



2021 Allergy & Asthma Network Federal Agenda



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INTRODUCTION

Allergy & Asthma Network (Network) is the nation's leading voice and patient advocate for more than 50 million Americans with allergies and over 24 million with asthma. For 35 years, the Network has worked to end needless death and suffering due to asthma, allergies and related conditions through outreach, education, advocacy and research.

Asthma remains one of the most serious chronic diseases and costly health issues (approximately \$80 billion annually in direct and indirect healthcare costs) in the United States. Approximately 3,600 Americans die each year due to asthma. The disease has greater impact on vulnerable populations, including children and older adults as well as those living with other diseases. Populations that are low-income and certain ethnic groups also have a higher rate of diagnosed asthma, increased hospitalizations and deaths.

Of the millions of Americans living with allergies to the environment, food, insect venom, medications and latex, there are 15 million at risk for a severe allergic reaction, or anaphylaxis. Symptoms of anaphylaxis vary and can include hives, coughing, shortness of breath, tongue and throat swelling, vomiting, stomach pain and shock. Severe anaphylactic reactions can lead to death. There are approximately 700 deaths annually due to anaphylaxis, and children and adolescents are among those most at risk.

Together with patients, families, healthcare professionals and industry partners, the Network seeks to ensure that federal and state laws, policies, regulations and resources support our role in achieving optimal health outcomes for people with asthma and allergies.

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FEDERAL AGENDA - 117TH CONGRESS

I. IMPROVE ACCESS TO MEDICAL CARE AND TREATMENT

- Biosimilars
- Drug Price Transparency
- Health Equity
- Medicare and Medicaid
- Out-of-Pocket Costs
- Step Therapy
- Surprise Billing
- Telehealth

II. ASTHMA AND ALLERGY PROGRAM FUNDING

- U.S. Department of Health and Human Services – CDC, NIH, HRSA
- U.S. Department of Housing and Urban Development – Healthy Homes Initiative
- U.S. Department of Defense – Peer Reviewed Medical Research Program (food allergy)
- U.S. Environmental Protection Agency - Asthma research, education and outreach initiatives

III. REDUCE HEALTH RISKS FOR ALLERGY AND ASTHMA EMERGENCIES

- School-Based Asthma Management
- Food Allergy Labeling
- Airline Passenger Safety

IV. MITIGATE ENVIRONMENTAL HEALTH HAZARDS

- Air Quality (Indoor/Outdoor)

V. COVID-19 PREVENTION AND TREATMENT

I. IMPROVE ACCESS TO MEDICAL CARE AND TREATMENT

Access to high-quality, affordable healthcare and insurance coverage is essential to achieve the most successful health outcomes for patients. This includes adequate coverage for patients who rely on government programs including Medicare and Medicaid. Access to innovative therapies and technologies (e.g., biologic medications, immunotherapy, telehealth, remote patient monitoring) are important to address specific medical needs and improve patients' lives.

Access to safe, effective and affordable medicines is critical as the rising costs of prescription drug prices puts Americans at risk for poorer health outcomes, especially those with chronic and life-threatening conditions such as asthma and severe allergies. Lack of access to affordable medicines has led to patients not filling a doctor's prescription, reducing the dosage to make a supply last longer, buying medicines from foreign countries or substituting alternative therapies. Stabilized treatments are necessary for patients with chronic conditions and access to medications is critical.

Biosimilars

Biologic medications are innovative treatment options for various diseases and benefit patients from the improved results so they can live healthier lives. Advancements in biologic research and development have helped patients make great strides in managing chronic and life-threatening diseases like asthma. Due to their complexity, however, biologics are often associated with high costs and limited patient access.

Biosimilars are FDA-approved biologic medications that are compared to the original biologic and help drive down prices by introducing competition. They may also provide patients with more access to important treatments, including those who previously may not have been able to afford them.

Recommendations:

- Improve access to generics and biosimilars in Part D of the Medicare program.
- Provide a separate Healthcare Common Procedure Coding System (HCPCS) billing code and reimbursement in Medicare Part B for each biosimilar biologic product.

Drug Price Transparency

Rising costs of prescription drugs and out-of-pocket costs for patients are major factors driving up the costs of healthcare and insurance for everyone. Americans spend more than twice as much per year on medications than their peers in other industrialized countries. Even with insurance, many patients still face high out-of-pocket costs, such as increased premiums, higher deductibles, rising copays and co-insurance forcing them to choose between their medication and their next trip to the grocery store.

When patient costs are too high, their access to medication is a challenge and results in medication abandonment and adherence which is harmful to patients' well-being and the overall healthcare system. This is particularly true for patients with chronic conditions such as asthma and severe allergies who rely on consistent use of their medications and cannot afford to miss a dose. Patients need quality insurance coverage with comprehensive health benefits, including prescription medications.

Recommendations:

- Require health plans to offer meaningful and broad prescription formularies that do not discriminate against people with serious or chronic conditions and include new and innovative medications (e.g., biosimilars and biologics).

- Remove high deductible barriers in accessing medications, particularly at the beginning of each plan year.
- Require manufacturers to implement cost-saving programs (e.g., rebates, co-pay cards) and be fully transparent on drug pricing policies.
- Require Pharmacy Benefit Managers (PBMs) to report rebate policies and formulary placement determinations.

Health Equity

Development of health equity interventions are needed to support better health outcomes for all patients. Health disparities (e.g., access to care, poverty, environmental hazards, education inequities, language and cultural differences) cross ethnic and socioeconomic groups and impact individual health and well-being. Asthma and allergy rates are higher in poor urban areas and more common in African American and Hispanic children, according to CDC's National Center for Health Statistics. Proven intervention strategies (e.g., programs, services and policies) are needed to develop successful health equity interventions.

Recommendations:

- Expand asthma tracking and surveillance to all states.
- Expand in-home allergen education, monitoring and reduction programs.
- Increase health literacy and language tools and training in asthma and allergies.
- Provide transportation access for needed healthcare services.
- Mitigate environmental health hazards.
- Research on reducing minority disparities.

Medicare and Medicaid

Access to high-quality, affordable healthcare and insurance coverage is essential to achieve the most successful health outcome for patients. This includes coverage for patients who rely on government programs such as Medicare and Medicaid. Medicare serves over 60 million Americans over 65 years and young people with disabilities, while over 70 million Americans receive healthcare coverage through the Medicaid program, including low-income adults, children, pregnant women, elderly adults and people with disabilities.

Medicaid is a substantial source of coverage for people living with asthma and the disease disproportionately affects African Americans, Hispanics and those living in poverty. One of the main obstacles to treatment and care for asthma is the cost of medication and in the case of asthma, staying on a medication schedule is essential. Ultimately, when patients forgo medical care it creates a patient population that is in poor health, leading to increases in healthcare spending.

These important government programs are vital to ensure that our nation's most vulnerable population has access to health coverage.

Recommendations:

- Maintain adequate coverage for individuals who rely on Medicare and Medicaid.
- Ensure patient protections to prevent discrimination against those with pre-existing conditions.
- Improve access to generics and biosimilars in Part D of the Medicare program.
- Provide a separate Healthcare Common Procedure Coding System (HCPCS) billing code and reimbursement in Medicare Part B for each biosimilar/biologic product.

Out-of-Pocket Costs

For patients with chronic conditions like asthma, it is essential that they have the medications they need to effectively manage their disease. When faced with high out-of-pocket costs due to cost-sharing policies implemented by insurance companies, patients often do not use their medications appropriately by either skipping doses in order to save money or abandoning treatment altogether.

Co-insurance or cost-sharing policies are becoming increasingly common in employer-sponsored insurance plans to help limit company costs around pharmacy benefits. These policies have shifted more responsibility to the patient, reflected in higher out-of-pocket costs. In the past, pharmacy benefits have come with fixed copays for different tiers of medications. For example, copayments could be \$10/\$30/\$50 for the three tiers. Recently, however, some health insurance policies have moved vital medications (mostly biologics) into a fourth specialty tier. Specialty tiers require patients to pay a percentage (co-insurance) of their drug cost, often 25 percent to 50 percent, instead of a fixed dollar amount.

Due to difficulty understanding these cost-sharing percentages upon enrollment, patients can be left having to choose between their health and a heavy financial burden. Cost-sharing for prescription drugs should not interfere with access to necessary medications. This can lead to negative health outcomes for patients and increased costs in the healthcare system.

Recommendations:

- Reduce prescription drug costs for patients, particularly those with chronic or life-threatening conditions.
- Limit the total annual out-of-pocket costs for all prescription drugs to protect patients from extremely high costs for necessary medications.
- Provide patient option to spread their deductible out over the course of the year into reasonable payments instead of being required to pay it in the first months of their plan year.

Step Therapy

Step therapy, also known as “fail first,” is a health insurance protocol used to manage the cost of medications. It requires patients to try and fail one or more insurer-preferred medications, proving their ineffectiveness to the patient, before receiving coverage for the medication their physician recommends. If a patient ends up changing their health insurance plan, or a medication they are currently using is moved to a nonpreferred status during a coverage year, that patient may be put through the step therapy process again.

Physicians can request exceptions to step therapy requirements, but insurers may not respond promptly to such requests. This process can take weeks to months, resulting in patients not being able to access the medications they need, leading to worsened symptoms and disease progression. Additionally, by limiting medication options, both doctors and patients are forced to compromise their treatment decisions in a way that is dangerous, time consuming and more expensive in the long-term. Asthma medications are especially prone to step therapy because health plans frequently change the list of preferred medicines they cover.

Recommendations:

- Establish a transparent process for medications subject to step therapy.
- Ensure that step therapy requirements are aligned with the most current clinical data and clearly outline concise exemptions based on medical necessity.
- Require a timely response to exemption requests so a patient’s care is not further delayed.

Surprise Billing

Surprise billing, otherwise known as surprise balance billing, is a practice that occurs when patients receive unexpected bills from hospitals, physicians or labs that are not in their insurance network. Patients are required to pay the “balance” of any medical bills after they have paid their deductible, copayment or coinsurance and their insurance company has also paid all that they are obligated to toward medical bills. These bills often come from providers who patients do not choose, such as emergency room doctors or from certain services ordered by in-network doctors. Receiving care from an out-of-network provider can happen unexpectedly, even when patients try to stay in-network. This is especially true in cases of emergencies. These surprise bills can often be very expensive and leave patients in a very difficult financial position, especially if they are managing a chronic illness like asthma.

Recommendations:

- Require medical facilities and/or the providers to notify patients of the potential out-of-network charges before receiving treatment.
- Ensure protection for patients from surprise balance billing in emergency situations and in situations where the patient seeks care at an in-network facility and is then treated, without another option, by an out-of-network provider within the facility.

Telehealth

The discovery, development and commercialization of innovative technologies (i.e., telemedicine, remote patient monitoring) are important to address unmet medical needs and improve patients’ lives. Telemedicine functions as a complement to existing healthcare resources by increasing access to affordable medical treatment. The delivery system uses technology tools that are pervasive in modern daily life, and it can provide a valuable and cost-effective way for people to get necessary treatment.

Physicians who use telemedicine to deliver care should be held to the same standards as they would be if they were treating a patient in an office. Many patients who suffer from allergies, especially those with allergy-related skin conditions, would benefit from greater and more convenient access to a physician. For patients with chronic respiratory conditions like asthma and COPD, telemedicine would be an effective way to provide disease education and improved disease management. This is particularly true in rural areas, where visiting a physician’s office could require traveling lengthy distances.

Recommendations:

- Expand access to healthcare by enacting telehealth policies that increase broadband access and provide patient choice.
- Require insurers to cover telehealth services that support patients with allergies and chronic respiratory conditions.

II. ALLERGY AND ASTHMA PROGRAM FUNDING

Federal health programs that support disease awareness, management and research are essential to improve the healthcare quality and safety for all Americans, particularly those who live with chronic conditions.

Recommendations:

Continue funding in fiscal year (FY) 2022 for asthma and allergy research, education and outreach initiatives at:

- **U.S. Department of Health and Human Services (HHS)**
 - U.S. Centers for Disease Control and Prevention (CDC)
 - National Asthma Control Program
 - National Institutes of Health (NIH)
 - National Heart, Lung and Blood Institute (NHLBI)
 - Lung disease research
 - National Asthma Education and Prevention Program (NAEPP)
 - National Institute of Allergy and Infectious Diseases (NIAID)
 - Allergy, Immunology and Transplant Research
 - Consortium of Food Allergy Research (CoFAR)
 - Health Resources and Services Administration (HRSA)
 - Healthcare Workforce
- **U.S. Department of Housing and Urban Development (HUD)**
 - Healthy Homes Program
- **U.S. Department of Defense (DOD)**
 - Peer Reviewed Medical Research Program (PRMRP) – food allergy research
- **U.S. Environmental Protection Agency (EPA)**
 - Asthma research, education and outreach initiatives

III. REDUCE HEALTH RISKS FOR ALLERGY AND ASTHMA EMERGENCIES

School-Based Asthma Management

In the United States, there are approximately 6 million children with asthma under the age of 18 years old. Asthma is the leading cause of school absenteeism, causing more than 10 million missed school days annually. On average, students with asthma experience two more absences per year than students without asthma and some students experience more. Asthma-related school absenteeism is linked to lower academic performance, especially among urban minority youth.

With over 50 million school-age children in our country, the CDC recommends that schools have one nurse for every 750 students. Yet nearly 60% of schools have a higher ratio of students to available nurses. As the number of students with medical needs continues to increase it is vital that students have regular access to a school nurse.

This type of preparation and management in schools will not only help improve a child's health, but also ensure students are able to focus on learning.

Recommendations:

- Enact policies supporting asthma management in K-12 schools, including implementation of individual asthma-action plans, education and training, and emergency stock of asthma control medications.
- Increase the number of school nurses in elementary and secondary schools.

Food Allergy Labeling

More than 32 million Americans live with food allergies and many suffer from serious and potentially life-threatening food allergies, including an estimated 6 million children.

Sesame allergy has increased in recent years due in part to the growing number of products containing sesame seeds and sesame oil, including foods, cosmetics, lotions and pharmaceutical items. Exposure can lead to a severe or even life-threatening allergic reaction. There are eight major food allergens – milk, egg, peanut, tree nuts, soy, wheat, fish and crustacean shellfish – represented on packaged foods in the United States. Sesame is not recognized, unlike in Canada, the European Union, Israel, Australia, New Zealand and many others. In 2016, a report by the National Academy of Sciences recommended that sesame be listed as a major food allergen and identified on food labels. In November 2020, the U.S. Food and Drug Administration (FDA) issued draft guidance encouraging food manufacturers to “voluntarily” include sesame in the ingredient list on food labels.

Not labeling for sesame leaves consumers with sesame allergy unable to protect themselves from accidental exposure: adults with sesame allergy are more likely to report visiting the emergency department for a food allergy reaction in the past year than adults with any other allergy.

Additionally, unintentional cross contact with a food allergen can occur during manufacturer food processing when a small amount of an allergenic food gets into another food accidentally, or when it is present on a surface or an object. This small amount of an allergen could cause an allergic reaction.

Recommendation:

- FDA should require clear and consistent labeling of allergens in foods, particularly sesame and any potential for cross contact during food processing.

Airline Passenger Safety

Epinephrine is the first line of treatment when a person is experiencing a life-threatening allergic reaction, or anaphylaxis. However, only a handful of airline carriers stock emergency supplies of epinephrine auto-injectors on board their flights. While airline passengers with chronic conditions should take every precaution necessary and always be prepared, they should feel confident an airline can assist them when experiencing a medical emergency, and airline personnel should be trained to recognize the symptoms of an acute allergic reaction and administer medications if needed. Air travel policies should be precautionary, not reactionary, to support the public in the event of a medical emergency.

Recommendation:

- All airlines should carry no fewer than two packs of epinephrine auto-injectors as treatment for anaphylaxis and provide crewmember training to recognize the symptoms of an acute allergic reaction and administer an epinephrine auto-injector to support those living with asthma and severe allergies.

IV. MITIGATE ENVIRONMENTAL HEALTH HAZARDS

Air Quality (Indoor/Outdoor)

Patients who suffer from asthma and other respiratory illnesses are vulnerable to environmental contaminants from air pollution and the adverse health effects of climate change. Air pollution and climate change solutions must integrate public health to protect our most vulnerable populations – communities of color, the elderly, children, the sick and those living in poverty.

Ground-level ozone and particulate matter (e.g., dust, dirt, soot or smoke) and living and/or working within proximity to major sources of harmful air pollution (e.g., major roadways, solid waste landfills) can trigger

asthma symptoms. Indoor pollutants and environmental allergens, such as mold, dust mites, cockroaches and mice, pet dander, cigarette smoke, and living in substandard housing, can also trigger asthma symptoms.

The increase of carbon pollution and other greenhouse gases are impacting the climate, resulting in rising temperatures and a more expansive growing season. This has caused changes in flowering time and pollen development. Higher concentrations of pollen emitted into the air increases exposure to allergens that trigger asthma flares and worsen allergy symptoms. The increase in greenhouse gases is leading to a rise in wildfire severity, droughts, heavy rain events and floods – all putting respiratory health at risk.

Recommendations:

- Mitigate environmental health hazards and reduce exposure to pollution in and around schools and residential areas.
- Set pollution limits on particulate matter to protect the health of Americans.
- Implement policies that address the health impacts of climate change.

V. CORONAVIRUS (COVID-19) PREVENTION AND SAFETY

The COVID-19 outbreak has had a significant impact on the U.S. population and our overall healthcare system. It is important that the healthcare needs of all Americans are adequate to meet the demands on our healthcare system and protection is provided to the medical professionals who are working to provide quality care.

People with asthma, COPD and other chronic respiratory diseases are at greater risk for complications – such as life-threatening pneumonia or bronchitis – if they are diagnosed with this novel strain of coronavirus. Given that 24 million people in the United States have asthma, and 10 people die from the disease daily, prevention for those with this chronic disease is vital.

The number of Americans infected with COVID-19 continues to grow, as does the number of fatalities, according to data released from the CDC. The pandemic is highlighting levels of economic and racial disparity across the country where many minority communities still face barriers to healthcare access.

Recommendations:

- Provide continued federal funding for medical equipment to support health professionals.
- Assist people with chronic, underlying health conditions and maintain access to their medications and treatment. This includes removing burdensome barriers to obtain medications, such as limits on refills, to ensure supply of these medications, as well as advancing telehealth parity and remote patient monitoring.
- Conduct widespread testing and develop reporting systems to understand the impact on minority and tribal communities and other vulnerable populations to determine steps needed to reach equitable health outcomes.
- Ensure fair and equitable access to a safe and effective COVID-19 vaccine.

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Allergy & Asthma Network (Network) is a multidisciplinary network of patients, caregivers, healthcare professionals and community stakeholders all dedicated to ending needless death and suffering due to asthma, allergies and related conditions. One core mission area is advocacy where we empower stakeholders to impact public policy for the welfare of those living with these chronic and life-threatening conditions.

From Capitol Hill to local town halls, The Network supports issues that improve care for the 50 million Americans living with allergies, 24 million living with asthma and those with related conditions. Our goal is to raise visibility and influence policy that improves care and promotes lifesaving research. Through partnerships and raising awareness, we can help ensure that asthma and allergies remain front and center on the national healthcare agenda.

Allergy & Asthma Network has developed a proactive federal agenda to ensure the needs and interest of patients and their families are reflected in all major federal policies and regulatory decisions made in Washington, D.C. The Network is eager to work in collaboration with other healthcare stakeholders, the Administration and Congress to achieve these goals.



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