



August 15, 2016

Mr. Andrew Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

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

Dear Mr. Slavitt:

On behalf of the members of AdvaMedDx, we are writing to provide comments on the proposed rule on Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care.

AdvaMedDx represents the world's leading manufacturers of medical diagnostic tests, including those that are front line tools in the fight against antibiotic resistance. Diagnostic manufacturers are developing critical tests to help reduce the threat of antibiotic resistance. Diagnostic tests will be a critical component in any strategy to help reduce the threat of antibiotic resistance. These innovative tests can be used to identify, monitor, track, and prevent resistance and improve the judicious use of antibiotics. Empiric treatments without the benefit of prior identification of a specific pathogen associated with an infection greatly contribute to the spread of resistance. Newer, more accurate tests with faster times to test results are currently becoming available for pathogen identification. Rapid tests to identify drug-resistant organisms enable hospitals to quickly isolate patients in order to minimize the risk of transmitting the drug-resistant organism to other patients. Proper utilization of diagnostic tests enables the appropriate administration of antibiotics, thus reducing potential misuse of antibiotics which is a primary contributor to antibiotic resistance.

AdvaMedDx strongly supports the infection prevention and control and antibiotic stewardship provisions in the Centers for Medicare and Medicaid Services' (CMS') proposed rule. Antibiotic overuse is a major public health threat because it contributes to antibiotic resistance. These provisions will promote better alignment of a hospital's infection control and antibiotic stewardship efforts with nationally recognized guidelines and heighten the role and accountability of a hospital's governing body in program implementation and oversight. These changes also promote a more patient-centered culture of safety focused on infection prevention and control as well as appropriate antibiotic use, while allowing hospitals the flexibility to align their programs with the guidelines best suited to them.

AdvaMedDx provides the following feedback on certain elements of the proposed rule.

**I. Standards for Infection Control and Antibiotic Stewardship Programs; § 482.42(a) and (b)**

In the proposed rule at § 482.42(a) and (b), CMS is proposing the standards for the leadership of Infection Prevention and Control Program (IPCP) and Antibiotic Stewardship Programs (ASP). The leaders of those programs would be appointed by the hospital's governing body based on the recommendations of medical staff leadership, nursing services, and in the case of the Antibiotic Stewardship programs, pharmacy services.

An experienced and informed leadership is critical to the implementation and effectiveness of those programs and is a key factor in increasing compliance with prescribing recommendations. The role of the clinical/laboratory pathologist is essential in educating hospital executive staff, as well as in conducting, guiding and planning for the surveillance, detection and prevention of infectious organisms, reporting of emerging pathogens and tracking of antibiotic use and resistance trends in the hospital and community setting. In addition, the professional qualifications for a clinical/laboratory pathologist, including the education, training, and experience, would be well suited to working with the governing board to designate leaders of the infection prevention and control program and the antibiotic stewardship program respectively.

**Therefore, we recommend that CMS require that a hospital clinical pathologist, if available, or designated pathologist in-charge of hospital laboratories, be part of the process for identifying and contributing to the leadership of the IPCP and ASP.**

**II. Leadership Responsibilities; § 482.42(c)**

In the proposed rule, under § 482.42(c)(1), CMS is proposing requirements that provide greater specificity with respect to the responsibilities of hospital leadership in ensuring the effective functioning of those programs. CMS notes that these changes are necessary to its efforts to promote a hospital-wide culture of quality improvement. In particular, CMS would require that the governing body ensure that systems are in place and are operational for the tracking of all infection surveillance, prevention, and control, as well as antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

**We recommend that a clinical/laboratory pathologist be a contributor in the establishment and oversight of an Infection Control/Antibiotic Stewardship program.** The participation of those professionals would lead to valuable input on the proposed Infection Preventionists'/Infection Control Professionals' Responsibilities and The Antibiotic Stewardship Program Leader's Responsibilities. These include the development and implementation of facility-wide infection/antibiotic surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines; documentation of the surveillance, prevention, and control activities; communicating and collaborating with each other and with the hospital's QAPI program; training and education of hospital personnel and staff, including professional health care and contract staff on the practical applications of infection prevention and control/antibiotic

use guidelines, policies and procedures; and prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.

Finally, requiring the communication and collaboration with a clinical/laboratory pathologist on infection control and antibiotic use issues would provide valuable input on current hospital-available resources involving pathogen-related technologies/tests and, most importantly, on what additional innovations and capabilities are available and may be considered for including in the hospital's technology pool in the future concerning surveillance, prevention, detection, tracking, susceptibility testing and treatment of emerging pathogens. This would provide the governing body with critical information for short and long-term budgetary planning regarding the area of infection prevention and control.

Under § 482.42(c) (Leadership Responsibilities), CMS proposes a new standard that enhances the accountability of hospital leadership for the infection prevention and control and antibiotic stewardship programs as well as delineates the responsibilities for the leaders of the infection prevention and control program and the antibiotic stewardship program respectively. These changes would hopefully result in the implementation of successful programs such as Executive Walk Rounds (EWRs), instituted in the past by Brigham & Women's Hospital in Boston. The goals of these rounds – and others modeled from them – are to ensure that safety is a high priority for senior leadership, increase staff awareness of safety issues, educate staff about patient safety concepts such as non-punitive reporting and obtain information from staff about safety issues. If implemented, it is likely that these practices would expand accountability and involvement at all levels.

### **III. Meeting the Goals of the Antibiotic Stewardship Program; § § 482.42(b)(2)(i), (ii), and (iii)**

The proposed requirements at § 482.42(b) would require the hospital to ensure that the following goals for an antibiotic stewardship program are met: (1) Demonstrate coordination among all components of the hospital responsible for antibiotic use and factors that lead to antimicrobial resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services; (2) document the evidence-based use of antibiotics in all departments and services of the hospital; and (3) demonstrate improvements, including sustained improvements, in proper antibiotic use, such as through reductions in CDI and antibiotic resistance in all departments and services of the hospital. We believe that these components are essential for a robust and effective antibiotic stewardship program.

**In furtherance of meeting the goals of the ASP, AdvaMedDx suggests that CMS consider the recommendations described in The National Quality Forum (NQF) recently released Antibiotic Stewardship in Acute Care: A Practical Playbook.<sup>1</sup> This Playbook was developed by a team of experts and is based on CDC's Core Elements of Hospital Antibiotic Stewardship**

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<sup>1</sup> National Quality Forum. Antibiotic stewardship in acute care: a practical playbook.  
[http://www.qualityforum.org/Publications/2016/05/Antibiotic\\_Stewardship\\_Playbook.aspx](http://www.qualityforum.org/Publications/2016/05/Antibiotic_Stewardship_Playbook.aspx)

Programs and offers practical strategies for implementing high-quality antibiotic stewardship programs in hospitals.

Notably, the Playbook identifies that advanced diagnosis-specific and infection-specific interventions as examples that may be included in the implementation of an ASP to support optimal antibiotic use. Appropriate diagnostic testing for infectious organisms should be a key aspect of any ASP, including the ability to provide surveillance and prevention of pathogen-contaminated areas/items in the hospital facility. Specifically, the Playbook notes the use of real-time, rapid diagnostics such as rapid pathogen identification assays (e.g., influenza and MRSA) and biomarkers (e.g., procalcitonin) to improve antibiotic use. It is important in the clinical evaluation of patients with suspected infections to not only evaluate whether a bacterial pathogen is the key cause, but to also rule out other potential causative pathogens and identify concomitant organisms occurring in the same patient. Thus the rapid identification of specific microorganisms as mentioned in the Playbook, can be applied to proper use of antivirals, antiparasitics, and antifungals, as well as antibiotics. **The consideration of innovations in diagnosis-specific and infection-specific interventions should be noted by CMS in the Final Rule or the associated Interpretive Guidelines to aid hospitals in meeting the goals of the antibiotic stewardship program.**

Lastly, the proposed rule states that infection control and prevention and antibiotic stewardship programs should extend from the acute care setting to non-acute centers of care under the hospital. In the non-acute setting, better provider and patient education about the role of diagnostic tests in antibiotic prescribing is needed to help reduce the unnecessary use of antibiotics. Improved provider and patient education was a focus of the December 2015 meeting held jointly by the CDC and AdvaMedDx. <https://www.cdc.gov/drugresistance/pdf/cdc-advameddx-ar-diagnostic-meeting-summary.pdf>

#### **IV. Provision of Services Proposals: Authorizing Dietitians to Write Therapeutic Diet Orders in Critical Access Hospitals (CAH)**

We support CMS's proposal to expand authorization for dietitians to write therapeutic diet orders in acute care and CAHs. We agree with CMS comments that early identification of Medicare beneficiaries at risk for malnutrition and prompt nutrition intervention for patients diagnosed as malnourished or at risk of malnutrition is critical to help reduce morbidity, mortality, and costs.

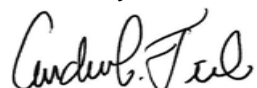
As CMS seeks to improve the health of the U.S. population by supporting proven interventions to deliver higher-quality care, we recommend the Agency consider the following policies in future rulemaking to ensure high quality, timely and coordinated malnutrition care:

- Include nutritional status and a nutrition care plan in this transfer of health information for patients, caregivers and medical providers; and
- Address malnutrition measure gaps in future quality programs across healthcare settings. This can start with the adoption of four new electronic clinical quality

measures recently submitted by the Academy of Nutrition and Dietetics through the 2016 pre-rulemaking process for the Hospital Quality Reporting Program.<sup>2</sup> These new electronic quality measures align with CMS priorities to address clinical variations in care, improve patient outcomes, decrease costs, and reduce burden of data collection for providers.

AdvaMedDx greatly appreciates the opportunity to provide these comments. Please contact me or Steven J. Brotman, M.D., J.D. ([sbrotman@advamed.org](mailto:sbrotman@advamed.org)) if you have additional questions or need any additional information.

Sincerely,



Andrew Fish  
Executive Director

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<sup>2</sup> McCauley, Sharon M., Malnutrition Care: Preparing for the Next Level of Quality, *Journal of the Academy of Nutrition and Dietetics*, Volume 116, Issue 5, 852 – 855; May 2016.