

June 24, 2019

The Honorable Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Verma,

We, the undersigned groups representing health care providers, scientists, patients, public health, advocates and industry, write to thank you for your attention to the public health crisis of antibiotic resistance and the urgent need for new antibiotics. We appreciate your proposal in the Fiscal Year 2020 Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule to increase New Technology Add-On Payments (NTAP) to 65 percent to improve reimbursement for novel antibiotic therapies. While we agree that current antibiotic reimbursement is insufficient and poses obstacles to patient access to antibiotics and to research and development in this critical therapeutic area, we remain concerned about the resistance crisis because the NTAP mechanism does not adequately address these issues. Instead, **we strongly encourage you to consider carving novel antibiotics to treat serious or life-threatening infections out of the diagnosis-related group (DRG) and to adopt new requirements for antibiotic stewardship and surveillance.**

Antibiotic resistance is rendering increasing numbers of infections difficult or even impossible to treat. These infections lead to longer hospital stays, increased health care costs, suffering and even death. Some patients can only be treated with decades' old, highly toxic antibiotics that cause severe kidney damage, often requiring long-term dialysis, while others have untreatable infections resistant to all available therapeutic options. Furthermore, the opioid epidemic is driving an increase in serious, hard-to-treat infections, as the Centers for Disease Control (CDC) reported that individuals who inject drugs are 16 times more likely to develop an invasive methicillin-resistant *Staphylococcus aureus* (MRSA) infection. We risk losing access to a variety of medical advancements currently made possible by safe and effective antibiotics, such as organ and bone marrow transplants, joint replacements and other complex surgeries, and cancer chemotherapy. While resistance impacts increasing numbers of patients, we are failing to develop a sufficient arsenal of new antibiotics.

The antibiotic market is broken. Factors unique to antibiotics make it extremely challenging for companies to earn a return on their investments: 1) antibiotics are typically given for a short duration; 2) the most highly resistant infections are still relatively rare; 3) new antibiotics must be used judiciously to preserve their effectiveness. These factors have resulted in nearly all major pharmaceutical companies exiting the antibiotics market, leaving the critical innovation domain of discovering and developing new antibiotics to small biotech companies with limited budgets and R&D capacity. These small biotech firms that are responsible for over 90% of the antibiotics in development worldwide are struggling to stay in business – even those that have launched or are close to launching products. Urgent action is needed to stabilize the antibiotics market.

The complexity of this problem requires a multi-pronged solution. Adjustments to the current Medicare reimbursement structure is one area that can help improve patient access to the most appropriate antibiotics. Many infectious disease physicians report significant challenges in adding a new antibiotic to their hospitals' formularies, attributable in part to the structure of the DRG. In addition to harming patients, this situation further depresses already small revenue opportunities for antibiotic developers.

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Some new antibiotics have been provided NTAP payments, but they have had little to no impact on increasing appropriate access. Current NTAP requirements make it difficult for companies to apply for and receive NTAP designation, NTAP is administratively cumbersome for hospitals to participate in, there is general unfamiliarity with the NTAP process among hospitals, the NTAP payments do not impact a hospital's pharmacy budget, and the percentage of costs covered are not sufficient to overcome the other barriers. Consequently, the current NTAP mechanism has not been shown to alter the availability and use of new antibiotics in hospitals.

The policy rationale underlying the NTAP is also not representative of the problem with antibiotic reimbursement. The purpose of NTAP is to facilitate the adoption of new technologies with the expectation that, within 2-3 years, utilization data will enable the assignment of the product to an appropriate level MS-DRG. In short, the NTAP payment is designed as a temporary bridge to help increase the utilization of a given technology so that it achieves adequate claims volume for assignment to (or creation of) an MS-DRG. By contrast, the policy intent for any antibiotic incentive is *not* to increase wholesale utilization. Stewardship programs expressly seek to ensure use is appropriate by prescribing certain guidelines for their use. It is, instead, the availability of and access to novel antibiotics that is important, to ensure physicians can make the best clinical treatment decisions for their patients.

Carving antibiotics out of the DRG and reimbursing for them separately would help level the playing field for new products, allowing physicians to make the best clinical treatment decisions for their patients and helping to stabilize the very tenuous situation innovators currently face.

In addition to improving patient access to new antibiotics and strengthening the market for innovators, it is equally important to promote appropriate use of antibiotics to limit the development of resistance. We strongly encourage you to also require all hospitals to: 1) establish antibiotic stewardship programs that are aligned with CDC recommendations; and 2) report antibiotic use and resistance data to the CDC National Healthcare Safety Network. Significant evidence has demonstrated that stewardship programs improve patient outcomes, lower health care costs, and reduce inappropriate antibiotic use. Antibiotic use and resistance data are essential to identify and track emerging threats and evaluate the impact of interventions to address antibiotic resistance.

Once again, we thank you for your attention to this important issue and we encourage your continued efforts to combat antibiotic resistance and ensure the availability of new safe and effective antibiotics for the millions of Americans who need them.

Sincerely,

Accelerate Diagnostics

American Public Health Association

Becton Dickinson (BD)

Biotechnology Innovation Organization (BIO)

Cystic Fibrosis Foundation

Duke Center for Antimicrobial Stewardship and Infection Prevention

Emory Antibiotic Resistance Center

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Infectious Diseases Society of America

Making-A-Difference in Infectious Diseases

Merck

NovaDigm Therapeutics

Pediatric Infectious Diseases Society

Peggy Lillis Foundation

Qpex Biopharma

Sepsis Alliance

Small World Initiative

Society of Infectious Diseases Pharmacists

The Antimicrobials Working Group (Amplify Pharmaceuticals, Aridis Pharmaceuticals, Cidara Therapeutics Inc., ContraFect Corporation, Entasis Therapeutics Inc., Iterum Therapeutics Ltd., Melinta Therapeutics Inc., Nabriva Therapeutics US Inc., Paratek Pharmaceuticals Inc., Qpex Biopharma Inc., SCYNEXIS Inc., Summit Therapeutics plc and VenatoRx Pharmaceuticals Inc.)

The Foundation to Combat Antimicrobial Resistance

The Gerontological Society of America

The Pew Charitable Trusts

Thermo Fisher Scientific

Trust for America's Health