Alliance FOR AGING RESEARCH

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August 15, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

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

Dear Administrator Slavitt:

The Alliance for Aging Research is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging and health. The Alliance believes that advances in research help people live longer, happier, more productive lives and reduce health care costs over the long term. In September of 2014, the Alliance held a policy roundtable to examine the disproportionate impact of healthcare-associated infections (HAIs) on older adults. This roundtable resulted in a number of recommendations to improve the HAI prevention and treatment paradigms targeting this vulnerable population. We applaud the Centers for Medicare and Medicaid Services (CMS) for releasing a proposed rule to update requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. We agree with CMS that many of the planned changes will decrease the incidence of hospital-acquired HAIs, curb inappropriate antibiotic use, and strengthen patient protections. We appreciate the opportunity to comment on this proposed rule.

Every year 1.7 million people acquire HAIs, leading to costs upwards of $20-45 billion[i]. The average length of hospital stays are 19 days longer with HAIs than without them (24.4 days versus 5.2 days)[ii]. The results of a project known as the HAI Prevalence Survey reported that in 2011 there were an estimated 722,000 HAIs in US acute care hospitals**.** Of those infected, about 75,000 patients died during their hospitalizations**.** Sadly, hospitalized elderly patients are 2 to 5 times more likely to develop a HAI than younger patients[iii]. In fact, around 45 percent of all hospital-acquired HAIs in 2007 were in patients age 65 and older [iv].

Although significant progress has been made in preventing some types of infections, infection rates remain alarmingly high—particularly among older adults. Not only are infection rates high, but many of these infections are also resistant to available treatments. For this reason, a National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB) was developed to outline strategies for executing an executive order issued by President Obama on antibiotic resistance

and to address policy recommendations from the President's Council of Advisors on Science and Technology. The CARB Plan includes steps to improve the appropriate use of antibiotics and calls for the establishment of stewardship programs in all acute care hospitals by 2020. The Alliance supports implementation of the CARB Plan and our comments are limited to quality assessment and reporting, antibiotic stewardship requirements, and infection prevention standards in the proposed rule that advance these CARB priorities.

I.) Quality Assessment and Performance Improvement (QAPI) Programs

Infection data can give healthcare facilities information they need to design, implement, and evaluate prevention strategies. According to the Centers for Disease Control and Prevention (CDC), research shows that when healthcare facilities and providers are aware of infection problems and take action to prevent them, rates of HAIs can decrease by more than 70 percent. [v] We believe that the proposed rule makes a modest but important modification to existing hospital Quality Assessment and Performance Improvement (QAPI) programs in § 482.21 that would enable improved data capture on hospital readmissions and hospital-acquired conditions, including HAIs. Hospitals are already collecting data on hospital readmissions and hospital-acquired conditions for other quality reporting and quality performance programs, the proposed change would require them to incorporate this quality indicator data into their QAPI programs.

The original intent of establishing QAPI programs in 2003 was to help distinguish and avoid mistakes in the healthcare system. Requiring that hospital readmission and hospital-acquired condition data be included in QAPI programs allows for this information to be fed back into systems that hospitals have already developed, where all hospital departments and services are focused on improving health outcomes while preventing and reducing medical errors, such as HAIs.

Further the Alliance supports changes in the proposed rule to § 485.641 that requires the establishment of QAPI programs as a condition of participation in Medicare and Medicaid for critical access hospitals. The current periodic evaluation and quality assurance review model utilized by critical access hospitals does not allow for the same level of alignment of services as a QAPI program where opportunities for improvement are proactively identified. As noted by CMS in the proposed rule, the current model utilized by critical access hospitals is "reactive" and only allows for corrective modifications after a problem, like an infection, has been identified.

We urge you to retain these provision for hospitals and critical access hospitals in the final rule.

II.) Medical Record Services

Many older adults suffer from multiple chronic conditions that require hospitalization and frequent transfers between settings of care. These transfers can leave them vulnerable to acquiring HAIs, put them at risk for spreading infections at home or in long-term care facilities, and it also presents challenge to identifying the source of infections. The proposed rule makes several revisions to § 482.24 regarding inpatient and outpatient status that would improve medical record keeping of beneficiary diagnoses by hospitals. The changes go beyond the requirement for hospitals to document an "admitting diagnosis" and includes additional requirements for documentation of all diagnoses specific to each inpatient and outpatient visit.

Under the proposed rule, medical record contents would now be required to contain information on complications, hospital-acquired conditions, HAIs, and adverse reactions to drugs and anesthesia. The rule adds another proposed requirement that beneficiary records must document discharge and transfer summaries with outcomes of all hospitalizations, disposition of cases, and provisions for follow-up care services during all inpatient and outpatient visits. These are all welcome changes that we believe will assist in helping to identify patients who are admitted with, or discharged from, a hospital with a potential HAI and allow for better continuity of care when they are sent home or transferred to post-acute care and long-term care settings.

III.) Infection Prevention and Control Antibiotic Stewardship Programs

We are heartened that CMS is reexamining its twenty-year-old requirement for infection control in hospitals as a condition of participation in Medicare and Medicaid. HAIs remain a significant cause of morbidity and mortality in the US. This is especially true for older adults. It is gratifying that the proposed rule calls specific attention to the threats posed by Clostridium difficile infections (CDIs) in hospitals. A 2015 report from the CDC found that more than 80 percent of Clostridium difficile deaths occurred in people age 65 and older. The same report stated that of 15,000 CDI deaths in one year, 1 in 11 people 65 or older died within a month of their CDI diagnosis[vi]. In our view, CMS is taking important steps at a critical time to require hospitals to broaden infection prevention and control activities for CDI and other HAIs and maintain robust antibiotic stewardship programs.

By revising § 482.42 to reflect a terminology change from "infection control" programs to "infection prevention and control and antibiotic stewardship" programs, we hope that the proposed rule will promote a cultural shift within hospitals where the aim is not simply to control infections, but also to prevent them from occurring in the first place. The new program title further acknowledges the essential role hospitals play in reducing antimicrobial resistance through judicious use of antibiotics. We were pleased to see that CMS plans to go beyond this subtle terminology change by also mandating that hospital "infection prevention and control and antibiotic stewardship" programs are active for hospital-wide surveillance, prevention, and control of HAIs, and demonstrate adherence to nationally recognized guidelines for reducing infections, the development of antibiotic-resistant organisms, and improved antibiotic use. We strongly urge CMS to retain the addition of surveillance practices under § 482.42(c)(2)(ii) which requires hospitals to document surveillance activities that permit the identification and monitoring of infections throughout facilities. CMS should go beyond suggesting the CDC National Healthcare Safety Network (NHSN) as an example of widely-accepted standards for surveillance, and should mandate the use of NHSN for this purpose.

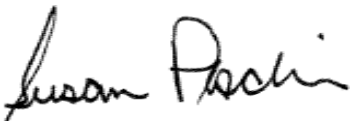
We understand that the proposed language change to § 482.42(a)(2) would refocus the scope of a hospital's "infection prevention and control" program from its current focus on transmission of infections between ''patients and personnel'' to transmission of infection broadly to patients, visitors, and even other healthcare facilities. As stated earlier, we are keenly aware that many older patients frequently move between settings of care. We feel that this change in terminology stresses the importance of hospitals approaching drug-resistant infections in a more holistic way in order to protect their patients, staff, and public health. Given the rise in HAIs, the proposed rule appropriately focuses attention on the sources of infections that need to be addressed by hospitals through "infection prevention and control" programs based on location under § 482.42(a)(3) and type of surgical procedures performed within a facility in § 482.42(a)(4).

Mandating the use of nationally accepted antibiotic stewardship programs across healthcare settings, was a recurring theme during the policy roundtable our organization convened in September of 2014 and within the CARB Plan. We applaud CMS for proposing enhanced standards under § 482.42(b) to require that hospitals have active hospital-wide antibiotic stewardship programs in place that would improve internal coordination among those responsible for antibiotic use and combating antibiotic resistance at the hospital, including "the infection prevention and control" program, the QAPI program, medical staff, nursing services, and pharmacy services. We agree that this type of comprehensive stewardship program is crucial to promoting evidence-based use of antibiotics and reducing their inappropriate use. We recognize the need for flexibility in allowing hospitals to implement stewardship programs that fit their individual circumstances, but we would urge CMS to provide additional guidance on the strengths and weakness between the five sets of stewardship programs suggested in the proposed rule. Our preference would be to emphasize the value of CDC's Core Elements of Hospital Antibiotic Stewardship.

Finally, CMS correctly identified limitations in current infection control requirements at critical access hospitals in the proposed rule. Research cited in the rule highlights deficiencies in knowledge at critical access hospitals that are hindering appropriate antibiotic use; insufficient processes and polies in critical access hospitals that are standing in the way of proactive infection monitoring; and a lack of teamwork among pharmacists and physicians in these settings on antibiotic prescribing. In keeping with our support for the creation of QAPI programs at critical access hospitals, we also support CMS' proposal to have each critical access hospital institute a facility-wide "infection prevention and control and antibiotic stewardship" program under § 485.640.

Thank you for the opportunity to comment on the proposed rule. We greatly appreciate your careful consideration of our views on how the rule can support a reduction in HAIs. If you have any questions or if we can be of assistance to CMS as you finalize this rule, please do not hesitate to contact us. Inquiries can be directed to the Alliance's Public Policy Associate, Ryne Carney, at (202) 293-2856 or by email at rcarney@agingresearch.org.

Sincerely,



Susan Peschin, MHS
President and CEO

Cynthia Bens
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[i] Healthcare-Associated Infections. http://advameddx.org/go.cfm?do=Page.View&pid=14. Last accessed on August 8, 2016.

[ii] Lucado, Jennifer, Kathryn Paez, Roxanne Andrews, and Claudia Steiner. Adult Hospital Stays with Infections Due to Medical Care, 2007. *Statistical Brief*. August 2010; 94. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb94.pdf.

[iii] Haley, Robert W., Hooton, Thomas W., David H. Culver, Richie C. Stanley, T. Grace Emori, C. David Hardison, Dana Quade, Richard H. Shachtman, Dennis R. Schaberg, Babu V. Shah, and Gary D. Schatz. Nosocomial Infections in U.S. Hospitals, 1975-1976. *Am J Med*. 1981; 70(4): 947-59. http://www.amjmed.com/article/0002-9343%2881%2990561-1/abstract.

[iv] Lucado, Jennifer, Kathryn Paez, Roxanne Andrews, and Claudia Steiner. Adult Hospital Stays with Infections Due to Medical Care, 2007. *Statistical Brief*. August 2010; 94. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb94.pdf.

[v] Centers for Disease Control and Prevention. January 2015. National Center for Emerging and Zoonotic Infectious Disease and Division of Healthcare Quality Promotion. Available at: http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html. Last accessed on August 8, 2016.

[vi] Deadly Diarrhea C. Difficile Causes Immense Suffering, Death. Centers for Disease Control and Prevention. Available at: http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_infect.html. February 2015. Last accessed August 10, 2016.