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July 10, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1735-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-1735-P: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals Proposed Rule

Dear Administrator Verma,

Thank you for the opportunity to provide comments on the FY2021 Inpatient Prospective Payment System (IPPS) Proposed Rule. We commend you and The Centers for Medicare and Medicaid Services (CMS) for your public support to modernize Medicare payment systems for antibiotics, which is important to bring focus to the failing antibiotics industry and a clear signal of the administration's recognition of its responsibility to address these issues.[1] However, the minor changes to the New Technology Add-On Payments (NTAP) in this proposed rule are disappointingly insufficient to salvage the antibiotics market. Pew recommends that CMS implement the more significant reform articulated in the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act, under which CMS would reimburse eligible inpatient Qualified Infectious Disease Product (QIDP) antibiotics separately from diagnosis-related groups (DRGs) while also requiring antibiotic stewardship and surveillance.

Antibiotics are unique, both in terms of their value to health care as a whole and because of the significant market challenges that antibiotic developers face. New antibiotics face a significant challenge immediately upon entry into the market, as hospitals and doctors purposefully limit their use in order to preserve potency for as long as possible and slow the development of resistance. Further, most patients can be treated with the older, cheaper generic drugs, so the potential market for new, inpatient antibiotics is small. These factors limit sales of antibiotics, hampering a developer's return on investment, and contributing to the broken market for new antibiotics. As a result, most large pharmaceutical companies have exited this space and it is very difficult for the remaining smaller companies to survive. Last year alone, two small biotech companies with five combined branded antibiotics on the market filed for bankruptcy, despite being part of the small group of companies that

[1] Verma, S., "Seema Verma: CMS's 'expanded pathway' for new antibiotics can help fight antimicrobial resistance," *STAT First Opinion*, 6 November, 2019, https://www.statnews.com/2019/11/06/antimicrobial-resistance-cms-expanded-pathway/.

have recently brought new antibiotics through U.S. Food and Drug Administration (FDA) approval. These market failures mean that current and future patients will not have access to the drugs needed to treat their infections. Given these market challenges and the growing public health threat of resistance, CMS should make more significant changes to the IPPS to provide both fair reimbursement and access to lifesaving inpatient antibiotics. Importantly, this can be done without setting precedent for drugs in other therapeutic areas.

Changes to NTAP in the FY2021 IPPS Proposed Rule are redundant

Although we appreciate the targeted improvements to NTAP, which acknowledge that antibiotics are unique and should be reimbursed differently, the antibiotic-related updates to the IPPS in the FY2021 proposed rule are insufficient. The proposed rule adds Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) drugs to the NTAP program at an additional payment amount of 75% and allows for NTAP quarterly effective dates. Inclusion of LPAD drugs will have limited effect on the antibiotic development pipeline, since most (if not all) LPAD drugs will already have QIDP designation, and therefore already be NTAP-eligible. In fact, the only two drugs approved under LPAD since enactment of legislation in 2016, Arikayce and Pretomanid, received QIDP designation in 2014 and 2017, respectively. LPAD and QIDP were similarly and appropriately designed to focus on supporting the development of "antibacterial or antifungal drugs for human use intended to treat serious or life-threatening infections," with LPAD having a slightly narrower focus to address limited populations of patients.[2,3] Therefore, the proposed rule change is unnecessarily redundant and will not improve access to or reimbursement of antibiotics.

NTAP reforms are insufficient to address the broken antibiotic market

Although NTAP may be beneficial for other new and much costlier treatments in other therapeutic areas, for antibiotics the administrative burden of submitting an additional reimbursement request can outweigh the financial benefit, especially for small or rural hospitals. These limitations may hinder NTAP from significantly affecting uptake of new antibiotics, even with an increase in additional reimbursement. As a result, the impact of NTAP on revenues for antibiotic companies is likely minimal and will not prevent further bankruptcies. Though the changes to NTAP and AMR-related severity codes in the FY2020 IPPS final rule were a welcome sign of CMS's awareness of problems with antibiotic reimbursement, Pew and other public health and industry organizations continue to be concerned that the NTAP mechanism is inadequate and insufficient to improve antibiotic patient access and stimulate research and development of critically needed antibiotics.

Antibiotic Reimbursement Reform Recommendation

We recommend that CMS work to implement a separate payment for QIDP antibiotics, carved out from the DRG payment system, as is described in the 2019-introduced DISARM Act. When hospital administrators decide whether to add novel antibiotics to a hospital formulary, or when physicians select the most medically appropriate antibiotic to reduce a patient's stay in the hospital or save their life, considerations of the price

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[2] "Limited Population Pathway for Antibacterial and Antifungal Drugs – the LPAD Pathway," *U.S. Food & Drug Administration*, Accessed 18 June, 2020, https://www.fda.gov/drugs/development-resources/limited-population-pathway-antibacterial-and-antifungal-drugs-lpad-pathway.

[3] "Qualified Infectious Disease Product Designation- Questions and Answers- Guidance for Industry," *U.S. Food & Drug Administration*, January 2018, https://www.fda.gov/media/111091/download.

differences between an older generic and a new, branded antibiotic should be removed from the treatment decision. The current DRG system disincentivizes hospitals and doctors from procuring and using new antibiotics. By removing QIDP-designated antibiotics from the DRG, branded antibiotics would be appropriately reimbursed outside of the bundled payment, hence ensuring patients have access to these life-saving drugs. Additionally, allowing hospitals to make evidence-based decisions rather than being influenced by cost to select the proper drug would reduce antibiotic resistance, improve patient outcomes, and save money.[4] This separate payment approach is an important and immediate step forward to creating a much-needed suite of economic solutions to revitalize a currently insufficient antibiotics pipeline.

It is critically important that any mechanism intended to stimulate antibiotic development also promote appropriate use of antibiotics to limit the development of resistance. Requiring antibiotic use and resistance reporting is a key component of antibiotic stewardship, which is proven to improve patient outcomes, lower health care costs, and reduce inappropriate antibiotic use. Widespread reporting of antibiotic use and antibiotic resistance data is essential to identify and track emerging threats and evaluate the impact of interventions to address antibiotic resistance. In spite of the fundamental importance to effective antibiotic stewardship, participation in the U.S. Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) Antimicrobial Use and Resistance (AUR) Module is currently voluntary. Pew recommends that CMS work with CDC to require AUR reporting through existing regulatory requirements for acute care hospitals and establish funding programs to provide financial support and technical assistance to help facilities report data to NHSN.

Thank you again to CMS for the opportunity to provide input and for your continued dedication to this issue.

Sincerely,

Kathy Talkington
Director, Health Programs
The Pew Charitable Trusts

[4] Barlam, T.F., et. al., "Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America," *Clinical Infectious Diseases*, 15 May 2016, https://doi.org/10.1093/cid/ciw118.