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Seema Verma, MPH

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1716-P

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Submitted electronically via: <http://www.regulations.gov>

Dear Administrator Verma,

The Infectious Diseases Society of America (IDSAs) thanks you for your attention to the public health crisis of antibiotic resistance and the urgent need for new antibiotics. We appreciate the 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 for novel antibiotic therapies. We agree that current antibiotic reimbursement is insufficient and presents obstacles to patient access to antibiotics while also curtailing research and development in this critical therapeutic area. However, the NTAP mechanism does not adequately address antimicrobial resistance, an increasing problem in the United States, facilitate patient access to new drugs or create an adequate incentive for new antibiotic development. Instead, **we strongly encourage the Agency to consider carving payment for novel antibiotics to treat serious or life-threatening infections out of diagnosis-related groups (DRGs) while also adopting new requirements for antibiotic stewardship and surveillance.**

Antibiotic resistance is rendering increasing numbers of infections difficult or even impossible to treat. These infections often lead to longer hospital stays, increased health care costs, suffering and even death. Some patients have infections that are so highly resistant they can only be treated with decades' old, highly toxic antibiotics that cause severe kidney damage, which may lead to long-term dialysis, while other patients 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.¹ Patients are at risk of 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 antimicrobial resistance impacts increasing numbers of patients, we are failing to develop a sufficient arsenal of new antibiotics.

The current antibiotic market is broken. Factors unique to antibiotics make it extremely challenging for companies to earn a return on their research and development (R&D) investments including: 1) antibiotics are typically given for a short duration; 2) the most highly resistant infections are still relatively uncommon; and 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 domain of discovering and developing new antibiotics to small biotech companies with limited budgets and R&D capacity. Small biotech firms, 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. In April 2019, one small antibiotics company—Achaogen—filed for bankruptcy, despite having launched an important new antibiotic in 2018. In June 2019, another small antibiotics company—Tetraphase—announced massive layoffs, including eliminating its research function. The few remaining small antibiotics companies face similar fates.

The complexity of this problem requires a multi-pronged solution that addresses the need for antibiotic innovation and antibiotic stewardship. Adjustments to the current Medicare reimbursement structure is one area that can help improve patient access to appropriate antibiotics. Many infectious diseases physicians report significant challenges in adding a new antibiotic to their hospitals' formularies, attributable in part to the DRG payment structure. In addition to harming patients, this situation further depresses already small revenue opportunities for antibiotic developers. Some new antibiotics have been provided NTAP payments, but those payments 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. Hospitals and physicians report unfamiliarity with the NTAP process and find it administratively cumbersome. 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 does not align with the principles of the appropriate use and reimbursement of antibiotics. NTAP is designed to serve as a temporary bridge to facilitate the adoption of new technologies with the expectation that, within 2-3 years, enough utilization data will enable the assignment of the product to an appropriate DRG. By contrast, the policy intent for any antibiotic incentive is *not* to increase wholesale utilization. Instead, it is essential that new antibiotics are available for prescribers to make the best clinical decision

¹ Jackson KA, Bohm MK, Brooks JT, et al. Invasive Methicillin-Resistant *Staphylococcus aureus* Infections Among Persons Who Inject Drugs — Six Sites, 2005–2016. *MMWR Morb Mortal Wkly Rep* 2018;67:625–628. DOI: [http://dx.doi.org/10.15585/mmwr.mm6722a2external icon](http://dx.doi.org/10.15585/mmwr.mm6722a2external%20icon).

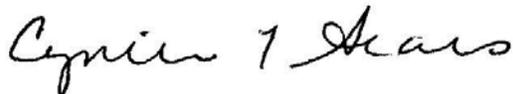
adhering to good stewardship—namely, maintaining that antibiotics be available for rapid treatment when needed, as delays in treatment of even a few hours can dramatically impact outcomes of patients with serious infections.

Carving antibiotics out of the DRG payment structure and reimbursing for antibiotics 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 optimize and to limit the development of resistance. CDC data indicate that roughly 30 percent of antibiotics used in hospitals are unnecessary or prescribed incorrectly, and we must reduce inappropriate use to improve patient outcomes and reduce resistance. We strongly encourage the Agency to require all hospitals to: 1) establish antibiotic stewardship programs that are aligned with the CDC Core Elements of Hospital Antibiotic Stewardship Programs; and 2) report antibiotic use and resistance data to the CDC National Healthcare Safety Network. Antibiotic use and resistance data are essential to identify and track emerging threats and evaluate the impact of interventions to address antibiotic resistance. As of 2017, 76 percent of hospitals had implemented such programs, an increase from 65 percent in 2016 and 48 percent in 2015. IDSA continues to promote universal adoption of robust, comprehensive stewardship, so that all patients and communities can benefit from improved patient outcomes, reduced rates of resistance and lower health care costs associated with stewardship.

Once again, we thank you for your attention to this vital issue. IDSA encourages the Agency's 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,

A handwritten signature in cursive script that reads "Cynthia Sears".

Cynthia Sears, MD, FIDSA
President, IDSA