Deception of Allergy & Asthma Patients

AANMA Position

AANMA urges your support to defend safe evidence-based practices, patient access to quality health care via board-certified allergy specialists and reimbursement only for those products and services that meet well-established medical standards.

AANMA’s key message:
- We strongly urge Members of Congress to sign a bipartisan letter urging an intergovernmental investigation (Federal Trade Commission and U.S. Department of Health and Human Services) into deceptive business practices by many third-party clinics.

Key Points

- Primary care physicians are entering into lucrative third party business arrangements that put patients at risk in addition to defrauding the health care system.
- Patients are often unknowingly given an experimental and investigatory treatment (sublingual immunotherapy or SLIT) not approved by FDA that can result in anaphylaxis.
- Patients are advised to administer it at home, which is contrary to practice standards of care and puts patients at risk for death.
- SLIT is not reimbursable. However, the physician often bills as subcutaneous immunotherapy (SCIT) which is reimbursable and collects from insurance company.
- The Office of Inspector General (OIG) issued an opinion that discourages primary care practices from participating in these questionable business arrangements.
- The Federal Bureau of Investigation (FBI) encourages physicians and patients to report fraudulent behavior without fear of recourse (FBI report and OIG advisory statement).

Background

- 2 people die from anaphylaxis, a life-threatening allergic reaction, each day and 10 people die from asthma each day.
- Thousands of people suffering from asthma or allergies get approached by others claiming to be “certified allergy specialists.” Patients think these people are medically trained/licensed, but they are not – Board-certified allergists have 2-3 years beyond medical school in allergy and immunotherapy training.
- Pseudo-specialists will administer simple symptom questionnaires and universally recommend allergy testing; 80-90% of patients are then recommended to begin immunotherapy. (Board-certified allergists usually do this to less than 30% of patients.)
• Immunotherapy is designed to significantly alter a person's immune system.
• Pseudo-specialists additionally will give patients these allergy shots at thousand-times-lower concentrations compared to real doses and allow patients to inject themselves at home without medical supervision, which could result in anaphylaxis.
• These pseudo-specialists are often people who have recently been waiting tables/bartending and now are mixing “dangerous allergy cocktails” to unsuspecting victims. They have absolutely no previous medical or scientific training and receive only a few hours of allergy education before being put in charge of an entire immunotherapy program in a primary care office.
• Inducements are paid for every patient tested. Estimated billings > 124M in previous 2 years.
• Patients should check their medical bill after the visit to make sure the provider billed them and the insurance provider correctly.

Status

• Working in cooperation with AANMA, the National Association of Attorneys General has disseminated a Consumer Fraud Bulletin and a Criminal Division Investigations Alert to the Attorneys General of the 50 states and the District of Columbia and the chief legal officers of the Commonwealths of Puerto Rico (Secretary of Justice) and the Northern Mariana Islands, and the territories of American Samoa, Guam, and the Virgin Islands.
AANMA strongly urges Congress to ask the U.S. Food and Drug Administration to close regulatory loopholes that would permit new Metered-Dose Inhalers (MDIs) to enter the market without an integrated dose counter. AANMA believes integrated dose counting mechanisms should be required on all metered-dose inhalers.

AANMA's key messages:
1. There is a clear measurable quality of life benefit and fiscal benefit to having integrated dose counters.
2. Dose counters are the only reliable means for patients to track the number of doses remaining and in an inhaler ensure there is medication available when it is most needed—during an asthma attack.

Key Points
- Every day in the United States, 30,000 people have an asthma attack and 5,000 people visit an emergency room for asthma. Asthma is the number one reason that children go to the emergency department (except injuries). Each year the cost of treating asthma exceeds $20 billion in direct costs.
- Dose counters on metered-dose inhaler bronchodilators (rescue inhalers) can save your life and cut respiratory-related emergency department visits by almost half.

Background
- Asthma is a potentially deadly, disruptive and expensive disease affecting one out of every 12 Americans, or approximately 25 million people in the United States. There are more than 3,300 deaths due to asthma each year, many of which are avoidable with proper treatment and care.
- Metered-dose inhaler bronchodilators act quickly to reverse the airway constriction patients experience during an asthma attack. Given the potential life-saving implications of these devices, the value of knowing whether medication is available through a dose counter is immeasurable.
- The FDA has long recognized the importance of dose counters for the safe and effective use of MDIs. The agency encouraged pharmaceutical companies to include dose-counting mechanisms in 2003 through guidance. In April 2013, FDA released a draft guidance proposing that a generic MDI should have a dose counter if the brand has a dose counter.
**Problem**

- Despite the fact that the first dose counter guidance was finalized more than 10 years ago, there are still approved MDIs that do not have dose counters. Of the four bronchodilator rescue inhalers currently available in the U.S., only two are approved and marketed with dose counters.
- The 2013 draft guidance states that a generic rescue inhaler should have a dose counter only if the brand has one. However, given that not all brand inhalers have a dose counter, there is nothing to prevent the FDA from approving a generic inhaler without a dose counter.
- It is common for health care providers to write “albuterol” and not the brand name of the product on their prescriptions. Given the prevalence of generic substitution – there is real potential for a generic inhaler without a dose counter to be substituted for an inhaler with a dose counter.
- Today, approximately 85 percent of inhaler prescriptions include a dose counter. A switch to a non-dose-counter inhaler could interrupt the continuum of care patients and caregivers have come to expect. That is why patient advocacy groups and respiratory professional societies support dose counters on all metered-dose inhalers.

**Status**

- In addition, FDA does not currently require dose counters on proposed over-the-counter inhalers. Dose counters are particularly important for these products, which many patients could use in emergency situations.

AANMA has submitted comments on integrated dose counters to the FDA and Teva Pharmaceutical has submitted a Citizens Petition to the FDA. Co-Chairs of the Congressional Allergy & Asthma Caucus have submitted a joint letter to FDA in support.
AANMA believes FDA should exempt albuterol and epinephrine from OTC consideration. Including these specific life-threatening allergy and asthma medications runs contrary to well-established national guidelines, has unintended public policy consequences and lacks demonstrated safety and efficacy data for the intended use.

AANMA’s key message:
• We urge Members of Congress to sign a bipartisan letter to the Secretary of Health and Human Services expressing substantial concerns around OTC status of allergy and asthma medications.

Key Points

• New technologies better inform and help physicians and patients manage their disease but should never replace the physician or the patient/physician relationship.
• OTC life-threatening allergy and asthma medications (epinephrine and albuterol) run contrary to well-established National Institutes of Health evidence-based guidelines (NAEPP asthma and NIAID food allergy guidelines-based care).
• Allergy and asthma are not “do-it-yourself” diseases. Recognize these life-threatening diseases can kill without warning and in minutes.
• FDA should remove asthma and anaphylaxis medications from OTC consideration.

Background

• In an effort to address undertreatment of many common diseases and conditions in the United States, OTC drug products are playing an increasing role in the health care system. In 2012, FDA put forth a proposed paradigm and more allergy and asthma medications have been considered for OTC in recent years.
• Making allergy and asthma medications OTC is inconsistent with NIAID and NAEPP guidelines. The guidelines consistently advocate (1) asthma cannot be properly self-diagnosed, (2) a physician should make the initial diagnosis of asthma and (3) the patient should receive
continued care from a physician because asthma is a chronic and progressive disease. 

- Many proposed OTC asthma medications provide short-term relief but do not address underlying inflammation or prevent asthma attacks. Asthma currently affects an estimated 25 million people in the United States and the number is expected to rise significantly by 2025. Patients with asthma have also been shown to underestimate the severity of their airway obstruction. Many patients fail to tell the difference between mild, moderate and severe asthma.

- There are more than 3,300 deaths due to asthma each year, many of which are avoidable with proper treatment and care.

- Unfortunately, many people misuse or overuse these asthma treatments. Over-the-counter drugs are not meant for long-term use, yet OTC availability could lead people to use them every day. Because medications do not control asthma or its underlying causes, people who take them may not be receiving proper treatment of their asthma.

- A variety of health conditions may coexist or be mistaken for asthma. People with comorbid diseases such as high blood pressure, diabetes, thyroid disease, or heart disease are at greater risk when simply trying to relieve their allergy symptoms.

- The NAEPP Guidelines recommend that a primary care physician or a specialist diagnose asthma based on the patient’s medical and family histories, a physical exam, and test results. Diagnosis and treatment recommended by a kiosk will be less than thorough compared to a physician’s analysis.

- The guidelines also stipulate that asthma is a chronic and progressive disease. Improperly treated, asthma in most cases will worsen at various rates. This chronic disease can be slowed and even halted by treatment under continued physician’s care.

**Status**

- Supported by the American Academy of Allergy, Asthma & Immunology, the American Association for Respiratory Care, the American College of Allergy, Asthma & Immunology, the American Latex Allergy Association, the American Thoracic Society, and the COPD Foundation.


NIH, National Heart, Lung and Blood Institute. How Is Asthma Diagnosed?
http://www.nhlbi.nih.gov/health/health-topics/topics/asthma/diagnosis.html
AANMA urges your support and co-sponsorship of HR 2619, The Medicare Respiratory Therapist Access Act. This legislation would amend Medicare Part B to provide coverage of pulmonary self-management education and training services furnished by qualified respiratory therapists in the physician practice setting for patients diagnosed with pulmonary diseases such as asthma, chronic obstructive pulmonary disease (COPD), pulmonary hypertension, pulmonary fibrosis and cystic fibrosis.

AANMA’s key messages:

1. We urge co-sponsorship of HR 2619, and introduction of a Senate companion bill.
2. HR 2619 will provide better access to qualified respiratory therapists in the physician practice, better care, and lower costs to the health care system.
3. HR 2619 is estimated to cost the Medicare program $245 million over the 10-year period 2014-2024 or approximately $25 million annually.

Key Points

- HR 2619 will provide Medicare beneficiaries suffering from COPD, asthma, pulmonary hypertension, pulmonary fibrosis, and cystic fibrosis greater access to respiratory therapists’ expertise outside of the hospital.
- The Medicare law currently recognizes a number of non-physician practitioners and occupational therapists, physician assistants, and others, but RTs are not included. With the new paradigm in health care and the value Medicare places on quality, we believe it is time for Congress to recognize the contributions that can be made by qualified respiratory therapists who are the only allied health professional with comprehensive education in all aspects of pulmonary care.
- The Bill will establish pulmonary self-management education and training when furnished by RTs as a separate benefit, much like the successful diabetes outpatient self-management training benefit Congress passed over a decade ago.
Background

- COPD ranks fourth among the most costly preventable readmissions and is the third leading cause of death. A recent study found the readmission rate within 30 days post-discharge for Medicare beneficiaries with COPD to be 22.6%.
- COPD will be added to the list of conditions subject to the hospital readmissions reduction penalty this fall. Reducing excess preventable hospital readmissions is one of the most important issues facing the Medicare program today with the penalty rate jumping from 2% to 3% effective October 1, 2014 (fiscal year 2015). Pneumonia is already on the list.
- In 2010, Medicare beneficiaries with two or more chronic conditions including COPD and asthma accounted for almost 98% (1.9 million) of all hospital readmissions. The cost of multiple chronic conditions among Medicare beneficiaries is considerable with Medicare spending over $300 billion in 2010. Health care spending for COPD and asthma, which are among the 10 most costly health conditions, was $75 billion in 2011.
- The $245 million over the 10-year period or approximately $25 annually assumes that 70% of Medicare patients who had an emergency department visit between 2009-2011 and who meet criteria of the Act will qualify for self-management based on the physician’s assessment and be able to successfully self-manage their disease working with qualified respiratory therapists.
- It is possible the bill could achieve budget neutrality over a 10-year period: 1) if one-half of the 1% of the patient cohort avoided emergency department visits due to successful self-management, or 2) if 24% of the patient cohort who had a claim for oxygen improved their oxygen utilization and adherence to inhaled medications by proper self-management.

Status

- Supporters of HR 2619
- Board of Medical Advisors
- Alpha 1 Foundation and the Alpha 1 Association
- American Association of Cardiovascular & Pulmonary Medicine
- American College of Chest Physicians
- American Thoracic Society
- COPD Foundation
- Cystic Fibrosis Institute
- National Association for Medical Direction of Respiratory Care
- Pulmonary Hypertension Association
- American Association for Respiratory Care
Continued Federal Funding of Allergy & Asthma

AANMA Position

The School-Based Food Allergy Management Grants program will support the efforts of school districts to comply with Federal guidelines and follow state laws allowing or requiring stock epinephrine in schools.

AANMA requests your support for the National Asthma Control Program at the Centers for Disease Control and Prevention (CDC). Specifically, we ask that your appropriations request for FY 2015 increase funding for CDC’s National Asthma Control Program at $28 million.

AANMA encourages your support and continued funding of the Environmental Protection Agency’s (EPA) FY 2015 budget. EPA’s budget funds various projects and programs that focus on asthma and indoor air quality issues through the Healthy Communities Grant Program.

AANMA’s key message:
- We urge continued federal funding for allergy and asthma programs in FY 2015.

Key Points and Background

School-Based Food Allergy Management Grants
- In 2010, Congress passed the Food Allergy and Anaphylaxis Management Act (FAAMA) that (1) directed the U.S. Department of Health and Human Services to develop model school guidelines for the management of students with food allergies and (2) establish the School-Based Food Allergy Management Grants program to support the efforts of school districts to implement the guidelines.
- The FAAMA guidelines released last year recommend that schools stock non-student-specific epinephrine auto-injectors. FAAMA authorized $30 million.
- The funding authorization for the School-Based Food Allergy Management Grant program expires in FY 2015. We are asking appropriators for $5 million for FY 2015.
- This will support school districts’ purchases of stock epinephrine.

CDC’s National Asthma Control Program
- It is estimated that 25 million Americans have asthma, of whom 7 million are children under the age of 15. Asthma is a leading cause of school absences since it is a chronic disease.
• Asthma is responsible for $50.1 billion annually in health care costs, 10.5 million missed school days, and 14.2 million missed days of work and costs $5.9 billion in lost productivity.
• While asthma still claims the lives of 3400 Americans each year, death rates have decreased 38 percent since the National Asthma Control Program’s inception in 1999.
• The National Asthma Control Program has worked to integrate and coordinate the public health response to asthma control. Now there are national and state-specific surveillance systems in place which allow officials to track and better understand asthma trends -- and ultimately enable decision-makers to focus resources on strategies that work and populations that are most in need.

**EPA’s Healthy Communities Grant Program**
• The EPA’s FY 2015 Annual Performance Plan budget of $7.89 billion is almost $310 million, or nearly 4%, below the FY 2014 Enacted budget of $8.2 billion.
• An essential aspect of the FY 2015 budget is the Healthy Communities Grant Program. This program funds various projects and programs that focus on asthma and indoor air quality issues throughout the country.

**Status**

• These measures are recommended and supported by national medical and educational organizations such as the Food Allergy Research Education, the American Lung Association, Asthma and Allergy Foundation of America, the National Association of School Nurses, the Association of Asthma Educators, the Association for Respiratory Therapists, the American Academy of Allergy Asthma & Immunology and the American College of Allergy, Asthma & Immunology.
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**ADDITIONAL MEETING NOTES:**

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