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September 14, 2015

Andy Slavitt

Acting Administrator

Centers for Medicare & Medicaid Services

U.S. Department of Health and Human Services

7500 Security Boulevard

Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs: Reform of Requirements for Long-Term Care Facilities [CMS-3260-P]

Dear Mr. Slavitt:

Established in 1943, the AAAAI is a professional organization with more than 6,700 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases. We are writing to express our strong support for the antibiotic stewardship provisions in CMS' proposed rule revising the requirements long-term care facilities (LTCFs) must meet to participate in Medicare and Medicaid programs. As part of CMS' strategy to prevent the inappropriate use of antibiotics, we believe that patients who suspect they have a penicillin allergy or who have documentation in their health record regarding a penicillin allergy should be tested by a board certified allergist/immunologist to verify if they are truly allergic before an alternative non-penicillin antibiotic is prescribed.

Broadening requirements of LTCF's infection prevention and control programs to incorporate antibiotic stewardship programs that include both antibiotic use protocols and a system to monitor antibiotic use would allow facilities to optimize antibiotic use, combat the rise of resistant infections, and avoid antibiotic-related adverse outcomes for all residents. Requiring penicillin allergy testing as part of these programs would greatly accelerate progress towards these national goals. According to published research, without testing, an unverified history of penicillin allergy can contribute to longer hospitalizations, higher costs, greater risk for adverse effects of alternative (non beta lactam) antibiotics, and increased rates of serious antibiotic resistant infections such as *C. difficile* and methicillin-resistant *Staphylococcus aureus* (MRSA). It is for these reasons that the AAAAI recommended in 2014, as part of the American Board of Internal Medicine Choosing Wisely® program, that physicians should not overuse non-beta-lactam antibiotics in patients with a history of penicillin allergy without an appropriate evaluation.

While about 10 percent of the population reports a history of penicillin allergy, studies show that approximately 90 percent or more of these patients are not

allergic to penicillins and are able to take these antibiotics safely. Targeting this population could, therefore, have a substantial impact on national efforts to minimize inappropriate use of antibiotics.

Penicillin allergy testing is safe, easy, and effective, and can be performed even in critically ill patients. Further, people with a penicillin allergy that has been verified through skin testing can be offered penicillin desensitization if they require penicillin or a penicillin-like (beta lactam) drug and there is no equally effective alternative. Like penicillin testing, penicillin desensitization is an important component of a comprehensive antibiotic stewardship program.

Overall, the AAAAI urges CMS to adopt antibiotic stewardship requirements for LTCFs and requests that it consider penicillin allergy testing and penicillin desensitization as critical parts of a comprehensive antibiotic stewardship program in LTC and other settings.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Lemanske, Jr.", with a stylized flourish at the end.

Robert F. Lemanske, Jr., MD, FAAAAI
President