August 12, 2016

Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Submitted electronically via regulations.gov

Re: CMS-3295-P: Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care

Thank you for the opportunity to submit comments on the conditions of participation for hospitals and critical access hospitals (CAH) by the Centers for Medicare & Medicaid Services (CMS).

The Pew Charitable Trusts is an independent, non-profit research and public policy organization with a number of initiatives focused on improving the quality of care as well as reducing the inappropriate use of antibiotics in both humans and agricultural animals. These comments will focus on provisions of the proposed regulations to include a new standard that requires hospitals and CAH to develop and maintain an antibiotic stewardship program (ASP).

Thank you for considering our comments. Should you have any questions, please contact Sarah Despres at sdespres@pewtrusts.org or (202) 540-6601.

Sincerely,

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Implementing Antibiotic Stewardship Programs to Improve Antibiotic Use and Slow the Spread of Resistance

Antibiotic overuse is a major public health threat because it contributes to antibiotic resistance. Up to 50 percent of all antibiotics prescribed in the United States are estimated to be inappropriate by indication, agent, or duration of therapy.[1] The Pew Charitable Trusts is an independent, non-profit research and policy organization working to address the growing issue of antibiotic resistance in the United States by advancing policies that will encourage the appropriate stewardship of antibiotics in health care settings, eliminate the overuse of antibiotics in animal agriculture, and spur innovation of new antibiotics.

We support proposed changes to the Centers for Medicare & Medicaid Services (CMS) conditions of participation that would require hospitals, including critical access hospitals (CAH), to develop and maintain an antibiotic stewardship program (ASP) in order to participate in Medicare and Medicaid reimbursement programs. ASPs can be an effective means to improve hospital antibiotic-prescribing practices and curb patient risk for antibiotic resistant infections.

Stewardship programs in hospitals play an integral role in:[2]

- *Optimizing antibiotic use*: Studies suggest that antibiotics are frequently prescribed unnecessarily and inappropriately in inpatient facilities.[3] ASPs help to ensure that antibiotics are used only when necessary and that clinicians select the most effective type, dose, and duration of antibiotics for their patients.
- *Combating antibiotic resistant infections*: Antibiotic-resistant infections are a growing public health threat and are associated with higher morbidity and mortality, as well as increased healthcare costs.[4] By improving antibiotic prescribing, ASPs minimize the risk of drug-resistant infections in hospitals.
- *Reducing antibiotic-related adverse outcomes for patients:* Antibiotics are associated with adverse events such as *Clostridium difficile* infections (CDIs), which result in approximately 15,000 deaths annually in the United States.[5] ASPs can reduce the incidence of CDIs and other side effects associated with antibiotic use.

There is wide consensus from professional societies, public health organizations, and the federal government that hospitals should implement ASPs to reduce inappropriate antibiotic prescribing. The White House National Action Plan for Combatting Antibiotic-Resistant Bacteria outlines a goal of

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[1] Centers for Disease Control and Prevention, "Antibiotic Resistance Threats in the United States, 2013," (Accessed July 7, 2016), http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf.

[2] Timothy H. Dellit et al, "Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship," *Clinical Infectious Diseases* 44, no. 2 (2007):159-77, doi:http://dx.doi.org/ 10.1086/510393; Tamar F. Barlam 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*, doi: 10.1093/cid/ciw118.

[3] Amy Pakyz et al., "Trends in Antibacterial Use in US Academic Health Centers: 2002 to 2006," *Archives of Internal Medicine* 168, no. 20 (2008): 2254–2260, doi:10.1001/archinte.168.20.2254; Scott Fridkin et al., "Vital Signs: Improving Antibiotic Use Among Hospitalized Patients," *Morbidity and Mortality Weekly Report* 63, no. 9 (2014): 194–200.

[4] Centers for Disease Control and Prevention, "Antibiotic Resistance Threats in the United States, 2013," (Accessed July 7, 2016), http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf.

[5] Fernanda C. Lessa et al., "Burden of Clostridium difficile Infection in the United States," *New England Journal of Medicine* 372 (2015): 825–834, http://dx.doi.org/doi: 10.1056/NEJMoa1408913.

implementing ASPs in all hospitals by 2020.[6] The proposed CMS requirement for ASPs in hospitals would significantly advance efforts towards achieving this goal.

Under the proposed conditions of participation for Medicare and Medicaid programs, CMS outlines select components of ASPs that hospitals must implement. These requirements describe the types of leadership structures and goals of stewardship activities that are essential to establishing an effective ASP, and are consistent with national guidelines and expert recommendations. The components are also broadly defined so that hospitals can tailor their stewardship programs to the scope and complexity of the care they provide.

- *Leadership Structure and Responsibilities for ASP*: CMS proposes that hospitals and their governing bodies appoint "an individual who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship" as the leader of the ASP. The program leader will be responsible for the development and implementation of a stewardship program, documentation of all stewardship activities, and communication, collaboration, training, and education of hospital staff and administration. The proposal underscores the importance of designating a single leader who is accountable for the outcomes of a program. The broad scope of the ASP leader's designated responsibilities ensures that hospitals will adopt key elements of a comprehensive stewardship program, as outlined by national guidelines.

  We agree that ASPs should ideally have a leader with expertise in infectious diseases or antibiotic stewardship as described by CMS. We do, however, recommend that when surveying for compliance CMS take into account the inherent resource limitations that exist for small hospitals and CAHs, where personnel with infectious diseases or stewardship expertise may not be readily available. These facilities would benefit from CMS providing further guidance on stewardship training opportunities for existing staff to sufficiently meet the qualifications for ASP leaders. Additionally, small and rural hospitals should be encouraged to supplement a lack of infectious diseases, pharmacy, and stewardship expertise with external sources by collaborating with other hospitals and public health agencies in the region.

  CMS also proposes that hospital governing bodies take an active role in supporting antibiotic stewardship programs by ensuring "systems are in place and operational for the tracking of" antibiotic use activities needed to "demonstrate the implementation, success, and sustainability" of ASPs. Support from hospital leadership is critical to the success of ASPs. A recent study found that leadership support, including written and salary support for an ASP leader, was predictive of having a comprehensive ASP.[7] We encourage CMS to further expand on the current proposals to include richer detail about the types of provisions hospital leadership and governing bodies can provide, such as: written policies for the ASP, dedicating staff time and efforts to stewardship activities, dedicated funding, and technical resources for data collection and analysis. The degree of support provided by hospital leadership should be appropriate for the facility's size,

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[6] Society for Healthcare Epidemiology of America (SHEA), Infectious Diseases Society of America (IDSA), and Pediatric Infectious Diseases Society (PIDS), "Policy Statement on Antimicrobial Stewardship by SHEA, IDSA, and PIDS," *Infection Control and Hospital Epidemiology*, 33 (2012), doi:10.1086/665010; "ASTHO Antimicrobial Resistance and Stewardship Position Statement," last modified 2014, http://www.astho.org/Policy-and-Position-Statements/Position-Statement-on-Antimicrobial-Resistance/; Dellit et al, "Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship," *Clinical Infectious Diseases* (2007), doi:http://dx.doi.org/ 10.1086/510393; The White House, "National Action Plan for Combating Antibiotic-Resistant Bacteria," March 2015, accessed July 6, 2016, https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf.

[7] Loria A. Pollack et al, "Antibiotic Stewardship Programs in U.S. Acute Care Hospitals: Findings from the 2014 National Healthcare Safety Network Annual Hospital Survey," *Clinical Infectious Diseases*, doi:10.1093/cid/ciw323.

complexity of care provided, and the scope of the stewardship program. Including this language in the finalized regulations will not only promote a collaborative culture of stewardship within the facility, but will also help ensure that the ASP leader has adequate resources to implement a meaningful program and meet all of the responsibilities proposed by CMS.

- *Goals of Antibiotic Stewardship Programs*: the proposed provisions would require hospitals and CAH to "demonstrate coordination among all components of the hospital responsible for antibiotic use and resistance…document the evidence-based use of antibiotics…and demonstrate improvements, including sustained improvements, in proper antibiotic use." Tracking antibiotic use and measuring improvements in outcomes are essential elements of a successful ASP. This data-driven approach to stewardship allows the program to identify inappropriate antibiotic prescribing patterns, target stewardship interventions, and assess the effectiveness of the interventions once applied.

  We also support CMS for providing hospitals with a broad array of stewardship components to implement by recommending that ASPs "adhere to nationally recognized guidelines as well as best practices." This will give hospitals the flexibility to adopt stewardship practices that most suit their needs, such as evaluating antibiotic utilization patterns specific to their patient populations. CMS should consider including more detailed language around how they will assess improvements in outcomes when surveying facilities for compliance, as meaningful outcome measures may differ between some hospitals and CAH.

We strongly support the proposed conditions of participation requiring ASPs in hospitals. There is extensive evidence that ASPs are essential to improving antibiotic prescribing and optimizing patient outcomes, and that all inpatient facilities should implement these programs. With these potential changes to existing regulations, CMS has reinforced the importance of ASPs and the critical role they play in reducing the threat of antibiotic resistance.

Thank you for your consideration of our comments in support of the antibiotic stewardship provisions in this proposed rule.