

October 31, 2014

Marilyn B. Tavenner, RN, Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8013  
Baltimore, MD 21244-8013

Dear Administrator Tavenner:

The undersigned organizations representing healthcare providers, patients, scientists, industry, and public health are deeply concerned about antibiotic resistance. Inappropriate use of antibiotics is a key driver of this public health crisis. To help address this serious problem, **we urge you to adopt a recommendation made recently by the President’s Council of Advisors on Science and Technology (PCAST): Require hospitals and long term care facilities to implement an antibiotic stewardship program (ASP) as a Condition of Participation (COP) in Medicare and Medicaid.**

Over the last several decades, there has been a significant increase in antibiotic use in hospitals and long term care facilities. Unfortunately, antibiotics are often administered needlessly, continued when they are no longer necessary, or prescribed at the wrong dose. In some cases, broad spectrum antibiotics are used when a narrow spectrum antibiotic would be equally effective. In other instances, ineffective antibiotics are prescribed to treat an infection. Inappropriate antibiotic use can lead to sub-optimal patient outcomes, preventable adverse events, and development of dangerous infections such as *Clostridium difficile* (*C. diff*).<sup>1</sup>

Inappropriate use of antibiotics is also a driver of the development of antibiotic resistance. As the PCAST report—along with many other recent reports by the Centers for Disease Control and Prevention (CDC), World Health Organization (WHO) and others—noted, increasing rates of resistance pose a significant threat to patients and public health. Resistant infections are killing patients and contributing to increased healthcare costs.

Antibiotic stewardship refers to systematic efforts to optimize the use of antibiotics – not just reduce the total volume used – in order to maximize their benefits to patients, while minimizing both the rise of antibiotic resistance as well as adverse effects to patients from unnecessary antibiotic therapy. Antibiotic stewardship programs have been shown clearly to reduce the percentage of antibiotic-resistant organisms in a facility, reduce the occurrence of *C. difficile* infections, improve patient outcomes, decrease toxicity, and reduce pharmacy costs. Stewardship programs need not be burdensome for healthcare facilities. They can typically be operated utilizing existing staff, including infectious diseases physicians, pharmacists, and infection control professionals.

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<sup>1</sup> Dellit T.H., R.C. Owens, J.E. McGowan, et al. “Infectious Disease Society of America and the Society for Healthcare Epidemiology of America: Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship.” *Clinical Infectious Diseases* (Jan. 2007) 44: 159–177

Despite clear benefits for patients, public health and healthcare costs, many healthcare facilities still lack antibiotic stewardship programs and, as a result, are continuing to contribute to the problems associated with antibiotic misuse, including increasing resistance. We believe that requiring stewardship as a CoP would be an extremely useful mechanism to ensure that hospitals and long term care facilities—two categories of facilities with high antibiotic use and large numbers of patients at risk for serious infections—implement stewardship programs, given that CoPs have proven to be an effective lever to change other healthcare practices.

We are encouraged that the PCAST report on antibiotic resistance, the Combating Antibiotic Resistant Bacteria (CARB) National Strategy and Executive Order all present tremendous opportunities to improve patient care and public health. We look forward to working with all relevant federal agencies to implement the recommendations and achieve the goals set forth in these documents.

Sincerely,

Accelerate Diagnostics Inc.  
Alliance for Aging Research  
Alliance for Natural Health-USA  
Alliance for the Prudent Use of Antibiotics  
American Academy of Pediatrics  
American College of Preventive Medicine  
American Pharmacists Association  
American Public Health Association  
American Thoracic Society

Antibiotics Working Group (Cempra, Durata Therapeutics, Optimer Pharmaceuticals, Melinta, The Medicines Company and Theravance)

Association for Professionals in Infection Control and Epidemiology  
Association of State and Territorial Health Officials  
bioMérieux  
Cempra, Inc.  
Health Watch USA  
HIV Medicine Association  
Infectious Diseases Society of America  
International Centre for Migration, Health and Development  
Making-A-Difference in Infectious Diseases  
National Association of County and City Health Officials  
National Association of Pediatric Nurse Practitioners  
National Foundation for Infectious Diseases  
ONCORD, Inc.  
Pediatric Infectious Diseases Society  
Society for Healthcare Epidemiology of America  
Society for Women's Health Research

Society of Critical Care Medicine  
Society of Infectious Disease Pharmacists  
Stop TB USA  
The Peggy Lillis Memorial Foundation  
The Pew Charitable Trusts  
Theravance Biopharma  
Trust for America's Health  
UPMC Center for Health Security