/SB 26.

Good morning Mr. Chairmen, Mr. Vice Chairmen, and members of the Assembly Health and Senate Health and Human Services committee. My name is **Stephanie Block**. I am here to speak in support of SB26 and AB24, to help patients across Wisconsin suffering from chronic disease and conditions.

For people like me who suffer from a few chronic conditions, our doctors know what works best to bring our complex conditions under control. However, there are times when health plans use of step therapy, or fail first, can impede on my health care and what my health care provider and I believe is best for my treatment. I realize that my insurer uses step therapy to help control drug costs, but it is important that we strike a balance in that the use of step therapy helps do that while also ensuring that patients can access the drugs that they need and are being prescribed by their health care provider.

My chronic conditions include rheumatoid arthritis, Crohns, and others. Working to treat multiple chronic conditions is very complex and requires personalized care.

I have experienced the effects of step therapy twice – once as a teen, and again as an adult. I am here today because I know this legislation will help keep me from suffering a third time.

In my teens, I was required to step through medications that caused me to become violently sick and irritable for more than six months until my mom and doctor demanded I be taken off them.

As an adult, an insurer stopped coverage on a medication that was working for my condition. I was moved to another medication for an entire year and ended up hospitalized because the step therapy required medication made me so sick. Once I was finally able to return to my doctor's prescribed medication, the side effects disappeared completely. This legislation provides continuity of care and if a patient is receiving a positive therapeutic outcome, they will be able to remain on their therapy. Had this been law before, I would not have missed time by being hospitalized.

I don't want anyone else to undergo a similar experience due to step therapy. I ask you to please vote in support of SB26/AB24 as a common-sense way to address this issue and ease the suffering of so many people living with chronic conditions. I know our sponsors worked with health plans across the state, patient groups, health care providers and others to bring common sense legislation today. I want to thank you all for working hard for WI patients and ensuring we can access the medications we need. Thank you for your attention, and I would be happy to answer your questions.

Mr. Chairmen, Vice Chairmen, and members of the Senate Health and Human Services and Assembly Health committees, thank you for holding a hearing on this critically important bill. My name is **Anne Hefty**, I am a Middleton resident, and my 13-year old daughter was recently impacted by the current fail first step therapy process.

My daughter has a very complex health situation, including pediatric psoriasis covering her body, which causes painful itching, red blotches and severe discomfort. She has also had heart surgery, has one kidney and has a compromised immune system due to a rare chromosomal deletion.

Despite our daughter's unique situation, our insurer decided that before covering the medication her doctors prescribed for her pediatric psoriasis, our daughter would first need to try-and-fail on six different drugs. The list of drugs from the insurer included several that were not FDA-approved for use with children.

Of course, my daughter's multiple physicians warned against this step therapy required treatment and helped us to appeal the insurer's decision. Yet, despite our daughter's unique situation and her physicians' recommendations, the insurer denied our appeal.

After exhausting the entire step therapy appeals process through our insurer and being my daughter's advocate, I eventually appealed the insurer's decision at the federal level through the Affordable Healthcare Act. This was a lengthy, cumbersome process that was difficult to navigate, and I know that the vast majority of people in my daughter's shoes don't have the time, resources, or ability to complete nor understand this complex appeals process. Thankfully, the insurer eventually was required to cover the medication originally prescribed because of my daughter's unique medical profile and the risks of the other step therapy drugs. Once my daughter received the doctor's original prescription, she dramatically improved, but it took many, many extra steps, hours of advocating and it delayed her treatment.

No family or patient should have to go through this. I worry for other children like our daughter, who don't safely fit the step therapy mold. Hearing all the other stories today of suffering under step therapy, it is very clear we are not alone.

Proper health care is not always a one-size-fits-all treatment regimen. Under the proposed law, the step therapy requirements will be developed using clinical practice guidelines and will ensure that there is a much needed exceptions process that our doctors can utilize to request an override when it is medically appropriate for my daughter, including when a required drug could be contraindicated or cause a serious adverse reaction, or in helping to provide protections to allow my daughter to stay on the medications that are working.

This legislation will help us to stop fighting with our insurers, and instead allow us to work with them to access the proper medications that can help and heal our children. SB26/AB24 will provide reasonable exceptions and reforms to step therapy. Thanks to all stakeholders across the health care system who worked together to reform the step therapy process. I strongly urge you to vote in favor of the legislation.

Good morning Mr. Chairmen, Mr. Vice Chairmen, and members of the Assembly Health and Senate Health and Human Services committee. My name is **Samantha Espinosa**, I live in New Lisbon with my husband and two children. I am here to speak in support of AB24 and SB26.

I speak from experience on this matter. I've personally been affected by step therapy practices. I've struggled with psoriasis for most of my life. Over the years I have been prescribed creams, ointments, liquids-anything to relieve the excruciating pain.

In 2012, my doctor prescribed a new medication for me. However, my insurer would not cover this biologic. I was informed that I would need to try a series of other medications and treatments first, before they would cover the medication I was prescribed.

As a result, while going through the step therapy, my condition only worsened-to the point where 80% of my body was covered and I could no longer dress or bathe myself without assistance. I was living in absolute misery.

Luckily, my doctor was able to obtain a year's worth of samples of the medication he prescribed for me. My condition resolved almost completely on the medication, proving that it what I needed. I then received the approval for the coverage of this medication in 2016.

Since then, my health and overall wellbeing has significantly improved. I no longer live with debilitating pain and can live a normal, productive life. I am so thankful to have an incredible doctor who fought so tirelessly and went above and beyond for me.

I'm grateful to the sponsors who brought all stakeholders across the health care system together, including my own Senator, Howard Marklein, who worked together and are leading this legislation that will restore the voices of the patient and doctor in this process. I also appreciate that our state's health plans came to hear the challenges faced by patients and health care providers and worked with us on improving the practice of step therapy for patients. I sincerely thank you for caring.

When living with chronic conditions, time is often of the essence. Patients should have access to medications their doctor knows will quickly help ease their pain and relieve their symptoms. Passage of this bill will put a responsible medical exceptions process in place that allows those living with chronic diseases, like mine, to be put first in determining treatment. Thank you for listening, and I am happy to answer any questions.

Mr. Chairmen, members of the Senate Health and Human Services and Assembly Health committees, thank you for listening to us today. My name is **Deb Constien**, I live in Sun Prairie, and I am here to speak in favor of AB24 and SB 26. This issue is vitally important to countless residents of Wisconsin who, like me, are battling a chronic disease.

I was diagnosed with rheumatoid arthritis at age 13. I went through my own step therapy challenge about 15 years ago, when I was raising a young child and trying to support a husband climbing the corporate ladder.

I suffered severe gastroesophageal reflux disease (GERD) as a side effect of one of my many arthritis drugs. I was doing well on a stomach medication, but at the start of a new year, the insurance company changed its formulary. I had to stop taking the higher-level drug that was working and try and fail at three lower-tier alternatives.

To be blunt, the other drugs didn't work. My pain became so intense that at times, I thought I was having a heart attack. I couldn't eat, I couldn't think, I couldn't take care of my family or myself.

The insurance company required an endoscopy and colonoscopy. It was only after those test results showed I had severe GERD that I was allowed to go back on the medication that had been working. Of course, I already knew all that, and knew that the original medication was the one for me. This legislation would have prevented this from happening as there is a step therapy override provision that enables patients who are receiving a positive therapeutic outcome to remain on their therapy. This could have helped me years ago but it passed into law, will help me today and in the future.

For some chronic patients, changes to medications can be devastating. For a patient with progressive MS, a change could mean the difference between walking and never walking again. For someone with Alzheimer's or another type of dementia, it could mean irreversible memory loss at a much faster pace. For someone with a severe respiratory condition, it could be the difference between breathing on one's own, or constantly relying on an oxygen tank and for someone with rheumatoid or juvenile arthritis it could me irreversible joint damage and a wheelchair.

Health care decisions belong with the patient and a trained physician. Please put our voices back into this process and take action to reform step therapy practices. Please support the bill before you today. In homes throughout Wisconsin, people are suffering every single day. You can change that. Thank you for your time

Good morning Mr. Chairmen, Vice Chairmen, and members of the Senate Health and Human Services and Assembly Health committees. My name is **Donald Diehl**, I am a resident of Kenosha. I am here to support SB26/AB24 so we can ensure the use of step therapy works for the health care system and for patients.

I'm tired of hurting but my rheumatoid arthritis gives me no choice. I trust my doctor to help ease my pain, but her hands were tied as I was forced to follow my insurer's step therapy protocol. I had to take the insurer's recommended medication, instead of the medication my doctor prescribed.

Unfortunately, because of the required medication, I was in excruciating pain for months. Pain shot through my arms, fingers and body, and joint inflammation caused further degeneration in my knees. I'm 58 years old. The crippling effects of this step therapy decision left me feeling like I was 90.

The drug my doctor recommended was eventually covered, but the cost to my health was steep - my doctor says I'll need both knees replaced soon.

It's time to stop this hurting and start the healing. I want to thank the legislative sponsors, insurers, health care providers and patients for coming together. Thank you for hearing our stories and working with the WI legislature to ensure proper step therapy reform. I urge the members of the committee to vote in favor of SB26/AB24. Thank you Senator Darling and Rep. Nygren for bringing this very important legislation to the legislature. This will bring greater health care access for Wisconsinites and make us healthier. Thank you for listening.

WI Assembly and Senate Joint Health Committee Hearing

Re: AB 24 and SB 26

Good morning Chairman Sanfelippo, Chairman Testin and members of the Assembly and Senate Health committees.

My name is Dr. Raven Henderson and I reside in Milwaukee, Wisconsin. I am here today as someone who lives with MS since 2014, as well as arthritis and chronic pain daily. I have dedicated my life to my education and my community by providing community service and working in the nonprofit sector with troubled youth and their families. In September of 2012, I was injured on the job, which resulted in a back surgery and four more surgeries to follow.

While visiting family I slipped on liquid soap in a store, my knee instantly swelled. After countless emergency room and doctor visits, I began to have a numb feeling around my right foot/ankle (much like when one has a rubber band around their wrist and cuts of the circulation), which moved into my leg. I struggled for weeks not knowing what was going on and hoping the now pain that I was having would leave. Next the numb sensation moved into my hand and moved into my arm, still scared I hoped this would pass. Shortly after I began to have pain on the right side of my face, electric shocks to be exact.

This pain was beyond word all I could do was ball up into a fetal position rock and cry. I called the doctor and with immediate concern for the facial pain an appointment was scheduled. I was diagnosed with MS on Oct. 28, 2014. I of course feared the worst, and worried about experiencing step therapy, which I had witnessed my colleagues and clients experience. I worried that step therapy would delay my accessing medications, reduce my quality of life and increase my risk of being hospitalized.

While step therapy can be an effective tool when used appropriately, you will hear today from doctors and administrative staff that step therapy often limits their ability to prescribe medications based on their patients' needs and encumbers their informed medical decision-making process. Step therapy also often delays access to treatment by weeks, months or years – Postponing access to medication that addresses chronic, progressive and complex conditions can lead to increased hospitalizations, lost wages, irreversible joint destruction, and a lower quality of life. I recently participated in the coalition's advocacy day, and the most heart-breaking stories to hear are those from families with loved ones or children who struggle for months or in some cases years, while taking insurer-selected medications their doctors know are unlikely to work.

While I can't say for certain that I experience step therapy first hand, on behalf of the MS Society and myself, I urge you to pass AB 24 and SB 26, legislation that will empower doctors to help their patients get the right medication at the right time. I will take great pride in knowing that my state lawmakers put strong protections in place that will help me when and if my insurance changes, ensuring that if I'm stable on my treatment I won't need to go through step therapy.

It's time that Wisconsin join the 20 states, including Illinois, Indiana, Iowa, and Minnesota that have passed laws putting commonsense guardrails in place to protect patients from having to "try and fail" a series of medications before getting the medication their prescriber knows will work. Those of us living with the effects of MS, arthritis and related diseases believe that it is imperative that Wisconsin lawmakers pass step therapy legislation.

I would like to extend my deepest graduated to you for taking time to allow me to provide my patient perspective on this bill.

Respectfully,

Dr. Raven Henderson Milwaukee Resident and MS Advocate Good morning, Mr. Chairmen, Vice Chairmen, and members of the Senate Health and Human Services and Assembly Health committees. My name is Jordan Ellefson. I am a Madison resident.

I do not know if any of you must cope with a chronic disease. I pray that you don't. For 30 years, I have lived with psoriasis, which is embarrassingly dry, flaky skin that covers the body, causing severe pain and near-constant discomfort.

Psoriasis has negatively impacted every part of my life – work, relationships, everything. I would do anything to make the disease go away, and over the years have tried everything from light therapy and various moisturizers, all to no avail.

Ultimately, my doctor prescribed a medication that finally brought permanent relief, and thanks to my insurance, it was covered. What this legislation does for me is to help ensure that moving forward, I have less concern and know that I will be able to continue the therapy that is working for me or be able to access any future therapy that my doctor believes is best in the future.

The fact is that thousands of people with chronic diseases like mine are now encountering step therapy, which can delay access to needed medication. My heart breaks for those patients facing such delays, which is why I appear before you today in support of new legislation to put common sense guardrails around the use of step therapy. Thank you to Senator Darling and Rep. Nygren for bringing all stakeholders across the health care system together to bring common sense reforms and to improve the step therapy process for Wisconsin patients. Please take favorable action on AB24/SB26, which will provide relief to Wisconsinites. Thank you for listening. Hello Mr. Chair and members of the committees, my name is **Rachel Snethen**, and I am here to testify in support of this legislation on behalf of the National Multiple Sclerosis Society. I am a 34 year-old from Fort Atkinson. I am a wife and mother to a seven year-old first grader. I was diagnosed with Relapsing Remitting Multiple Sclerosis in 2013 at the age of 28, when my son was just a year old. I have been on a number of medications to help reduce the onset of episodes since that time.

MS is an unpredictable, often disabling disease of the central nervous system. MS interrupts the flow of information within the brain and between the brain and body. Symptoms range from numbness and tingling to blindness and paralysis. There is currently no cure for MS and since the disease is not fatal, a person can live with the disease their entire life. Research shows that early and ongoing treatment with a disease-modifying therapy is the best way to slow the course of disease and disability from relapsing forms of MS. However, people living with MS often encounter hurdles to accessing their medications, such as with step therapy protocols.

When patients are required to "fail first" and document a "step"—or in some cases, more than one step or medication—the process may result in substantial delays in treatment as prescribed by their healthcare provider. This process may affect patients' ability to immediately start treatment, or their ability to continue a treatment that has been effective. Prolonging ineffective treatment and delaying the appropriate treatment may result in disease progression and irreversible disability for people living with MS. When it comes to MS medications, delaying access to the appropriate drug may be the difference between walking and using a wheelchair for people living with MS, such as myself.

Several provisions of the bill will help people living with MS get the right MS medication, at the right time. For example, the bill ensures step therapy protocols are based on widely-accepted medical and clinical practice guidelines, which will help prevent a MS medication from being denied on the grounds of cost alone. The clear and expeditious process to request a medical exception outlined in the bill will help reduce administrative burden and stress on both people living with MS and their providers.

The National MS Society is thankful to the bill sponsors, bipartisan legislative leaders, and stakeholders across the health care system, including health plans, health care providers, patient advocacy organizations and others, who worked together to bring common sense health care solutions in SB 26 and AB 24, legislation that improve the step therapy process for the health care system and ensures patients can access the medications they need, when they need it. Thank you for your time. Good morning Chair Testin, Chair Sanfelippo, and members of the Committees. Thank you for the opportunity to speak today, I'm **Rob Gundermann**, Executive Director of the Coalition of Wisconsin Aging and Health Groups.

The provision in the bills that means the most to my organization is the one creating a timeframe for the appeals process. I'm referring to the language that provides an answer to an exemption request within three business days or in exigent circumstances, one day. This is important to us because many of the people we represent are taking multiple medications to address a variety of ailments and illnesses and this provision will mean a great deal to them.

Often, when we look at Step Therapy or other types of prior authorizations, we are looking at one specific medication because the request for an exception is usually for one specific medication but it's often much more complicated.

Let me just give you an example: Patient John Doe has lived with epilepsy for his whole life but has been successfully medicated and hasn't had an event for many years. A few years ago, he was diagnosed with arthritis and most recently he was diagnosed as having moderate dementia. Like many people diagnosed with dementia, John develops depression and begins having bouts of delirium and has to be medicated for this as well. His blood pressure is high so he's on medication to lower that and his cholesterol is high so he's on a medication to lower his cholesterol too. At this point John Doe is taking prescription medications to treat seven conditions and that doesn't include any over the counter medications he's taking. Now John gets something new, he develops pneumonia, or shingles, or something else and the physician needs to introduce a new medication. This is one of those times when an exemption to the Step Therapy protocol can be critical, when the physician is adding a new medication to a cocktail of drugs already cycling through the patient.

When someone is on a host of different medications to treat different ailments, managing the interactions between drugs can become very tricky and when a physician is adding in a new medication to this drug cocktail they have a lot to consider in terms of how that new medication interacts with what the patient is already taking. These bills will help patients in situations like this by speeding up the exemption process and preventing delays in obtaining the medications they need.

Thank you for your time and consideration. I'm happy to try to answer any questions.

Good morning Honorable members of the Senate and Assembly Health Committees. Thank you for allowing me to testify on AB24/SB26.

My name is Dona Wininsky and I'm here today to represent the American Lung Association in Wisconsin and the 1.4 million Wisconsinites with lung disease that we serve throughout the state.

While the Lung Association offers programs and services for all lung diseases, I'd like to focus my testimony today on one that is prevalent with both adults and children – asthma. Almost a half million Wisconsin residents have asthma; 75% of them are children. Asthma is not curable, but it is manageable IF patients have the tools they need to do so. At the top of that list of tools is their meds.

Asthma meds come in two forms – preventive meds, which as the name implies, work to prevent asthma episodes. Rescue meds are used when an asthma episode occurs, to reverse the symptoms that could lead to hospitalization and even death. Not every asthma patient needs both. It depends on the severity of their asthma.

A person can live without oxygen for approximately four minutes before the brain starts to die. This critical need for immediate and correct medications was recognized several years ago when the state legislature passed a bill allowing school aged children with asthma to carry their rescue inhalers with them at all times. They recognized that the precious minutes, and even seconds necessary to retrieve an inhaler from the classroom teacher, office, or school nurse could mean the difference between life and death.

The same can be said about the meds themselves. Since asthma is based on triggers that can vary from one patient to the next, the meds they take are very specific to their condition, severity and environment. While one medication may work for one patient, it may not be as effective, if at all, for another.

Imagine this scenario – a child wakes up in the middle of the night struggling to breathe. His parent rushes for the rescue inhaler. The child takes a puff or two, feels his airways relax and the swelling and mucus in his bronchial tubes subside and after a few minutes is breathing normally again. Happy ending.

The same scenario could also play out like this – the parent rushes to get the rescue inhaler, the child takes a puff or two, but the symptoms don't subside. The child and parent both become overwhelmed and frightened, exacerbating the swelling and mucus build up until the child is literally gasping for breath. 911 is called. The child ends up in the Emergency Department on a breathing machine and, at the very least is kept overnight for observation. In an equally likely case, that child could be hospitalized for several days until he is stable. This leads to unnecessary medical costs, missed school days, lost work time for the parents and possibly even the worst outcome, the child doesn't make it.

There is no one – and I repeat, NO ONE, better qualified to determine what meds a child with asthma should be taking than his or her own physician. That physician is THE expert on the child's health. No one else. I would ask you to keep this in mind as you consider this legislation, which can save the life of a person with asthma.

The American Lung Association strongly supports AB24 and SB26 and asks for your vote for passage. Thank you again for your time and consideration and please remember, when you can't breathe, nothing else matters[®].

Dona Wininsky, Director, Advocacy, Grassroots and Patient Engagement



Our Mission: To drive efforts to cure psoriatic disease and improve the lives of those affected.

April 17, 2019

Good morning Chairman Testin, Chairman Sanfelippo and members of the Assembly Health and Senate Health and Human Services committee.

My name is Angie Thies and I am the State Government Relations Manager for the National Psoriasis Foundation. NPF is a non-profit, voluntary health agency dedicated to curing psoriatic disease and improving the lives of those affected. We are the leading patient advocacy group for the 8.3 million Americans and roughly 146,053 Wisconsonites living with psoriasis or psoriatic arthritis.

Psoriatic disease is a systemic illness associated with life-altering symptoms as well as very serious comorbid conditions, such as heart disease, anxiety and depression. The timely and effective treatment of psoriasis and psoriatic arthritis if of the utmost importance when managing long-term patient health.

In addition to serving the National Psoriasis Foundation, I am proud to lead the coalition of more than thirty patient advocacy organization known as the Wisconsin step therapy coalition. This coalition is comprised of organizations that represent individuals in Wisconsin that have been impacted by the practice of step therapy or fail first, and will be directly impacted by the legislation. before you today. The coalition came together in the fall of 2018 around one goal – establishing important patient protections for the practice of step therapy in Wisconsin.

On behalf of the National Psoriasis Foundation and the Coalition, I want to thank you for the opportunity to provide testimony in support of AB 24 and SB 26, legislation that does just that, puts common sense patient protections for the practice of step therapy in place for all residents of Wisconsin who utilize the individual market for health insurance.

Step therapy is an increasingly common practice utilized by insurers that requires an individual "step through" a series of medications before they will cover the medication recommended by their physician. Step therapy has become increasingly prevalent and detrimental to patients facing chronic, progressive and complex conditions such as psoriasis and psoriatic arthritis and the conditions represented through our coalition. Our patients routinely share that being "stepped" results in delays of weeks, months and years before they get the medication that effectively treats their condition. For many of these individuals, these delays jeopardize functionality, long-term mobility and can cause irreversible joint disease. You have heard from numerous resident advocates who have experienced step therapy and the delays associated – at the most extreme, four years.

The bipartisan legislation before you today represents an effort by which advocates, providers, insurers and stakeholders worked together at the request of sponsors Rep. Nygren, Sen. Darling,

Sen. Jaque and Rep. Oldenburg to craft Wisconsin solution. This solution, supported by the Wisconsin Step Therapy Coalition ensures the following:

That step therapy protocols that are developed with evidence based and peer reviewed clinical guidelines and are done so in a transparent fashion, with the criteria on the insurers' website

- A clear process for a doctor or patient to request an exception to step therapy protocol if at least one of the following criteria are met:
 - The required drug is contraindicated or likely to cause a serious adverse reaction or physical or psychiatric harm.
 - The required drug is expected to be ineffective based on the mechanism of action or pharmacological class.
 - The patient has tried and failed the required prescription drug while under their current or a previous health benefit plan.
 - The patient is currently stable on a prescription drug.
- A clear and timely process to receive an answer concerning the exception request the end of the next business day in exigent circumstances and 3 business days in non-exigent circumstances. If no response is received, the decision is made in favor of the patient.

The provisions highlighted will ensure that patients can access the right medication in a timely fashion – and limit delays that will cause irreversible progression of their condition. In closing, I'd again like to thank Rep. Nygren, Sen. Darling and co-authors of the legislation, many of whom are here today for their work on this bipartisan legislation. I urge your timely support and passage of AB 24 and SB 26.

Thank you for the opportunity to provide written testimony. I'd be happy to assist with questions or information. Please feel free to reach me at <u>athies@psoriasis.org</u> or by phone at (614) 208-3794.

Angie Thies State Government Relations Manager National Psoriasis Foundation



April 17, 2019

The Honorable Patrick Testin Chairman Committee on Health and Human Services Wisconsin State Senate Room 131 South State Capitol PO Box 7882 Madison, WI 53707 The Honorable Joe Sanfelippo Chairman Committee on Health Wisconsin State Assembly Room 314 North State Capitol PO Box 8953 Madison, WI 53708

Re: SUPPORT for AB 24 and SB 26 – Step therapy protocols for prescription drug coverage and requiring the exercise of rule-making authority

Dear Chair Testin and Chair Sanfelippo:

On behalf of the Alliance for Patient Access (AfPA), I write in support of Assembly Bill No. 24 (AB 24) and Senate Bill No. 26 (SB 26) that are before your respective committees for consideration.

Founded in 2006, AfPA is a national network of physicians, including in Wisconsin, dedicated to ensuring patient access to approved therapies and appropriate clinical care. AfPA advocates for health policies that support clinical decision making, promote personalized care and protect the physician-patient relationship as the cornerstone of quality health care.

Step therapy is a utilization management tool used by health insurers to contain health care costs. Sometimes referred to as "fail first," step therapy protocols require patients to first try and fail on one or more medications directed by the insurer, usually lower costs medications, before the patient can access the medicine as prescribed by their treating physician.

Attached you will find AfPA's position statement on step therapy, which is based on four key principles:

- Step therapy must be rooted in clinical evidence.
- Repeated failures are inappropriate.
- Insurers must offer a straightforward exemption process.

Alliance for Patient Access 1275 Pennsylvania Ave. NW, Suite 1100A Washington, DC 20004 • Insurers' communication must be timely and clear.

AB 24 and SB 26 will make treatment more accessible through a series of step therapy reforms that will give providers the ability to determine the best treatment regiment, without unnecessary risk or delay to the patient. The bills would create a clear and expeditious process for both patients and providers to request a medical exception to step therapy protocols. Importantly, the legislation does not prevent insurance companies from using step therapy, nor does it limit the number of steps required by the insurer.

Step therapy reform bills support the principles that AfPA members believe lead to optimal healthcare outcomes, including cost savings, specifically:

- Preserving the patient-physician relationship whereby a patient may access optimal and timely treatment, as prescribed by her or her health care provider.
- Protecting patients from repeating treatments that have already been proven ineffective or to cause harm or an adverse reaction, or those that would put their stable condition into jeopardy; and
- Promoting better health by limiting the unnecessary need for additional doctor's visits or hospitalization that may result from the use of a step therapy protocol.

On behalf of the Alliance for Patient Access and Wisconsin prescribers and patients, I urge your support of AB 24 and SB 26. Thank you for your consideration of these bills.

Sincerely,

Brian Kennedy Executive Director Alliance for Patient Access

Attachment

Alliance for Patient Access 1275 Pennsylvania Ave. NW, Suite 1100A Washington, DC 20004



Step Therapy

A POSITION STATEMENT from the Alliance for Patient Access

OVERVIEW

To get the medicine prescribed by their health care provider, patients must first prove that older, less expensive or insurerpreferred alternatives don't work. That's the crux of step therapy, or "fail first."

In some cases, step therapy makes sense. A logical progression of treatment options may represent best practice for certain diseases or reflect the wisdom of clinical guidelines.

In other cases, step therapy can be excessive, arbitrary and even damaging to patients' health. Insurers may use step therapy as a deliberate access hurdle meant to protect their own profits.

Doing so hurts patients, whose condition may worsen or who may suffer unnecessarily in the process of failing insurer-preferred treatments. It also undermines the relationship between the physician and patient, to whom treatment decisions rightfully belong.

POSITION

The Alliance for Patient Access presents the following principles for step therapy and the laws that govern insurers' use of it:



Step therapy must be rooted in clinical evidence. If insurers dictate a progression of treatment options, they must be able to trace their requirement to clinical guidelines from relevant medical associations. Insurers should not be able to require therapies that are inappropriate or unproven for the condition being treated.

Repeated failures are inappropriate. Patients who have tried a treatment with a previous insurer should not be asked to fail on the same drug again just to satisfy the new insurer's requirement.



2

Insurers must offer a straightforward exemption process. Some patients will have allergies, side effects, comorbidities or other health factors that render a step therapy protocol inappropriate. They and their health care providers need a straightforward process for bypassing the requirement.

Insurers' communication must be timely and clear.

Delays associated with step therapy can impact a patient's life and health. That means that responses to a patient's request for a step therapy exemption should occur within a reasonable timeframe. Similarly, details about the exemptions process should be readily available and in plain language for patients and health care providers to access.

With these safeguards in place, legislators can ensure that insurers do not overuse or misuse step therapy to the detriment of patient health.



Assembly Bill 24 / Senate Bill 26 Proponent Testimony

Pam Fields State Director, Advocacy and Access Arthritis Foundation Joint Health Committee – April 17, 2019

Chairmen Sanfelippo and Testin and Members of the Committee:

On behalf of the Arthritis Foundation and the 1,104,000 adults living with doctor-diagnosed arthritis in the state of Wisconsin, we support Assembly Bill 24 and Senate Bill 26.

Arthritis affects 24.8% of the population in Wisconsin. The passage of bipartisan legislation AB 24/SB 26 will help to provide patients with timely access to the medications they need. These bills will not eliminate step therapy protocols or require insurers to develop new appeal processes but will improve step therapy protocols for patients with chronic illnesses and serious healthcare needs. These bills seek to improve the step therapy process by balancing cost containment with common sense patient needs.

Step therapy is a practice used by insurers that requires people with arthritis to try lower-cost medications before permitting more expensive treatments despite a physician's recommendations for treatment. As a result, more expensive, effective drugs can only be prescribed if the cheaper drugs prove ineffective. While a patient with arthritis works through the step therapy process, they can experience irreversible joint damage.

When a person changes their insurer or a drug they are currently taking is moved to a non-preferred status, the person may be put through the step therapy process again. Some step therapy protocols also impose these requirements on patients remaining on stable treatments.

We respectfully urge you to prioritize the passage of this legislation. Wisconsin would join the growing list of 21 states that have enacted similar step therapy reform legislation, including Indiana, West Virginia, Iowa, Minnesota, Louisiana, New Mexico, Ohio and Texas.

The Arthritis Foundation is part of the Step Therapy Coalition and appreciate all who have contributed to the crafting of this important piece of legislation. Thank you holding this joint hearing and thank you to the sponsors and cosponsors of this strong legislation.

Sincerely,

Pam Fields, State Director Advocacy and Access Arthritis Foundation (513) 600-0752 pfields@arthritis.org



AMERICAN ACADEMY of DERMATOLOGY | ASSOCIATION

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April 17, 2019

The Honorable Joe Sanfelippo Chair, Assembly Committee on Health PO Box 8952 Madison, Wisconsin

The Honorable Patrick Testin Chair, Senate Committee on Health and Human Services PO Box 788 Madison, Wisconsin

Re: SB 26 / AB 24 – Support step therapy reform

Dear Chairs Testin and Sanfelippo,

On behalf of the nearly 14,000 U.S. members of the American Academy of Dermatology Association ("Academy"), we write in strong support of SB 26 and AB 24. This legislation would be a critical step to ensure patients have access to their prescription medicines. Pursuant to SB 26 and AB 24, 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 you and the members of the Senate Committee on Health and Human Services and Assembly Committee on Health and to support SB 26 and AB 24.

Step therapy protocols, a 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. The provisions in SB 26 and AB 24 address this by ensuring that patients may access the medications their physicians believe will work best for their condition through a transparent exceptions process. Of note, the language in this legislation will protect patients that have already tried and failed on a medication in the past

George J. Hruza, MD, MBA, FAAD President Jane M. Grant-Kels, MD, FAAD Vice President

Bruce H. Thiers, MD, FAAD President-Elect 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 26/AB 24 April 17, 2019 Page **2** of **2**

from having to try and fail on that medication again, which may occur when a patient's insurance changes. Additionally, we appreciate that the sponsors and cosponsors of the legislation have included language to ensure patients who are stable on a medication remain on that medication.

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. SB 26 and AB 24 address this by ensuring that when step therapy protocols are developed, health plans in Wisconsin 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 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 of SB 26 and AB 24. 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 <u>lalbany@aad.org</u> (202) 842-3555.

Sincerely,

George Hura

George J. Hruza, MD, MBA, FAAD President American Academy of Dermatology Association

cc: Members of the Senate Committee on Health and Human Services Members of the Assembly Committee on Health



Global Healthy Living Foundation 515 North Midland Avenue Upper Nyack, New York 10960 USA +1 845 348 0400 +1 845 340 0210 fax www.ghlf.org

TESTIMONY – STATE STEP THERAPY LEGISLATION Wisconsin Regular Session Joint Health Committee Hearing to Consider Step Therapy Reform Writer: JP Summers Patient Advocate Global Healthy Living Foundation

April 17, 2019, Disclosure: I have no disclosures to make today. The Global Healthy Living Foundation accepts grants and charitable contributions from pharmaceutical companies, the government, private foundations and individuals. The organization has received scientific briefings from pharmaceutical companies, as well as from our independent medical advisory board and staff physician.

Good Morning Mr. Chairman and Committee Members.

My name is JP Summers. I'm a volunteer patient activist and member of the Global Healthy Living Foundation's 50-State Network. I am a resident of Suring, Wisconsin. My legislators are Representative Jeffrey Mursau and Senator Tom Tiffany. Thank you for allowing me to submit testimony in support of the passage of Senate Bill 26 and Assembly Bill 24, which implements common sense, patient-focused reforms to "step therapy" and ensures that patients and their physicians will have much greater say in the treatment plan.

For more than 30 years, I have been a victim of relentless migraine attacks accompanied by severe nausea, vertigo, dizziness, and head pain. For more than three decades – since I was a teenager -- I've been trying to find medications to deal with my pain and other symptoms. There have been times in my life when my symptoms were so persistent that I felt that I was unable to drive, which impacted my ability to live a productive and high quality of life.

It took me a very long time to secure an appointment with a neurologist who specialized in treating migraine. I felt very hopeful after that first visit because my doctor seemed to understand the severity of my disease and be familiar with the newest and more advanced treatment options. However, instead of bringing me relief, this appointment initiated a four-year long step therapy battle to gain access to the medicines prescribed by my doctor.

Immediately, my insurance declined my doctor's initial prescription, insisting that I instead try medicines in their preferred order first. Being forced to fail these medications was a terrible process because they often caused me side effects without noticeable improvement in my symptoms. For example, one therapy caused me to sleep for almost 18 hours per day; Others caused side effects that put me in the hospital. In fact, over four years, I had to endure six hospital stays. Despite these consequences, I couldn't get approved for a newer for my doctor prescribed medication. Additionally, each medication prioritized ahead of my neurologist's prescription had its own process of weening on and off. It took four years to cycle through those options. Maddeningly, I was also stuck in the "fail first" cycle with my rheumatologist, following a diagnosis of rheumatoid arthritis.

According to <u>The Partnership to Fight Chronic Disease (PFCD)</u> Wisconsin more than 1 in 2 <u>adults in Wisconsin lives with at least one chronic condition and nearly 1 in 3 have two or more chronic conditions. Every day patients like me across the country are forced by payers to first fail to test whether they might work or, in my case, not work at all and cause complications, before approving costlier medications that their physicians recommend. But chronic disease patients build relationships with physicians who understand our personal medical history.</u>

I have experienced "step therapy" as a patient, caregiver, mother, and friend. Sadly, my 15-year old son also has chronic migraine and as much time as I spend trying to get coverage for myself, I spend trying to get medicine for him. Thankfully, state Senator Alberta Darling, Representative André Jacque and my former state Representative John Nygren agree that this is an issue and have drafted Senate Bill 26 (SB26) and Assembly Bill 24 (AB24) that implement patient-focused reforms to "step therapy" and ensures that patients and their physicians will have much greater say in the treatment plan. Thank you, Senator Darling, Representative Jacque, and Representative Nygren for protecting people like me.

I urge this committee to support AB24 and SB26, which implements common sense, patientfocused reforms to "step therapy" and ensures that patients and their physicians will have much greater say in the treatment plan. I hope that by sharing my story today, I can help ensure that other patients are not forced to go through the same experience that I did. Lastly, I want to thank you for your time, attention, and consideration of this necessary piece of legislation.

> Sincerely, JP Summers



Assembly Bill 24 / Senate Bill 26 Proponent Testimony

Gary Dougherty Director, State Government Affairs and Advocacy American Diabetes Association Joint Health Committee – April 17, 2019

Chairmen Sanfelippo and Testin and Members of the Committee:

I write to you today to share the support of the American Diabetes Association for Assembly Bill 24 and Senate Bill 26.

With more than 10.6% of adult Wisconsinites living with diabetes, AB 24/SB 26 will help to ensure they get the medications that meet their medical needs as they work with their physicians to prevent costly and horrific diabetes complications including amputation, blindness, kidney failure, and heart attack.

Health insurers are increasingly using step therapy protocols, which require patients to try one or more prescription drugs before coverage is allowed for a drug selected by the patient's health care provider. While we recognize and applaud efforts to control cost within the diabetes community, step therapy often results in significant delays in accessing necessary medication. While the patient is "stepping through" medications, he or she may experience worsening of conditions that can be debilitating or even life threatening. The Association believes that ensuring patients receive the most effective treatment for their condition in a timely manner, as recommended by their treating physician, should be a primary goal of our health care system.

A patient-centered approach should be used to guide medical decisions. AB 24/SB 26 does just that and gives health care providers the tools they need to provide appropriate patient care. This important legislation does not ban the practice of step therapy, but rather it establishes common sense patient protections in the practice, including providing a pathway so that an individual can request an exception and receive an answer within three business days at the latest.

The American Diabetes Association is a proud member of the coalition and thanks all parties involved for their work in constructing a very strong piece of legislation. On behalf of the Association and the 517,000 Wisconsinites living with diabetes, I would like to thank the sponsors and cosponsors for this important, bipartisan legislation and urge your support of AB 24/SB 26

Thank you very much for your consideration.

Gary Dougherty Director, State Government Affairs & Advocacy 1-800-676-4065 x4832 <u>gdougherty@diabetes.org</u>







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TESTIMONY – STATE STEP THERAPY LEGISLATION Wisconsin Regular Session Joint Health Committee Hearing to Consider Step Therapy Reform Speaker: Corey Greenblatt Manager, Policy and Advocacy Global Healthy Living Foundation

April 17, 2019, Disclosure: I have no disclosures to make today. The Global Healthy Living Foundation accepts grants and charitable contributions from pharmaceutical companies, the government, private foundations and individuals. The organization has received scientific briefings from pharmaceutical companies, as well as from our independent medical advisory board and staff physician.

Good Morning Mr. Chairman and Committee Members.

My name is Corey Greenblatt and I am commenting on behalf of the more than one million chronically ill patients living in Wisconsin, whom we represent. I want to thank you for allowing me to comment today in support of the passage of Senate Bill 26 and Assembly Bill 24, adapting Step Therapy protocols. These bills put the patient first by regulating an often damaging utilization review practice often used by pharmacy benefit managers and health insurers to control administrative and pharmacy costs.

Passage of SB 26 or AB 24 would improve step therapy protocols, currently a one-size-fits-all utilization management practice which requires patients to try and fail first on one or more prescription drugs before coverage is provided for the medication originally chosen by the patient's health care provider. At GHLF, we prefer that patients succeed first.

These are fair bills. Neither prohibits insurers from using step therapy and neither require insurers to cover any specific medication. The bills seek to improve the step therapy process by balancing cost containment with common-sense patient needs.

The patients GHLF represents are among the millions of Wisconsin patients who are subjected to unnecessary barriers put into place by insurance companies in their quest to increase their profits, not as insurers often say, "to lower drug costs." The patient does not experience a lower cost because of step therapy or "fail first" tactics. In addition, oftentimes patients have to "fail" up to five times before they are finally given the prescription that their doctor originally prescribed. The duration of this protocol is left up to the insurance company and can last up to 130 days per

medication. Using step therapy, insurance companies have the ability to delay or even override a treatment plan created by a doctor and patient to the point where permanent, irreversible damage can occur.

Step therapy undermines physicians' ability to effectively treat patients and lowers the quality of care, resulting in set-backs and disease progression, which, even if reversible, causes undue suffering and disease lingering, resulting in poor quality-of-life and lost productivity.

At its core, SB 26 and AB 24 are about one thing: patient protection. They guarantee that health care protocols are implemented with the patient's interest at their core, not the profit motives of private companies with opaque operations. GHLF hopes that you will consider people living with complex autoimmune diseases, and the undue suffering they endure with step therapy when voting for these bills. A vote in favor of SB 56 or AB 24 will improve their happiness, their health, and their productivity.

Wisconsinites cannot wait any longer to have the patient protections granted in SB 26 and AB 24. If either of these bills are passed, Wisconsin would join the growing list of 20 states that have enacted similar step therapy legislation, including Indiana, Minnesota, Kentucky, West Virginia, Iowa, Arkansas, Ohio, Missouri, and Texas.

We appreciate your thoughtful consideration of this legislation and would be pleased to provide any further information you may require.

Respectfully,

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Corey Greenblatt Manager, Policy and Advocacy Global Healthy Living Foundation



April 12, 2019

Memorandum in Support of AB 24/SB 26

The National Infusion Center Association (NICA) is a 501(c)(3) nonprofit advocacy organization that provides a national voice to patients relying on office-based Infusion Centers for the highquality, cost-effective care they need. NICA represents the thousands of community-based Infusion Centers across the country, including those in Wisconsin, and the hundreds of thousands of patients they serve. On behalf of the infusion providers and patients we serve, NICA strongly supports AB 24/SB 26 and the protections it provides to Wisconsin patients.

NICA and its infusion provider partners are committed to providing a safe, accessible and compassionate care setting for some of our nation's most vulnerable patients living with autoimmune and chronic diseases that require provider-administered intravenous and/or injectable therapies. AB 24/SB 26 would ensure that Wisconsin citizens can rely on receiving the health coverage and benefits under their health plan for the contracted year and so they can obtain the critical care they need.

Patients must have access to a wide range of therapeutic options to find the right treatment protocol — the one that works. This is particularly important in the case of medications covered under the medical benefit, including intravenous immunoglobulin (IVIG) and biologic therapies for patients with primary immunodeficiency diseases and immune-mediated inflammatory conditions, like rheumatoid arthritis, Crohn's disease, ulcerative colitis, multiple sclerosis, psoriasis and lupus. It can take these patients take years of working with their healthcare providers and trying many different medications to find the one medication that is effective, well-tolerated, and successfully manages their debilitating condition(s).

Step therapy, sometimes referred to as Fail First, is a tool used by insurance companies to mitigate drug costs. Step therapy requires patients to try and fail lower cost medications before he or she can receive the medication prescribed by their doctor. Imposing blanket requirements for all patients to try and fail health plan prescribed drugs before pursuing doctor prescribed drugs may delay therapeutic benefit, increase costs, restrict patient access to needed therapies, and expose patients to additional risk.

AB 24/SB 26 does not remove an insurance company's ability to implement step therapy protocols, it simply creates a clear pathway for patients and their doctors to request an exemption



to the process. This decision will be based on the patient's medical history and their provider's knowledge of their unique case. AB 24/SB 26 require a decision within 72 hours of an insurance provider receiving the request for exemption, and 24 hours in exigent circumstances. These exemptions could help patients stay stable on their medications, or help them get on the correct medication quicker.

Based on these concerns, we strongly support AB 24/SB 26 which provide guardrails to protect patients against harmful step therapy practices. Step therapy policies, when used inappropriately, seriously threaten access to treatment for vulnerable patients. On behalf of the patients we serve, battling chronic conditions for the rest of their lives as they work to find the right treatment and stay on it, we sincerely request your support for AB 24/SB 26, which would protect Wisconsin patients' access to care.

Sincerely,

Brin - bygins

BRIAN NYQUIST, MPH | EXECUTIVE DIRECTOR NATIONAL INFUSION CENTER ASSOCIATION







April 12, 2019

Representative Joe Sanfelippo, Chair Assembly Committee on Health Wisconsin State Legislature State Capitol Madison, WI 53708 Senator Patrick Testin, Chair Senate Committee on Health and Human Services Wisconsin State Legislature State Capitol Madison, WI 53708

Re: AB 24/SB 26

Dear Chairmen Sanfelippo and Testin:

On behalf of the 1-in-10 individuals in Wisconsin with one of the over 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) urges you to support AB 24/SB 26, bipartisan legislation that would put in place incredibly important patient protections pertaining to step therapy protocols.

NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. We are committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services. NORD believes strongly that all patients deserve the medical care that is best suited for their medical situation and will give them the best results. Based on the reports we receive from member organizations and individuals, step therapy (also known as fail first) is increasingly being applied by health plans in Wisconsin with little regard for a patient's treatment history and specific medical needs.

Step therapy is a procedure by which insurers (public or private) require patients to take one or more alternative medications before being put on the medicine preferred by their provider. While this is done by insurers as an attempt to control health care costs, it can often be applied inappropriately, without consideration of the clinical practicalities. As a result, in many cases, these requirements can delay appropriate treatment and ultimately increase costs, not lower them.

As the use of step therapy has increased, so has the need for states to ensure that these requirements do not needlessly interfere with appropriate care for patients. For instance, in some cases, patients switching insurance plans may be required to stop taking a successful treatment and start taking a medicine that they have already failed on simply because the step therapy protocol does not take into account whether a patient has failed a medicine while covered by another insurer.

AB 24/SB 26, sponsored by State Representative John Nygren and State Senator Alberta Darling, would address this issue by providing new protections for patients when health plans implement fail first policies. First, this legislation would require that step therapy protocols be

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based on medical criteria and clinical guidelines developed by independent experts. Second, it would require insurers to have a simple and accessible process for patients and providers to request exemptions. Finally, it would specify certain conditions under which it is medically appropriate to exempt patients from step therapy and require insurers to grant or deny exemption requests within a specified timeframe.

In order to guarantee patient safety, Wisconsin needs to ensure that step therapy policies do not interfere with appropriate care. By implementing the protections created in AB 24/SB 26, your Committees will be protecting patients while still enabling health plans to achieve the cost-saving benefits of step therapy when appropriate.

Thank you for your consideration.

Sincerely,

Tim Boyd, Director of State Policy

Danyello Snn

Danyelle Sun, Wisconsin Rare Action Network Volunteer State Ambassador



8229 Boone Boulevard, Suite 260, Vienna VA 22182 · 800.878.4403 · AllergyAsthmaNetwork.org

Assembly Bill 24 / Senate Bill 26 Proponent Testimony Wisconsin Allergy & Asthma Network Joint Health Committee – April 17, 2019

Chairmen Sanfelippo and Testin and Members of the Committee:

Allergy & Asthma Network is a national patient education and advocacy organization dedicated to ending needless death and suffering due to asthma, allergies and related conditions. The Network is comprised of over 2M patients, caregivers, healthcare providers and community advocates including over 500,000 living with these conditions in Wisconsin. We are submitting written testimony to ask for your support of Assembly Bill 24 and Senate Bill 26. This important legislation will provide patients timely access to the medications they need.

While step therapy can be an appropriate way to control costs, for some patients this "one-size-fits-all" process can produce an adverse health outcome. Currently, Wisconsin law does not allow for common-sense exemptions to step therapy protocols or provide timelines for patients appealing these restrictions. For Wisconsin children and adults with chronic, debilitating and sometimes life-threatening diseases like asthma and allergies, 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. This can result in progression of their condition, loss of function or mobility, or other devastating consequences as well as increased overall healthcare costs.

Assembly Bill 24 & Senate Bill 26 create a common-sense reforms for all Wisconsin 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 appropriate use of step therapy. One such patient is 42 year-old single mom, Chernette. She is a respiratory therapist who has devoted her life to helping others breathe better, that is until her own severe asthma worsened. It was over 6 months of fighting for Chernette before the best treatment was finally approved and another 3 months before she was able to initiate therapy. This delay could have easily cost her everything----her job, her family and her life. Provisions in this legislation will help people like Chernette.

Your support will help ensure a healthier and more productive Wisconsin patient population. I would like to thank the sponsors and cosponsors for this important, bipartisan legislation and urge your support of AB 24/SB 26.

Sincerely,

Anga A. Winders

Tonya A. Winders President & CEO

McCarthy, Steven

From:	Hoisington, Joshua
Sent:	Wednesday, April 17, 2019 8:44 AM
То:	Rep.Kurtz; Rep.Rodriguez; Rep.Edming; Rep.Skowronski; Rep.Wichgers; Rep.Murphy;
	Rep.VanderMeer; Rep.Felzkowski; Rep.Magnafici; Rep.Kolste; Rep.Riemer; Rep.Subeck;
	Rep.Anderson; Rep.Vining
Cc:	McCarthy, Steven; Larson, Brian; Brauer, Andrea; Inabnet, Kay; Veserat, Jeryn; Martyn,
	Julie; McKee, Pat; Heitman, Kathryn; Bentz, Nick; Wender, Kaitlyn; Longsine, Tyler;
	Cooper, Wyatt; Gibbs, Sarah; Fischer, Alexander; Neville, William; Mietus, James;
	Handrick, Diane; Moscicke, Michael; Brooks, Kyle; Johnson, Jesse; Ellisen, Tyler; Portz,
	Elisabeth; Hoyer-Booth, Andrew; Pearson, Mike; Groshek, Dave; O'Donnell, Clare; Miller,
	Joshua; Vidal, Logan; Palzewicz, Maddie; Miller2, Joshua; Wimmer, Matt
Subject:	FW: AB 24

From: Anne Morgan Giroux <morgangiroux@tds.net> Sent: Tuesday, April 16, 2019 1:13 PM To: Hoisington, Joshua <Joshua.Hoisington@legis.wisconsin.gov> Subject: Re: AB 24

Regarding Step Therapy Bill AB 24

I am submitting written testimony in support of AB 24 (Step Therapy Bill) as I cannot come to the Wednesday hearing in person.

About 22 years ago at the age of 2, my daughter, Lily, was diagnosed with epilepsy. She was having hundreds of seizures a day. Over many years, we tried dozens of meds, a special ketagenic diet and surgery. Finally, after years of watching her seize, we gained some control...and some peace of mind on one drug: Depakote ER.

Years later, our HMO wanted us to switch to a generic brand. We were SO fortunate that our neurologist said absolutely not. Our daughter's seizure control was a candle in the wind, and the slightest variation of the formula might have devastating effects. Our HMO respected the doctor's advice and we were able to continue on the brand name.

In my position as founder of Lily's Fund for Epilepsy Research, I have heard from SO many people about their seizure control going awry when switching to generics, or between generics. While the pharmaceutical companies will tell you the active ingredients are the same, ANY deviation of active or inactive ingredients for people whose seizure control is so tenuous, is NOT imagined. It is real, and can have devastating effects.

Thank you.

-Anne



Anne Morgan Giroux Lily's Fund for Epilepsy Research

608•446•6052 <u>lilysfund.org</u>