



Engage - Educate - Empower

2021 STATE ADVOCACY AGENDA

ABOUT ALLERGY & ASTHMA NETWORK

Allergy & Asthma Network (“Network”) is the nation’s leading voice and patient advocate for more than 50 million Americans with allergies and 24 million with asthma. For 36 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 (\$80 billion annually) in the United States. Approximately 3,600 Americans die each year due to asthma. The disease has a greater impact on vulnerable populations, including children and older adults as well as those living with lung disease. Populations that are low-income and some ethnic groups also have a higher rate of diagnosed asthma and increased hospitalizations and deaths due to asthma.

In addition, 15 million Americans are at risk for anaphylaxis, a severe allergic reaction that causes approximately 700 deaths annually. One in every 13 children are at risk due to food allergies alone.

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, allergies and related conditions.

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STATE ADVOCACY ISSUES

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- Health Equity
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- Out-of-Pocket Cost
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I. IMPROVE ACCESS TO AFFORDABLE MEDICAL CARE AND TREATMENTS

Co-Pay Accumulators

Many patients are not able to afford medications prescribed by their doctors to manage their chronic conditions and maintain health. In order to make expensive medications more accessible, manufacturers sometimes provide co-pay coupons or copay assistance cards to help patients cover the cost.

In past years, the value of co-pay coupons has counted toward a patient's annual deductible. However, insurance companies are increasingly refusing to count this third-party assistance toward patient out-of-pocket requirements. They have created new "co-pay accumulator adjustment programs" which allow patients to access and pay for high-cost prescription drugs but do not apply their value toward a patient's deductible or out-of-pocket costs. This is particularly concerning when there is no generic alternative for medications, which is the case for most drugs used to treat chronic illnesses. In these cases, failing to count co-pay coupons toward a patient's deductible leaves the patient with no affordable coverage option. Many must choose between the financial burden of covering these unexpected costs or not using their needed medications.

Recommendations:

- Require insurers to count manufacturer co-pay coupons or assistance cards toward an enrollee's annual deductible.
- Require insurer transparency about co-pay accumulator programs and patient's annual out-of-pocket costs at the time of open enrollment, with information provided in language easily understood by all patients.

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 racial, 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 the U.S. Centers for Disease Control and Prevention (CDC). Proven intervention strategies (e.g., programs, services and policies) are needed to develop successful health equity interventions.

Recommendations:

- Expand health insurance coverage for socioeconomic disadvantaged adults and children.
- Encourage and incentivize state and local health departments to adopt comprehensive community-based asthma programs.
- Increase diversity in health care workforce.
- Increase access to affordable, quality housing and transportation options.

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 Medicaid. Over 70 million Americans, including low-income adults, children, pregnant women, elderly adults and people with disabilities have Medicaid healthcare coverage.

With the Affordable Care Act (ACA) Medicaid expansion program, an additional 10 million uninsured Americans were provided affordable insurance coverage. This has been linked to greater access to care, more preventive care and improved chronic disease management.

Asthma 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 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.

The Medicaid program is vital to ensure that our nation's most vulnerable population has access to health coverage.

Recommendations:

- Maintain comprehensive coverage for individuals who rely on Medicaid.
- Expand Medicaid to provide affordable health care coverage for low income residents.

Non-Medical Switching

Non-medical switching occurs when a medically stable patient is forced by an insurance company to switch off the medication they rely on to a less costly and possibly less effective drug for financial reasons, not medical ones. Insurance companies may simply choose to no longer cover a certain drug on their formulary (a list of covered prescription drugs) or place it on a specialty tier, requiring the patient to be responsible for more of the cost.

Non-medical switching is based on the notion that cost savings can be achieved with less expensive versions of drugs from the same therapeutic class. The belief is that drugs in these classes are medically interchangeable because their mechanisms of action are similar, even though the chemical makeup of the individual drugs are different. Studies, however, have found this to be false in terms of both quality of care and actual cost savings. A switch to a patient's treatment can expose the patient to avoidable negative health outcomes and increased down-stream costs for both the insurer and the patient.

Recommendations:

- Patients must be allowed to continue using their medication while remaining with the same insurer. If a switch must occur, patients and their prescribing physicians should receive written notification and be given at least a six-month grace period.
- Implement common-sense reforms to the rules that insurance companies must abide by when deciding which medications to cover and ensure that health plans do not change their insurance formulary (their drug list) in the middle of the year.
- Provide physicians an opportunity to appeal the switch on behalf of their patients with a clear and transparent appeal process to minimize treatment disruptions and allow patients to stay on their prescribed medication during the process.

Out-of-Pocket Caps

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 co-pays 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 health care system.

Recommendations:

- 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.

Pharmacy Benefit Manager (PBM) Transparency

Pharmacy benefit managers (PBMs) are companies hired by insurance companies to manage drug benefit programs to reduce costs. They determine which drugs are covered by health plans, establish pharmacy reimbursement rates, and validate a patient's eligibility. However, lack of transparency and oversight into their methods have enabled the opposite to take place, as PBMs have been allowed to operate virtually unchecked. Since their inception, out-of-pocket costs for patients have continued to increase dramatically.

PBMs have become incredibly effective at negotiating discounts and rebates from manufacturers., Instead of passing these rebates on to patients, due to lack of transparency they can keep profits for themselves.

PBMs may also push manufacturers to increase their drug's price in order to be included on their formulary (list of covered drugs). Another common practice is to impose "gag clauses" on pharmacists, forbidding them to inform patients at the pharmacy counter when the cash price for a prescription is lower than the medication's co-payment, or whether a cheaper alternative is available.

Increasing drug exclusions on PBM formularies is also a growing issue. Exclusions can be particularly problematic for asthma patients who, once they are stable on a medication, can experience negative health outcomes as a result of disruption of care.

Recommendations:

- Increase oversight of PBMs to ensure that state money used on medications is spent efficiently at all points in the drug distribution chain.
- Provide greater protections for patients regarding their prescription drug benefits programs and establish greater oversight of the pharmacy benefit managers that administer those benefits.
- Register PBMs in all states, with regulation that provides robust oversight.
- Require PBMs to verify that they are sharing manufacturer rebates and negotiating the lowest possible costs for drugs to provide the services they were hired for.
- Enact policies that address pharmacy "gag clauses".
- Enact policies that prohibit manufacturers and wholesalers from price gouging.

Preferred Drug List (PDL)

Medicaid covers one in five Americans including millions of America's poorest and most vulnerable people. Children account for more than four out of 10 (43%) of all Medicaid enrollees, and the elderly and people with disabilities account for about one in four enrollees. Minority populations, many of whom are living with health disparities and chronic conditions like asthma, make up over 60% of those enrolled in Medicaid. Most state Medicaid programs maintain a Preferred Drug List (PDL), a list of outpatient prescription drugs within therapeutic drug classes that states use to encourage providers to prescribe over others in an effort to control costs. Currently, 46 states report having a PDL in place, and most are reviewed and updated annually.

If a drug is not on the PDL, a state may attach a higher copayment or require prior authorization and/or step therapy (*see step therapy details below*) in order to provide coverage for the medication. As a result, patient access to medications is restricted, particularly for newer drugs that have been linked to higher quality and better health outcomes. This may lead to reduced patient adherence to medication therapy, leading to poor health outcomes or a patient abandoning treatment altogether due to cost.

Recommendations:

- A state PDL should include at least one option of each essential medicines for asthma and allergy related conditions as defined by the World Health Organization (WHO). (See https://www.who.int/medicines/services/essmedicines_def/en/)
- Medications on a state PDL must be approved based on safety and clinical efficacy first, and then cost.

Prior Authorization

Prior Authorization refers to an insurance company policy which requires medical providers to obtain the insurer's approval before coverage is provided for certain medications and treatments. Prior Authorization can cause patients to be denied access to their medicine for days to weeks. These delays can be frustrating and even dangerous, especially for patients with a chronic disease like asthma. Not only does this practice create barriers to treatment for the patient, but it also increases the administrative burden on physicians and their staff who are required to spend hours filling out multi-page forms and submitting labs and patient records. If the insurer still denies coverage, patients and their physicians may appeal, but this delays treatment even further. Insurers claim that prior authorization is a cost-saving tool which limits unnecessary use of expensive medicines. In reality, it is making it difficult for patients to access appropriate treatment and get proper care.

Recommendations:

- Require insurers to use a unified, single form for the prior authorization of prescription medications and medical treatments which is electronically accessible and able to be submitted electronically.
- Insurers should also be required to consider and respond to a request within a set, reasonable period or the request is deemed approved.

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.

Currently, there are 27 states that have passed step therapy amendments. These amendments have not banned step therapy, but instead established sensible guardrails, striking a fair balance between cost containment and patients' health.

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 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.

II. REDUCE HEALTH RISKS FOR ALLERGY AND ASTHMA EMERGENCIES

Entity Stock Epinephrine

Severe food, insect venom, medication and latex allergies can be deceiving and lead to an anaphylaxis emergency – a serious allergic reaction that can occur quickly and is potentially life-threatening. There are approximately 700 deaths annually due to anaphylaxis. The first-line treatment for anaphylaxis is epinephrine. Data shows that deaths from anaphylaxis occur more often when the patient is away from home and there is either a delay before epinephrine is administered or it is not given at all. Immediate access to this lifesaving medication is critical.

The *School Access to Emergency Epinephrine Act of 2013* led to legislation in 49 states ensuring students with severe allergies had access to emergency supplies of epinephrine auto-injectors in school.

In recent years, states have expanded the range of businesses and organizations (e.g., restaurants, recreation camps, youth sports leagues, amusement parks, sports arenas and daycare facilities) permitted to maintain emergency supplies of epinephrine for use by trained non-medical staff. Currently, 37 states have "entity stock" laws or guidance to help create safer communities and protect some of our most vulnerable citizens.

Recommendation:

- Permit public venues to purchase, acquire, and possess epinephrine for use by trained non-medical staff with liability protections during an anaphylactic emergency.

Food Allergy Guidelines

Approximately 15 million Americans have life-threatening food allergies, which can quickly turn to anaphylaxis. Today, one in 13 children has food allergies, or roughly two in every classroom. Nearly 40 percent of these children have already experienced a severe or life-threatening allergic reaction.

Severe allergic reactions should always be handled as a medical emergency. To prevent and manage severe allergic reactions in schools, the Centers for Disease Control and Prevention (CDC) recommends a Food Allergy Management and Prevention Plan as best practice in their Voluntary Guidelines (See

www.cdc.gov/healthyyouth/foodallergies/pdf/13_243135_a_food_allergy_web_508.pdf).

Schools should regularly update their food allergy guidelines to protect students with severe food allergies and ensure a safe and effective educational environment.

Recommendation:

- Require schools to regularly update their food allergy guidelines to protect students with severe food allergies and prepare the school staff to respond appropriately when a severe allergic reaction occurs,

Latex Allergy

Approximately 1 to 6 percent of Americans have a diagnosed allergy to latex, a natural rubber product made primarily from rubber trees and found in more than 40,000 commonly used products in healthcare, food establishments, childcare, schools, communities and homes.

A latex allergy reaction can occur by not only touching a product containing natural rubber latex but also by breathing in airborne protein particles. The allergen can also be transferred to food prepared using latex gloves.

Latex allergy can result in mild to life-threatening symptoms, including hives, swelling, red and itchy skin, shortness of breath and anaphylactic shock. The only way for people with latex allergy to prevent symptoms is strict avoidance of latex.

Recommendation:

- Enact policies addressing public health risks associated with latex allergy to protect and improve the health of people with life-threatening allergies and respiratory diseases.

School-Based Asthma Management

More than 6 million children under the age of 18 are diagnosed with asthma in the United States. Asthma results in 13.8 million missed school days each year and can lead to decreased academic performance and stress associated with the chronic illness.

The *Asthmatic Schoolchildren's Treatment and Health Management Act of 2004* led to legislation in all 50 states ensuring schoolchildren with asthma had the right to self-carry and administer their quick-relief bronchodilator inhaler at school. There is movement in states across the country to pass laws or guidelines that standardize asthma management plans in schools and permit schools to stock emergency supplies of albuterol inhalers with a prescription and for trained personnel to administer to a student believed to be in a respiratory distress emergency. Currently there are 14 states with laws or guidelines permitting stock albuterol in schools.

Many children with asthma are undiagnosed, lack asthma management plans and don't have access to albuterol at school, posing a significant risk to their health. Stock albuterol can be a solution. This type of preparation and management in schools can not only improve a child's health but also ensure students are able to focus on learning.

Recommendations:

- Require an Asthma Action Plan for each grade K-12 student with asthma.
- Implement policies for schools to have access to emergency stock asthma medications that can be available to all students who are in respiratory distress.

III. 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 the poor.

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 hazards, such as mold, dust mites, cockroaches and mice, 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:

- Expand in-home allergen education, monitoring and reduction programs.
- Mitigate environmental health hazards and reduce exposure to pollution in and around schools and residential areas.
- Prohibit smoking in public places.
- Implement policies to address health impacts of climate change.

Water Management (Legionella Bacteria)

Legionella is a naturally occurring waterborne bacteria which lives throughout the water supply chain from source to tap in homes and buildings. Wherever there is water, the Legionella bacteria can be present. Furthermore, when water is used for drinking, bathing and other purposes, there is risk for exposure.

The immune system of most individuals is strong enough to fight back against Legionella exposure and prevent the development of disease. However, individuals with compromised immune systems and respiratory conditions like asthma are more susceptible to becoming sick once exposed.

Recommendation:

- Implement progressive policies addressing public health risks associated with Legionella to protect the health of Americans with respiratory conditions.