



PHPN Advocacy Day 2023

Participant Schedule

11:00 am: Registration opens, Lunch is available

11:30 am: Advocacy training at hotel

12:45 pm: Board buses

1:15 pm: Arrive at Capitol Hill & Group photo

2:00 pm: First visit

2:30 pm: Second visit

3:00 pm: Third visit

3:30 pm: Fourth visit

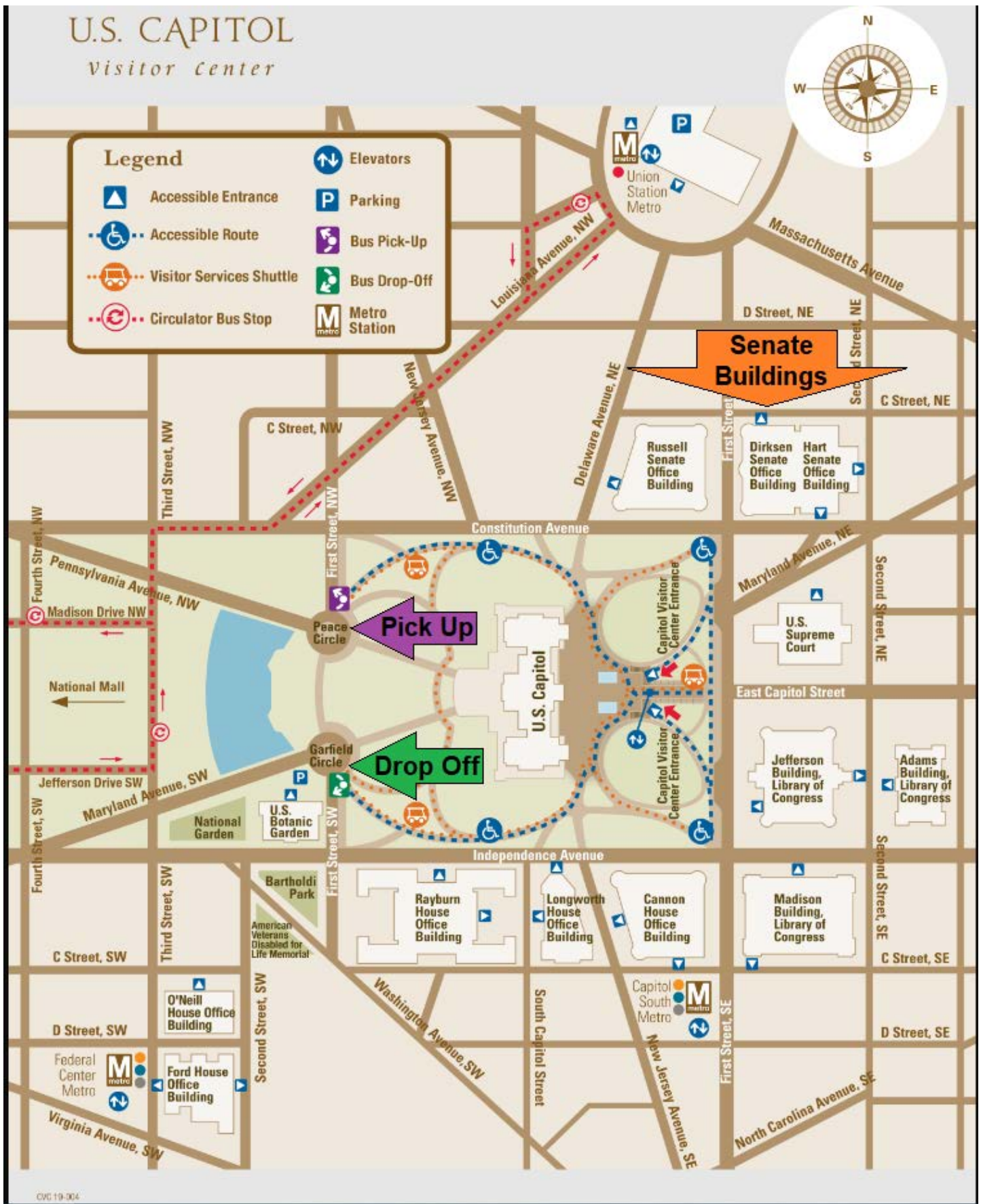
4:15 pm: Board buses*

4:30 pm: Buses depart

*Please board your assigned bus with your group on the return trip. If you will not be returning to the hotel, make sure to inform your bus captain.

Advocacy Day post-event evaluation form: <https://forms.gle/YuKXJbwRmwW6HUTi6>

Capitol Hill Complex map
[online, zoomable version of map](#)





PHPN Advocacy Day 2023

Talking Points and Asks

“What is pulmonary hypertension?”

- ▶ Pulmonary hypertension is an umbrella term describing a group of complex, potentially fatal lung conditions. PH is characterized by high blood pressure in the vessels of the lungs which can lead to heart failure.
- PH can occur in relation to left heart disease, lung disease, blood clots on the lungs, and other conditions. Genetics sometimes play a role, while in other cases there is no known cause at all. It occurs across all genders and age groups.
- The most common symptoms are shortness of breath and fatigue – very generalized symptoms that are often misdiagnosed as asthma or other less threatening illnesses. These delays can mean patients may not get the full benefit from available PH therapies once they do get a correct diagnosis.
- From time of diagnosis, most patients have about 2-3 years’ life expectancy without treatment. Luckily, with the currently available FDA-approved treatments, life expectancy is much improved.

Ask 1: *Please cosponsor the HELP Copays Act (S. 1375)*

- ▶ The **Help Ensure Lower Patient Copays (HELP) Act** prevents federally regulated insurance companies from implementing copay accumulator policies.
- Copay accumulator policies are a cost-limiting strategy used by insurance companies. Under these policies, patients can use financial assistance from a third party to cover their copay cost, but those payments won’t count towards their deductible or out-of-pocket maximum.
- Updates language in the ACA to specify that cost sharing payments “by and on behalf of” patients must be counted towards the patient’s annual deductible and out-of-pocket maximum, and closes an additional loophole.

Ask 2: *Please advance the Safe Step Act (S. 652)*

- ▶ This common-sense, bipartisan bill should be passed in this Congressional session.
- The **Safe Step Act** (S. 652) places reasonable limitations on step-therapy requirements in the case of high-risk health conditions, such as PH.
- Even a brief delay or disruption in access to appropriate therapy for pulmonary hypertension can result in irreversible decline and death.
- When insurance payers use fail-first requirements to shift a person with PH from one therapy to another without the agreement of a physician, these switches can create health setbacks from which the individual may never recover, as well as potentially increasing health care costs the insurer would have to cover later on.



PHPN Advocacy Day 2023

Ask 3: *Please take action to improve patient access to supplemental oxygen.*

- ▶ There are well-documented problems with access to supplemental oxygen – please support legislation addressing these problems when it is introduced to Congress.
- Needed reforms include:
 - Replacing “home” oxygen terminology for “supplemental” oxygen and creating a patients’ bill of rights to make oxygen services more patient-centric.
 - Providing access to liquid oxygen for patients for whom it is medically necessary.
 - Increasing access to specialist expertise by creating a statutory service element to provide adequate reimbursement for respiratory therapists.
 - Improving reimbursement process for supplemental oxygen suppliers by creating a template with national standardized documentation requirements.
- Details on liquid oxygen:
 - Supplemental oxygen equipment’s weight can be a barrier, and portable liquid oxygen systems or oxygen concentrators are often the only options light enough to make daily activities outside the home feasible.
 - Since CMS’s competitive bidding process began, reimbursement rates for liquid oxygen have fallen as much as two-thirds, leading to a range of access challenges for individuals needing supplemental oxygen.
 - Difficulties in accessing liquid oxygen have led to physicians prescribing it less often. Now some newer physicians don’t realize they can prescribe it, and some ordering forms no longer list liquid oxygen as an option.
 - When physicians do prescribe liquid oxygen, patients have significant challenges in receiving it; some have been involuntarily shifted to a different modality of supplement oxygen by their supplier.



PHPN Advocacy Day 2023

Tips for a Successful Legislative Visit

Thanks for joining the PHPN Symposium Advocacy Day this year! Here are a few quick tips to help make your visits a success.

- **Begin with a thank you.** Acknowledge the staff member's busy schedule and thank them for their time.
- **Plan what to say.** Each person in the visit should state their name and place of residence, and connection to pulmonary hypertension. Those in the legislative visit who live in the senator's state – their constituents – should do more of the talking during the meeting. Briefly define PH to the legislator or legislative assistant (LA), and share examples from your experience related to the key requests (see below). Make sure to take time before your meeting to plan with your group who will begin the conversation and who will share their story in the meeting.
- **Be flexible.** Each Member of Congress has an LA who focuses on health issues. LA's are knowledgeable, dedicated staff members who are worth talking to. Don't be disappointed if you end up speaking with an LA rather than your legislator.
- **State your request!** Depending on time, you will make between one and three asks:
 1. Please cosponsor the HELP Copays Act (S. 1375).
 2. Please advance the Safe Step Act (S. 652).
 3. Please take action to improve supplemental oxygen access.
- **Emphasize the PH community's reach.** The individuals in your group represent not only yourselves but the patients you treat, the many people in the pulmonary hypertension community who can't travel to an event like this. Remind the staff member that PAH may be a rare disease, but the impact of this disease is wide-reaching – not only to PH patients but also to their caregivers, loved ones, and healthcare providers.
- **Request a photo.** Ask if your Member of Congress is available to take a photo with you as a way to get a few minutes of face time if they are in the office. If not, it's still a great idea to ask for a photo with the legislative staffer you met with. If you do get a photo, don't be shy about posting it on social media and tagging the Member of Congress as well as PHA.
- **Take notes on questions.** Be sure to take notes during the meeting, and for any questions that you weren't able to answer, please write down the question, let them know PHA will follow up with more information, and be sure to share the question with a PHA staff person, to assist in PHA's follow-up with your legislator's office.
- **Restate your requests and end with a thank you.** Repeat your appreciation for their time and for listening to these issues which are important to the PH community. As you are able, follow up on your meetings with a brief thank you email to the staff person you met with.



PHPN Advocacy Day 2023

Advocacy Day Social Media Tips

- Use **#PHPNAdvocacyDay** and **#PHPN2023** in your posts.
- Use the social media platform(s) you are most comfortable with.
- Tag PHA so we can share your posts on our channels.
 - Twitter/X: @PHAssociation
 - LinkedIn: @PulmonaryHypertensionAssociation
 - Facebook: @PulmonaryHypertensionAssociation
 - Instagram: @PHAssociation

Posting a picture with your senator or a member of their staff is a perfect way to tell your social media story. Visitors to congressional offices are generally welcome to take photos but be sure to always ask permission first as a courtesy.

Tagging your legislator or a member of their staff on social media helps continue your work to advocate and raise awareness for the PH community. You can use Congress' online directories to find contact information [here for Senators](#).

Pro tip: Typing @LegislatorName will generally bring up the person's account as you compose your message.

Sample Social Media Messages

I'm joining my PHPN colleagues for **@PHAssociation's #PHPNAdvocacyDay**. We're asking **@LegislatorsName** to co-sponsor the **#SafeStepAct**, legislation that eliminates barriers to life-saving medication for people with **#pulmonaryhypertension**. **#PHPN2023**

Today I asked **@LegislatorsName** to co-sponsor the **#HELPCopaysAct** which protects access to charitable co-pay and premium assistance for individuals with rare, chronic conditions like **#pulmonaryhypertension**. **#PHPN2023 #PHPNAdvocacyDay @PHAssociation**

Today is PHA's **#PHPNAdvocacyDay**! I joined my fellow **#pulmonaryhypertension** professionals and asked Congress to improve access to supplemental oxygen to help patients access the most appropriate type of oxygen for their needs. **#PHPN2023 @PHAssociation**

I had a visit with **@LegislatorsName** to discuss the importance of the **#SafeStepAct**, **#HELPCopaysAct** and access to supplemental oxygen for my patients and the **#pulmonaryhypertension** community. **#PHPNAdvocacyDay #PHPN2023 @PHAssociation**



WHAT IS PULMONARY HYPERTENSION?

Pulmonary hypertension (PH) is an umbrella term used to describe a group of complex, potentially fatal lung conditions. PH is characterized by high blood pressure in the vessels of the lungs and can lead to right heart failure.

PH can occur in relation to left heart disease, lung disease, blood clots in the lungs and other conditions. Genetics also can play a role. In some cases, there is no known cause.

Symptoms of PH include shortness of breath, fatigue and chest pain.

Since PH often mimics symptoms of asthma and other less threatening illnesses, many people go months or years without an accurate diagnosis. As a result, they might not get the full benefit from available therapies once they are diagnosed.



WHAT IS PULMONARY ARTERIAL HYPERTENSION?

Pulmonary arterial hypertension (PAH) is one type of PH. Without treatment, people with PAH live 2.8 years past diagnosis on average.

Fortunately, there are 15 FDA-approved targeted PAH treatment options for adults and one FDA-approved drug for children. Although life expectancy has more than doubled,* these drugs are complex and expensive. Currently, there is no cure for PH.

The disease commonly occurs in conjunction with connective tissue diseases, such as scleroderma and lupus; HIV infection; liver disease; congenital heart disease; and exposure to certain drugs, such as methamphetamine.



WHO IS AFFECTED BY PULMONARY HYPERTENSION?

Adults and children of all ages can develop pulmonary hypertension.

Women develop PAH more than three times as often as men, and women of color have disproportionately poorer health outcomes.

**Benza RL, et al. Chest. 2012;142(2):448-456*



WHAT IS THE PULMONARY HYPERTENSION ASSOCIATION?

Founded in 1991 by patients, for patients, the Pulmonary Hypertension Association (PHA) is the oldest and largest nonprofit patient association in the world dedicated to the pulmonary hypertension community. Our mission is to extend and improve the lives of those affected by PH. To achieve our mission, PHA engages people with PH and their families, caregivers, health care providers and researchers worldwide who work together to advocate for the PH community, provide support to patients, caregivers and families, offer up-to-date education and information on PH, improve quality patient care and fund and promote research.



HOW DOES PHA CONNECT THE PH COMMUNITY?

PHA's 200 support groups serve patients, caregivers, medical providers, parents, children, bereaved families and anyone whose life is touched by PH. Along with telephone support groups, a toll-free Support line, Facebook groups and an email mentor program, PHA's support programs serve thousands of patients and caregivers each year.

As the oldest and largest PH association in the world, PHA leads global initiatives such as annual World PH Day campaigns, convenes dozens of leaders at a biennial summit and creates communication channels for nearly 80 PH associations worldwide.

Because PH often arises from another underlying condition such as COPD or blood clots, PHA partners with organizations that represent associated diseases to offer support and provide information about the risks, symptoms and screening for PH.

PHA's International PH Conference and Scientific Sessions unites 1,400 patients, caregivers and medical professionals every two years to learn about the latest research and lifestyle advice, and to connect and network. Other events provide patient and caregiver education.



DOES PHA PROMOTE QUALITY PATIENT CARE?

PHA has provided more than \$8 million for PH research and provides continuing education for medical professionals through PHA Online University and in-person CME programs.

Since 2014, PHA has accredited more than 80 hospitals and clinics as Pulmonary Hypertension Care Centers (PHCCs). Many of these PHCCs participate in the PHA Registry (PHAR), which has enrolled more than 1,600 patients to help advance research.



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LEGISLATIVE PRIORITIES 118th CONGRESS, 1st SESSION

Pulmonary Hypertension

Pulmonary hypertension (PH) is high blood pressure in the vessels of the lungs that develops when constriction of the vessels increases the pressure the heart must apply to pump blood. As with a tangled hose, pressure builds up and backs up forcing the heart to work harder while less oxygen reaches the body. It is a progressive, frequently fatal condition.

Individuals of any age can develop PH, which may occur without a known cause or in association with other conditions such as scleroderma, lupus or sickle cell disease. Common PH symptoms include fatigue, dizziness and shortness of breath, with the severity of the disease correlating with its progression. Innovative treatment options have been developed and approved. The effectiveness of treatment depends on accurate diagnosis and early intervention.

Patient Access Priorities

Please co-sponsor S. 1375, the *HELP Copays Act*, and take other steps to reduce out-of-pocket cost burden for people with chronic, life-threatening diseases. Individuals with pulmonary hypertension and other complex, life-threatening health conditions sometimes rely on charitable grants or other sources of financial assistance to make ends meet. Currently, many health insurance plans refuse to accept this assistance or accept it but then choose not to apply it to a patient's deductible and out of pocket maximum, effectively "double-dipping". The 118th Congress should codify protections to charitable copay and premium assistance and require health plans to fully apply these payments to patients' out of pocket responsibilities, beginning with passage of the HELP Copays Act (S. 1375)

Please advance S. 652, the *Safe Step Act*

When insurance payers use fail-first, or step therapy, requirements to shift a person with PH from one therapy to another without the agreement of a physician, these switches can lead to health setbacks from which the individual may never recover. The Safe Step Act (S. 652) places reasonable limitations on step-therapy requirements in the case of high-risk health conditions such as PH by requiring insurers to provide a clear exceptions process and timeline for their response.

Please work with CMS to ensure that individuals with chronic lung disease have access to the full range of oxygen modalities prescribed by physicians. For individuals who require supplemental oxygen, the weight of the necessary equipment is a significant barrier. For individuals who need a high oxygen flow rate per minute, a portable liquid system is likely the only equipment allowing them to engage in activities outside the home. Since the initiation of competitive bidding, reimbursement rates for liquid oxygen have fallen by as much as two-thirds and the number of suppliers has dropped. Even when physicians prescribe liquid oxygen, patients may be unable to receive it. Congress should work with CMS to ensure that oxygen suppliers are reimbursed appropriately for their services and held accountable for the provision of physician-specified oxygen equipment.

Funding Priorities

Please provide the National Institutes of Health (NIH) with at least \$50.924 billion in FY 2024. NIH and PHA have a strong track record of working together to advance our scientific understanding of PH. The multiple FDA-approved treatments are evidence of the return-on-investment from these activities. Please provide NIH with meaningful increases to facilitate expansion of the PH research portfolio so we can continue to improve life expectancy and quality of life for people with PH.

Please fund the Centers for Disease Control and Prevention's (CDC) Chronic Disease Education and Awareness initiative at \$6 million in FY 2024. Individuals with pulmonary hypertension experience significant delayed and misdiagnosis leading to 50% dying within 8-10 years of diagnosis despite the availability of multiple FDA-approved, targeted therapies. The CDC's Chronic Disease Education and Awareness Initiative offers the opportunity to reduce this delay in diagnosis through public and health care professional education. Please provide this program with a meaningful increase to improve diagnosis and effective treatment of individuals with PH and other life-threatening, chronic conditions.

Patient Perspectives

Chandani's son was diagnosed with severe PH at the age of two. Since his diagnosis, her son's medical care team has tried progressively increasing therapies in a stepwise fashion, which is often required by insurance companies but is known to lead to worse outcomes than when patients are allowed to immediately begin the treatment prescribed by their doctor. He has not been responsive to these therapies and due to the progression of his PH during this time, now faces the need for lung transplant.

Ashley relies on her husband's health insurance since she had to stop working due to PH. In 2022, her husband was considering a new job which would come with new insurance. The family did their best to check whether Ashley's three expensive PH medications, just one of which has a monthly copay of more than \$6,000, would be included on the new plan's formulary. The company assured they would be covered, so her husband took the new job. After two months with the new insurance and paying the monthly copays, Ashley discovered the two most expensive copayments were not being counted towards her deductible. The insurance company lists her life-saving medications as "non-essential" through a loophole. PH drugs are for a rare disease and therefore were not included on a list of essential drugs insurance companies have to cover, so her insurance has decided that copayments for those medications are not counted towards her deductible. Now Ashley must apply for charitable assistance each year to afford her expensive copayments.

Barbara has lived with PH for 22 years and with the treatment of liquid oxygen, she has managed to develop a comparatively active life. However, that changed when Barb's Medicare-contracted oxygen supplier stopped delivering liquid oxygen without notice and switched her to compressed oxygen gas tanks.

Liquid oxygen tanks are light enough to be carried hands-free strapped to the back and hold a sufficient volume of oxygen to provide a continuous stream for 6-8 hours at a time so that Barb is able to breathe easily while still walking around. Compressed oxygen tanks are heavier and hold a smaller volume of oxygen, so they sustain her for only a fraction of the time that liquid oxygen tanks do. The forced transition to compressed tanks caused a steep decline not only in Barb's quality of life but also in each subsequent pulmonary function test she's received. She now struggles with routine errands and is unable to comfortably visit her seven grandchildren.

Pulmonary Hypertension Association

The Pulmonary Hypertension Association (PHA) is dedicated to extending and improving the life of those affected by PH. PHA was the first organization in the world dedicated to providing comprehensive PH patient and caregiver support; medical education; specialty care services that improve patients' quality of life; and research funding.

We encourage you to contact PHA with questions about pulmonary hypertension as well as the broader challenges faced by individuals with rare, chronic health conditions and the medical professionals who treat them. Katie Kroner can be reached at KatherineK@PHAssociation.org or 240-485-0749.

PATIENTS ARE BEING HARMED BY COPAY ADJUSTMENT POLICIES

PATIENTS ARE SPEAKING OUT

When the assistance runs out, patients are still at square one with their insurance company and are faced with significant out-of-pocket costs for their medication. Often, it's enough to make a patient walk away and stop taking their prescription.¹

Melissa El Menaouar

Patient with Primary Biliary Cholangitis

For my family, not having this critical assistance count toward our deductible could result in us losing access to a drug that keeps my daughter alive and thriving.²

Jen Hepworth

Mother of a Cystic Fibrosis Patient

Copay accumulator programs can be devastating to MS patients and those battling other conditions who could very well lose access to the drugs they rely on to maintain their health and well-being.³

Jim Turk

Patient with Multiple Sclerosis

Copay accumulator adjustment policies and copay maximizer adjustment programs are insurer schemes that prevent patient assistance funds from counting toward a patient's out-of-pocket maximums, or deductibles.



EXPOSING VULNERABLE PATIENTS TO LARGE, UNEXPECTED COSTS

When insurers and pharmacy benefit managers (PBMs) pocket copay assistance, patients are burdened with high out-of-pocket costs that can exceed thousands of dollars because patients still have to pay themselves until they reach their deductible.



INTERRUPTING NECESSARY TREATMENT

When the sick and vulnerable are burdened with high-out-of-pocket costs, those patients often lose access to needed medications and stop necessary treatment.



UNDERMINING PATIENT PROTECTIONS

Insurers copay adjustment policies erode protections set in place by the Affordable Care Act because Pharmacy Benefit Managers (PBMs) and other middlemen define needed medications as "non-essential health benefits."

¹ https://captimes.com/opinion/guest-columns/opinion-loss-of-copay-assistance-would-impoverish-patients/article_cc58588b-dd0f-5369-8f80-8b34490751ac.html

² <https://www.deseret.com/opinion/2022/1/25/22901099/utah-legislature-copay-accumulator-insurance-company-financial-burden-families>

³ <https://www.jsonline.com/story/opinion/2021/10/22/why-wisconsin-lawmakers-need-protect-value-copay-assistance/6108016001/>

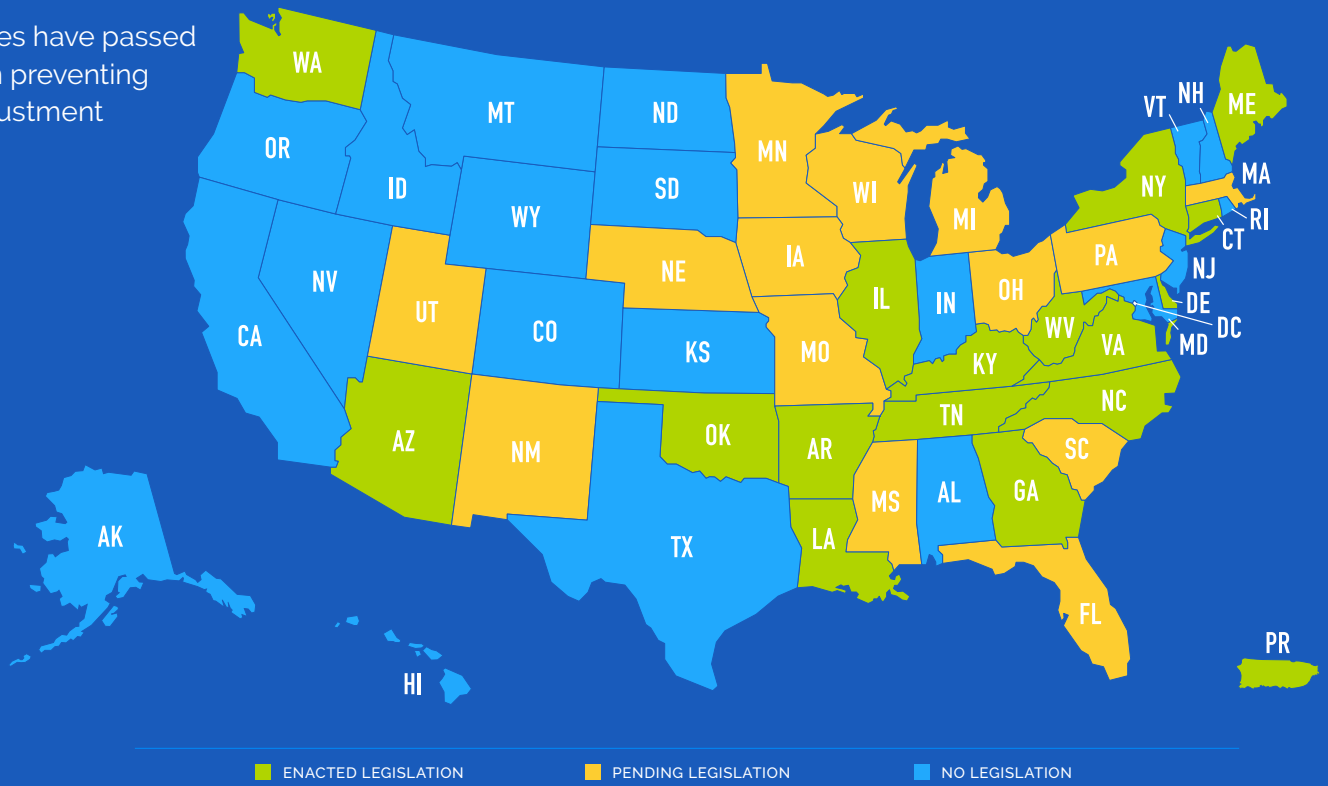
CONGRESS CAN PROTECT PATIENTS

BIPARTISAN LEGISLATION HAS BEEN INTRODUCED

The Help Ensure Lower Patient (HELP) Copays Act ([H.R. 830](#)) would protect millions of Americans from the copay adjustment schemes of insurers and pharmacy benefit managers.

STATES ARE TAKING ACTION

Many states have passed legislation preventing copay adjustment policies.



THE SOLUTION

Ensure that all copays count for all patients and **pass S. 1375** to protect vulnerable Americans.

LEARN MORE ABOUT HOW COPAY ADJUSTMENT POLICIES HARM PATIENTS AT [ALLCOPAYSCOUNT.ORG](#)



The HELP Copays Act Eliminates Harmful Health Plan Pricing Schemes and Protects Vulnerable Patients from Soaring Out-of-Pocket Costs

The sickest and most vulnerable patients—those who live with serious, complex chronic illness—are being targeted by health plan programs that undermine the benefits of copay assistance for medicines. The bipartisan Help Ensure Lower Patient (HELP) Copays Act eliminates barriers to treatment for patients ensuring that they can afford the necessary and life-saving medications prescribed by their doctors. The legislation requires health plans to count the value of copay assistance toward patient cost-sharing requirements. This would bring much-needed relief to vulnerable patients by ensuring that all payments—whether they come directly out of a patient's pocket or with the help of copay assistance—counts towards their out-of-pocket costs.

BACKGROUND

Patients are being asked to pay more. People living with serious, chronic health conditions often face multiple barriers to the therapies they need to treat their conditions, such as administrative hurdles like prior authorization and step therapy that limit access to specialty medications. And once approved, patients face skyrocketing deductibles and steep cost-sharing. With no other options to afford the medicine they need, many patients turn to charitable or manufacturer copay assistance to afford their drugs.

Copay accumulator adjustment programs (CAAPs) cut a critical lifeline for patients and leave them exposed.

Under CAAPs, insurers have disallowed copay assistance from counting towards a patient's annual deductible or out-of-pocket maximum. As a result, many are faced with unexpected costs of thousands of dollars to get the medicines they need.

- The overwhelming share of medicines that are subject to programs like these (95%, according to the National Hemophilia Foundation analysis of the SaveOn SP Formulary) have no generic or biosimilar equivalents, leaving patients without a less expensive alternative.
- These programs disproportionately impact the most vulnerable patients who rely on certain medicines. A recent survey found that 69% of those who depend on such assistance make less than \$40,000 a year, leaving them at risk of losing access to necessary health care.

The EHB loophole allows big companies to avoid paying for critical care for patients who most need help. A loophole under the Affordable Care Act (ACA) allows many employer health plans to deem certain categories of prescription drugs as “non-essential,” even when they are life-saving or necessary for people with serious pre-existing and chronic conditions. When a covered drug is deemed “non-essential,” the insurer will not count any cost-sharing toward the patient's deductible and out-of-pocket maximum. This loophole also allows employers to simply not cover drugs that treat expensive health conditions. By falling into the EHB loophole, patients in these plans often must pay hundreds or thousands of dollars in out-of-pocket costs for life-saving medicines and never hit their out-of-pocket maximum.

Together, these practices undermine coverage for pre-existing conditions, hurt patient access to medicines, decrease drug adherence, and likely cost our health care system even more money.

ABOUT The HELP Copays Act

The HELP Copays Act is a two-part solution that

- Clarifies the ACA definition of cost sharing to ensure payments made “by or on behalf of” patients count towards their deductible and/or out-of-pocket maximum.
- Closes the EHB loophole to ensure that any item or service covered by a health plan is considered part of their EHB package and thus cost sharing for these must be counted towards patients' annual cost sharing limits.

Congressional action is needed to protect patients. The bipartisan **HELP Copays Act** can help end these harmful pricing schemes and bring much-needed cost savings to vulnerable patients.



PHPN Advocacy Day 2023

Policy Priority: Supplemental Oxygen Access

For too long, patients who require supplemental oxygen have not had access to oxygen appropriate for their medical and quality of life needs, especially those requiring liquid oxygen.

Please support legislation addressing the well-documented problems with access to supplemental oxygen, including:

- Shift from “home oxygen” to “supplemental oxygen” terminology.
 - Patients needing oxygen therapy shouldn’t and often don’t need to be restricted to their home. The current terminology paints an inaccurate and limiting picture.
- Increase access to specialist expertise by making providers’ time spent providing education on the use of oxygen equipment also reimbursable.
- Reform the reimbursement structure for supplemental oxygen – currently all modalities of oxygen are reimbursed at the same rate.
 - Suppliers are incentivized to push patients towards lower cost options which has led to a decline in use of more expensive oxygen modalities like liquid oxygen.

Background:

- Supplemental oxygen is a statutorily covered service under the Durable Medical Equipment benefit for Medicare beneficiaries who show clinically relevant oxygen desaturation levels at rest or during exercise.
- There are several different modalities for the delivery of supplemental oxygen, each with its own strengths and limitations.
- Since the implementation of the competitive bidding program, claims for all oxygen modalities have dropped dramatically, with liquid oxygen seeing the most significant drop. Liquid oxygen is an important modality for patients with high oxygen flow needs.
- Between 2017 and 2021:
 - Liquid stationary went from 62,371 claims to 16,716 – a 73% decline.
 - Liquid portable went from 95,859 to 24,942 claims– a 74% decline.
 - No changes to respiratory disease patterns would explain this sharp decrease.

CMS and Congress Recognize Problems with Liquid Oxygen:

- In 2019, CMS established new payment classes for liquid oxygen
- Bipartisan Congressional letters to CMS identified concerns about declining access to supplemental oxygen, particularly in rural areas, and called for them to act.
- For FY 2021, the House appropriations bill included report language expressing continued concern over lack of access for liquid oxygen.
 - It requested CMS to report to Congress within 60 days on current access and trends in use between 2010 and 2019.
 - CMS acknowledged there are access issues and is monitoring the effect of its earlier revisions to payment rates noted above.

Pulmonary Hypertension and Oxygen Access

Pulmonary hypertension (PH) is high blood pressure in the vessels of the lungs that develops when constriction of the vessels increases the pressure the heart must apply to pump blood. As with a tangled hose, pressure builds up and backs up forcing the heart to work harder while less oxygen reaches the body. It is a progressive, frequently fatal condition.

With the correct treatment and oxygen modality, many people with PH continue to work and engage in activities of daily living. However, the weight of the necessary equipment is a significant barrier. For individuals who need a high oxygen flow rate per minute, a portable liquid system is likely the only equipment that would allow them to engage in activities outside the home. Since the initiation of competitive bidding, reimbursement rates for liquid oxygen have fallen by as much as two-thirds and the number of suppliers has dropped. Currently, even when physicians prescribe liquid oxygen, patients may be unable to receive it.

Patient Perspectives: Losing Independence and Quality of Life

Barbara has lived with PH for 22 years and with the treatment of liquid oxygen, she had managed to develop a comparatively active life. However, in 2021, Barb's Medicare-contracted oxygen supplier stopped delivering liquid oxygen without notice and switched her to compressed oxygen gas tanks. Liquid oxygen tanks are light enough to be carried hands-free like a backpack and hold a sufficient volume of oxygen to provide a continuous stream for 6-8 hours, so that Barb is able to breathe easily while still walking around. Compressed oxygen tanks are heavier and hold a smaller volume of oxygen, so they sustain her for only a fraction of the time that liquid oxygen tanks do.

These new limitations due to the loss of appropriate treatment for her PH caused a steep decline in her quality of life, as well as her health. Her subsequent pulmonary function tests were notably lower after the change and have not improved. Barb now struggles with routine errands and is unable to comfortably visit and play with her seven grandchildren. These declines in health and quality of life have led to Barb becoming depressed; at a medical visit shortly after Barb lost access to liquid oxygen, her PH specialist told her, "I've never seen you this bad."

Cash is a pediatric ph patient, diagnosed in 2015 at age 8. He has needed continuous high-flow oxygen since elementary school and struggles with wheeling the compressed oxygen tanks behind him while navigating the halls. At the beginning of 2022, Cash's family finally secured a portable oxygen concentrator (POC) for him. This machine only has a 2-hour battery life, so he still has to navigate his schedule around access to a wall outlet multiple times a day, but carrying the POC on his back is a significant quality of life improvement. Cash's father Jeff noted his son had more energy after school and was now willing to do things outside the house with his family.

However, Jeff has had an extremely frustrating battle trying to keep his son's POC running. Almost as soon as the equipment arrived, it stopped working due to a faulty battery. In April 2022, just a few weeks after finally getting the replacement battery installed, the POC's column, which converts air to medical grade oxygen, stopped working. After 10 months of reaching out with extremely poor communication and multiple delays from Lincare, the equipment supplier, Jeff was finally able to secure the replacement part in February 2023. Jeff filed a letter of complaint with Lincare and it took over a month to receive a response, which did not address his concerns.

S. 652 SAFE STEP ACT

Senator Murkowski (R-AK), Senator Hassan (D-NH), Senator Marshall (R-KS), Senator Rosen (D-NV), Senator Tillis (R-NC), Senator Merkley (D-OR), Senator Capito (R-WV), Senator Cortez Masto (D-NV), Senator Hyde-Smith (R-MS), Senator Blumenthal (D-CT), Senator Lummis (R-WY), Senator Smith (D-MN), Senator Cramer (R-ND), Senator Sinema (I-AZ), Senator Collins (R-ME), Senator Casey (D-PA), Senator Kaine (D-VA), Senator Wicker (R-MS), and Senator Gillibrand (D-NY)

Purpose: Improve step therapy protocols and ensure patients are able to safely and efficiently access the best treatment for them.

Background: Step therapy is a tool used by health plans to control spending on patient's medications. While step therapy can be an important tool to contain the costs of prescription drugs, in some circumstances, it has negative impacts on patients, including delayed access to the most effective treatment, severe side effects, and irreversible disease progression. Currently, when a physician prescribes a particular drug treatment for a patient, the patient's insurance company may require them to try different medications and treatments before they can access the drug originally prescribed by their physician. This protocol is known as "step therapy" or "fail first." Step therapy protocols may ignore a patient's unique circumstances and medical history. That means patients may have to use medications that previously failed to address their medical issue, or – due to their unique medical conditions – could have dangerous side effects.

The Safe Step Act: The Safe Step Act amends the Employee Retirement Income Security Act (ERISA) to require a group health plan provide an exception process for any medication step therapy protocol. The bill:

- **Establishes a clear exemption process:** The Safe Step Act requires insurers implement a clear and transparent process for a patient or physician to request an exception to a step therapy protocol.
- **Outlines 5 exceptions to fail first protocols.** Requires that a group health plan grant an exemption if an application clearly demonstrates any of the following situations:
 1. Patient already tried and failed on the required drug. A patient has already tried the medicine and failed before.
 2. Delayed treatment will cause irreversible consequences. The drug is reasonably expected to be ineffective, and a delay of effective treatment would leave to severe or irreversible consequences.
 3. Required drug will cause harm to the patient. The treatment is contraindicated or has caused/is likely to cause an adverse reaction.
 4. Required drug will prevent a patient from working or fulfilling Activities of Daily Living The treatment has or will prevent a participant from fulfilling their occupational responsibilities at work or performing Activities of Daily Living. Activities of daily living (ADLs) mean basic personal everyday activities such as eating, toileting, grooming, dressing, bathing, and transferring (42 CFR § 441.505).
 5. Patient is stable on their current medication. The patient is already stable on the prescription drug selected by his or her provider, and that drug has been covered by their previous or current insurance plan.
- **Requires a group health plan respond to an exemption request within 72 hours in all circumstances, and 24 hours if the patient's life is at risk.**

Safe Step Act

Exception Examples

- Patient already tried and failed on the required drug.

Michael was eight years old when his parents noticed his foot turning in when he walked, prompting a series of doctor's appointments. Following numerous misdiagnoses, Michael was finally diagnosed with Psoriatic Arthritis at the age of 12. The search to find an effective treatment for Michael's disease proved to be a long, frustrating process. In Michael's case, the first two drugs failed, and the "fail first" process he endured took nearly ten months during which he received no treatment. The first drug he tried did nothing to abate his pain; the second caused him to develop lupus-like symptoms, resulting in more appointments and tests. The insurance company then wanted Michael to *try another remedy that was the same type he had already failed twice before covering his physician's recommended medication*. Finally, Michael's doctor was able to get coverage approved for the medication he had initially prescribed. Despite the eventual success, this period of over a year without treatment caused Michael's disease to progress rapidly, resulting in Michael developing an additional chronic illness.
- Delayed treatment will cause severe or irreversible consequences.

Jake, from Alaska, was diagnosed with Crohn's disease as a young child. A year later, he experienced a severe flare and the doctors insisted he immediately be put on an anti-TNF biologic. Jake was a primary non-responder to the anti-TNF, which meant that he would not respond to any anti-TNF. His doctors then tried to put him on an alternative biologic, however, his insurance company required him to prove failure on an additional anti-TNF biologic even though it was against the clinical evidence and guidelines. This process delayed Jake's access to appropriate treatment for several weeks. By the time Jake was granted coverage for the new biologic, his disease had progressed so much that the treatment was not as effective as it would have been if prescribed earlier. As a result, Jake lost his colon. Jake turned 13 this year.
- Required drug will cause harm to the patient.

Jenn, from California, was diagnosed with psoriasis and psoriatic arthritis, her doctor prescribed a treatment that would ease her arthritis pain and slow down joint degeneration. Unfortunately, Jenn's doctor-prescribed treatment was denied by the insurance company and required her to take an alternate medication, which would have led to life-threatening side-effects on the patient's liver. After three months of back-and-forth between the provider, patient, and the insurance company, and explaining that the insurance preferred medication would result in a "death sentence" – Jenn was asked to try a third medication which exacerbated her condition. Finally after nearly a year, Jenn was approved for her original doctor-prescribed treatment and began seeing improvements within three weeks.
- Required drug will prevent a patient from working.

Elliot, nicknamed Duffy, from Alaska, is an epilepsy patient and works as a ski instructor and heavy machine operator. The first medication he tried controlled his seizures, however the side-effects made him feel like he was inebriated and dizzy, making it unsafe and even dangerous to perform the tasks necessary for his jobs. Despite his inability to work on the treatment, his insurer would not cover alternative treatments, and he was faced with the option of losing his job or paying out right for a different treatment, which would cost him \$700 a month. Duffy opted to pay for the new treatment with no coverage. The new medication controlled his seizures with less side effects so that he could perform his occupational duties.
- Patient is stable on their current medication.

Katie, a psoriatic arthritis patient, has been stable on her treatment for years. Her treatment was covered by her employer's private insurance until, in the middle of the plan year, her insurer sent her a letter stating that her current treatment would no longer be covered until she went through step therapy protocols. Within four weeks, Katie, who had been an active adult, was back in a wheelchair. Her step therapy journey lasted for ten months, leading to 14 surgeries, countless doctors' visits, missed time from work, and ultimately health care costs that far exceeded the price of her treatment.