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Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1752-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 2022 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Administrator Brooks-LaSure,

Thank you for the opportunity to provide comments on the FY 2022 Inpatient Prospective Payment System (IPPS) Proposed Rule. We commend The Centers for Medicare and Medicaid Services (CMS) for past efforts to improve the Medicare and Medicaid payment systems for antibiotics, which is important due to the failing antibiotics industry and crucial public health need of these drugs. However, as Pew and other stakeholders have commented in the past, the New Technology Add-on Payment program (NTAP) is insufficient to adequately and sustainably reimburse developers of new antibiotic drugs. 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 hurdles that antibiotic developers face. New antibiotics face a significant challenge immediately upon market entry, as hospitals and doctors appropriately use them only when absolutely needed, to preserve potency for as long as possible and slow the development of resistance. Further, most patients can be treated with older, cheaper generic drugs, so the current 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, with the remaining smaller companies finding it very difficult to survive. In 2019, two small biotech companies with five combined branded antibiotics on the market filed for bankruptcy, despite being part of the group of few companies that have recently brought new antibiotics through U.S. Food and Drug Administration (FDA) approval. The lack of market feasibility for these companies is a significant threat to public health, due to antibiotic resistant infections. These market failures mean that current and future patients will not have access to the drugs needed to treat their infections. Therefore, 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.

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. As a result, the impact of NTAP on revenues for antibiotic companies is likely minimal and will not prevent further bankruptcies or attract other companies to return to the antibiotic development space. Though the changes to NTAP and AMR-related severity codes in the FY 2020 IPPS final rule were a welcome sign of CMS's awareness of problems with antibiotic reimbursement, Pew and other public health and industry organizations remain 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 differences between an older generic and a new, branded antibiotic should be removed from treatment decisions. The current DRG system disincentivizes hospitals and doctors from procuring and using new antibiotics. By removing nearly all new 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.[1] This separate payment approach is an important and immediate step forward to creating a much-needed suite of economic solutions to revitalize an 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 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,

David Hyun
Project Director, Antibiotic Resistance Project
The Pew Charitable Trusts

[1] 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.