August 15, 2016

Via http://www.regulations.gov

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3295–P
P.O. Box 8010
Baltimore, MD 21244

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

Dear Mr. Slavitt,

The Infectious Diseases Society of America (IDSA) and The Society for Healthcare Epidemiology of America appreciate the opportunity to provide comments in response to the proposed rule, "Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care," within the Medicare and Medicaid programs, commonly referred to as the "Conditions of Participation (CoPs)."

IDSA represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. IDSA members possess clinical expertise in recognition, diagnosis, treatment, and prevention of infectious diseases.

SHEA represents more than 2,000 physicians and other healthcare professionals globally with expertise in healthcare epidemiology, infection prevention and antibiotic stewardship. SHEA is dedicated to advancing the science and practice of healthcare epidemiology and preventing and controlling morbidity, mortality, and the cost of care linked to healthcare-associated infections.

We begin with a sincere appreciation for the thoughtful manner that the agency, in collaboration with the Centers for Disease Control & Prevention (CDC), has engaged the health care provider community on the establishment of antimicrobial stewardship programs (ASPs) as a condition of participation. Our two societies have had an ongoing dialogue with CMS and CDC on this matter for many years and we are pleased to see this proposed rule in the context of our collective efforts.[1] Especially over the past two years, since the Presidential Council of Advisors on Science and Technology issued its Report on Antibiotic Resistance and the subsequent development of the National Action Plan for Combating Antibiotic-Resistant Bacteria, there has been momentum building behind the formal establishment of ASPs across the health care system. Infectious diseases physicians are on the frontlines battling antimicrobial resistance, caring for increasing numbers of patients with serious infections caused by multi-drug resistant organisms and *Clostridium difficile* infections, which are associated with antibiotic use. According to the CDC, at least 2 million people contract infections caused by antibiotic resistant

[1] Infectious Diseases Society of America. "Antimicrobial Stewardship (AS) as a Medicare Condition of Participation (CoP)." Letter to The Centers for Medicare & Medicaid Services, Clinical Standards Group, Center for Clinical Standards & Quality. 4 Mar 2014. Available at http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Advancing_Product_Research_and_Development/Antimicrobials/Letters/AS-IDSA-SHEA-CMS-CoP-Letter%20MAR_2014.pdf#search=%22condition of participation%22

bacteria each year and at least 27,000 die as a result. Patients cannot wait for federal action any longer.[2] As we applaud CMS for issuing the proposed rule, we ask that the agency continue to build momentum towards finalizing this rule during this calendar year. Our two societies stand ready to support CMS to achieve this and we are poised to take action in implementing ASPs, once finalized.

We feel it is important to state the core aspects of our position on antimicrobial stewardship programs, which has evolved through our long history of raising awareness of the threat of antibiotic resistance and our involvement in establishing clinical guidelines and resources for implementing antibiotic stewardship programs. These core aspects are as follows:

- Antibiotic stewardship is a patient safety program, separate and distinct from Infection Prevention, yet complementary. Antibiotic stewardship requires clinical intervention and guidance, often accomplished by direct physician-to-physician dialogue.
- We believe that antibiotic stewardship programs are best led by physicians trained and experienced in the subspecialty of infectious diseases who, as part of their routine training, are skilled in antibiotic stewardship, who hold accountability for effective performance, and who are able to provide clinical knowledge and judgment in peer-to-peer consultations involving the diagnosis of infection and the prescription of antibiotic treatments. Infectious diseases physicians have the requisite clinical training necessary to recognize and correctly diagnose serious infections, to assess the correct antibiotic agent, including dose and duration, to evaluate data from the clinical microbiology laboratory in the patient context to decide on de-escalation of therapy when warranted, and to review the facility-specific antibiogram in order to provide the leadership and decision-making to achieve success in patient populations specific to individual facilities. We suggest that infectious diseases physician leadership in these programs is desirable to drive appropriate clinical use of antibiotic agents and change inappropriate use, where necessary. In particular, we posit that physicians accept suggestions for change of therapy best from colleague physicians, than from non-physician providers.
- Antibiotic stewardship involves a multi-disciplinary team-based approach, also involving infectious disease-trained pharmacists, clinical microbiologists and other providers and leveraging healthcare information technology systems, (i.e. electronic health records).
- Effective antibiotic stewardship programs cover not only the judicious use of antibiotic treatments but also ongoing education and training efforts to other stakeholders involved in care delivery.
- Effective antibiotic stewardship programs should reduce inappropriate antibiotic use at the facility level and contribute to the stated goal of the Combating Antibiotic Resistant Bacteria National Action Plan of a 20% reduction nationwide of inappropriate antibiotic use in inpatient settings by 2020[3].

Below, we offer our comments on specific sections of the proposed rule that pertain to the establishment of ASPs in acute care and critical access hospitals (CAHs).

Antibiotic Stewardship Organization and Policies

Incorporated in the new language at §482.42 is the proposal to require hospitals to have policies and procedures for, and to demonstrate evidence of, an active and hospital-wide antibiotic stewardship program, and to require hospitals to improve their internal coordination of antibiotic use and to reduce the development of antibiotic resistance. **SHEA and IDSA support the proposal to require that hospitals**

[2] Centers for Disease Control and Prevention. Antibiotic Resistance Threats in the United States, 2013. http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf

[3] United States. The White House Office of Assistant Secretary for Health. *National Action Plan for Combating Antibiotic-Resistant Bacteria*. 2015. https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf

designate an individual with education and training in infectious diseases and with the support of the medical staff leadership and pharmacy leadership as the leader of the antimicrobial stewardship program. We also appreciate CMS recognizing that ASPs are led by physicians and pharmacists who have direct knowledge and experience with antibiotic prescribing. As we have stated, we believe infectious diseases physicians, with support from infectious diseases pharmacists, are best suited to lead ASPs due to their clinical training and their interactions with both medical and pharmacy staff within hospitals. Furthermore, we agree with CMS that it is important for the overall success of the hospital that both antibiotic stewardship programs and infection prevention and control programs have their own distinct structure and leadership responsibilities, yet that each works in close collaboration with the other. However, we urge CMS to use caution with the language of the final rule and the Interpretive Guidelines in recognition of cases where the leader of the antibiotic stewardship program and the leader of the infection prevention and control program may be the same clinician. We know from some of our members that they serve as both leader of the antibiotic stewardship program and infection prevention and control program in their hospital. For many facilities, especially CAHs who have access to limited resources, they may deem it most efficient to bestow the leadership responsibility for their antibiotic stewardship program and infection prevention and control program upon the same clinician.

We note with concern the use of the term "hospital-wide" to describe ASP implementation in this proposed rule. **We respectfully request that CMS provide clarification on whether "hospital-wide" refers to all populations in the hospital, including pediatrics, inpatient rehabilitative units, and outpatient populations, and whether the antibiotic stewardship standards outlined in §482.42 would apply to these populations as well.** The term "hospital-wide" could be interpreted to include, but not limited to, inpatient, emergency department, affiliated outpatient center, urgent care center, ambulatory surgery center, rehabilitative units, etc.

In the case of outpatient centers, clinics, and ambulatory surgery centers and similar departments that may be integrated within an inpatient acute care hospital, these departments are typically not included in antibiotic stewardship programs designed for the inpatient acute care setting. However hospitals that include these departments under the same provider number are subject to surveys that would apply the CoPs across the inpatient acute care setting as well as these other departments. These settings represent a completely different patient care delivery structure for which additional resources to implement a successful and effective antibiotic stewardship program would be needed. Furthermore we note that The Joint Commission, which published in June 2016 standards for the implementation of antimicrobial stewardship programs for hospitals, CAHs, and nursing centers, declined to put forward a standard that would cover ambulatory healthcare and office based surgery settings[4]. In comments to The Joint Commission, SHEA recommended The Joint Commission not move forward with a standard at this time, citing a paucity of supporting data and lack of infrastructure to support successful programs[5].

Although we understand that CMS is attempting to provide clarity on the applicability of the Medicare CoPs through its update of the Medical Record Services CoP, we believe there is an opportunity to provide additional clarity on how the antibiotic stewardship program CoP applies "hospital-wide" at the facility level. We therefore respectfully request that CMS clarify whether this standard applies to hospitalized populations versus patients that are discharged to the outpatient setting (e.g. emergency department, urgent care, and clinics affiliated with the hospital). We further recommend that CMS defer application of the standard set forth in §482.42 to a future rulemaking that will take into consideration data and resource needs to support successful programs in these settings.

[4] "Prepublication Standards – New Antimicrobial Stewardship Standard." The Joint Commission, 22 June 2016. Web. 09 Aug. 2016. <https://www.jointcommission.org/prepublication_standards_antimicrobial_stewardship_standard/>.
[5] The Society for Healthcare Epidemiology of America. "Proposed New Standard on Antimicrobial Stewardship." Letter to The Joint Commission. 30 Dec. 2015.

At §482.42(b)(1), CMS states:

> "*(1) An individual, who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body as the leader of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership."*

SHEA and IDSA strongly support the proposed requirement for an antibiotic stewardship leader designation separate from the infection preventionist/infection control professional. The responsibilities for leading each of these programs requires differing levels of knowledge and experience to develop, execute, and hold accountability for success. To ensure an appropriately qualified person is selected to lead these programs, SHEA and IDSA offer the following revision to the language:

> "*(1) A~~n~~ ~~individual~~ healthcare provider, who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body as the leader of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership."*

Although we acknowledge that the language following the term "individual" clearly states CMS' expectations with respect to criteria for leaders' qualifications, we believe the intent can be further articulated by replacing this term with the term "healthcare provider." We believe this revision will ensure that leaders selected to serve in these roles have current medical and clinical expertise and not be an individual whose background is limited to experience in hospital administration roles.

At §482.42(b)(2), CMS states:

> *"(2) An active hospital-wide antibiotic stewardship program must:*
> *(i) Demonstrate coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services.*
> *(ii) Document the evidence-based use of antibiotics in all departments and services of the hospital.*
> *(iii) 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 agree that a successful and active hospital-wide antibiotic stewardship program is one that carries out stewardship best practices, provides hospital leadership stewardship functionality, documents sustained improvements in antibiotic use, antibiotic resistance and CDI rates, and provides appropriate access to resources to support the program. We believe that facilities will be able to demonstrate this ability through documented correspondence between the antibiotic stewardship program, infection prevention and control program, and QAPI entities as well as through facility or system-wide communications (e.g. training, newsletters, medical/nursing/pharmacy leadership directives, etc.) that promote overarching goals of patient safety and quality care. We also recognize the importance of using antibiotics in an evidence-based manner as we promulgate the clinical practice guidelines for many infectious diseases that detail the appropriate use of antibiotics, based on a systematic review of the evidence. **Therefore, we support the language as proposed at §482.42(b)(2)(i) and §482.42(b)(2)(ii).** We believe this requirement would be satisfied by facilities producing written protocols or embedding clinical decision-

support in their EHR systems that require antibiotic use by indication (avoiding "bug drug" mismatch), or that provide guidance when using more than one antibiotic in combination.

With respect to §482.42(b)(2)(iii), **SHEA and IDSA advise against CMS interpreting the proposed regulatory language to suggest that the prevalence of CDI and antibiotic resistance at the facility level can be used as a marker of success for implementing antibiotic stewardship programs.** We do however strongly recommend CMS require facilities to monitor the prevalence of CDI and antibiotic resistance at the facility level. **We further request that CMS clarify that the intent of this provision is to ensure that antibiotic stewardship programs are resourced appropriately by hospital leadership.**

SHEA and IDSA understand the agency's interest in having antibiotic stewardship programs demonstrate measurable improvements and, as we detailed in our March 4, 2014 letter to CMS,[6] we are well aware of the medical literature evidence base that shows how antibiotic stewardship programs are associated with reduction in CDI rates and reduction in resistance. However, there are many external factors that contribute to CDI and antibiotic resistance patterns within a hospital including patient population risk factors, transfer of patients from non-affiliated facilities and outpatient acquired infections. Even with a strong program in place reflecting demonstrated and sustained improvements, antibiotic resistance may or may not be impacted by stewardship interventions in a reliably measurable way. Unlike other metrics commonly used to measure hospital quality performance, antibiotic stewardship is not a type of infection that must be prevented or controlled, but is a standard of best practices that complement infection prevention and control in order to prevent the spread of healthcare-associated infections and antibiotic resistance. Antibiotic resistance should be tracked not as an outcome of antibiotic stewardship program performance, but as a component of infection control and a guide for empiric therapy decision-making and identifying trends requiring modification in institutional treatment guidelines.

SHEA and IDSA are concerned the above proposed regulatory language at §482.42(b)(2)(iii) may raise performance measurement expectations higher than can be delivered, even with sustained improvements above and beyond current efforts. Outcomes measures for CDI and MDROs are currently poorly defined in the literature and lack insufficient information and evidence at this time. Hospitals should conduct their own risk assessments and determine priorities for their own facilities.

SHEA and IDSA offer the following revision to the proposed language at §482.42(b)(2)(iii):

> *"(iii) 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."*

SHEA and IDSA request that CMS address this issue in the forthcoming revision to the Interpretive Guidelines following the finalization of this regulation. We believe this is the best venue for CMS to provide flexible guidance for tracking and measure sustained improvement in antibiotic use. SHEA and IDSA welcome the opportunity to weigh in on the Interpretive Guidelines.

At §482.42(b)(3) and §482.42(b)(4), CMS states:

> *"(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use.*

[6] Infectious Diseases Society of America. "Antimicrobial Stewardship (AS) as a Medicare Condition of Participation (CoP)." Letter to The Centers for Medicare & Medicaid Services, Clinical Standards Group, Center for Clinical Standards & Quality. 4 Mar 2014.

(4) The antibiotic stewardship program reflects the scope and complexity of the hospital services provided."

Having hospital leadership support and accountability is key to success for antibiotic stewardship programs. **Therefore SHEA and IDSA support the language proposed in this section.**

At §482.42(c), CMS states:

> *"(c) Standard: Leadership responsibilities.*
> *(1) The governing body must ensure all of the following:*
> *(i) Systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.*
> *(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with hospital QAPI leadership."*

A successful and active hospital-wide antibiotic stewardship program must be supported by appropriate levels of personnel and have access to robust IT-capability to support surveillance, tracking, reporting and clinical decision support. As of today, lack of access to resources is a well-documented and major barrier to antibiotic stewardship implementation and success.[7][8][9][10] **SHEA and IDSA support the language as proposed at §482.42(c)(1)(i) and §482.42(c)(1)(ii).**

We appreciate the agency's intent to "introduce a catalyst at the leadership level" within facilities in order to enhance the accountability of hospital leadership for the infection prevention and control program and antibiotic stewardship program, and to delineate the responsibilities of the leaders of each respective program. In the rule, CMS suggests that facilities might implement successful programs (e.g. "Executive Walk Arounds") that ensure that safety is a high priority for senior hospital leadership with greater engagement of the facility's staff focused on safety issues. CMS also proposes several requirements of the facility's governing body, such as ensuring systems are in place for "tracking of all infection surveillance, prevention, and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities." Furthermore, CMS has proposed that the governing body ensure that healthcare-associated infection and antibiotic use issues are addressed through collaboration among the leaders of the infection prevention and control program, the antibiotic stewardship program, and the hospital QAPI program. It is clear that CMS, through this proposed rule, intends to elevate matters related to infectious diseases prevention and control as well as antibiotic stewardship to the highest levels of hospital leadership. CMS has also raised awareness of healthcare-associated infections through its Inpatient Quality Reporting (IQR) System, which ties payment penalties to poor performance on facility-level measures such as Central Line Associated Blood Stream Infections (CLABSI) and Catheter Associated Urinary Track Infections (CAUTI). Furthermore, the results of this hospital quality measurement are publicly available via HospitalCompare, of which many hospital leaders are aware.

CMS proposes at §482.42(c)(3):

[7] Doran S, et al. Clin Ther 2013; 35: 758-65
[8] Trivedi KK, et al. Infect Control Hosp Epidemiol 2013; 34: 379-84
[9] Pakyz A, et al. Am J Infection Control 2014; 42:S257-63
[10] Johannsson B, et al. Infect Control Hosp Epidemiol 2011; 32: 367-74

"(3) The leader of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the hospital's infection prevention and control and QAPI programs, on antibiotic use issues.

(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of antibiotic stewardship guidelines, policies, and procedures."

We support the provisions outlined in this section; however we present our concerns about the use of the term "competency-based training and education" at §§482.42(c)(3)(iv) which usually denotes demonstrating certain skills. We feel that implementation of this provision as written may set unrealistic expectations.

We recommend the following revisions at §482.42(c)(3)(iv):

*(iv) ~~Competency-based~~ **T**raining and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of antibiotic stewardship guidelines, policies, and procedures."*

Additionally, we would like to clarify this does not necessarily include documenting all activities related to prospective audit with intervention and feedback. Many antibiotic stewardship programs conduct audits primarily telephonically and not through systematic documentation of recommendations in the medical record. Documentation of recommendations in the medical record may negatively impact the effectiveness of antibiotic stewardship interventions given these notes may be perceived incorrectly as antagonistic by the primary treating team. Furthermore writing unnecessary notes when the recommendation has been acknowledged, accepted and/or implemented is not an effective use of time.

Critical Access Hospitals (CAHs)

We recognize that the proposed changes contained in this rule represent significant operational challenges for many Critical Access Hospitals. Many of the proposed changes related to antibiotic stewardship programs are the same as those that would apply to acute care hospitals. Our comments related to those changes apply to the changes proposed for CAHs. In recognizing that many CAHs have no access to infectious disease physicians, which would prevent the implementation of an ID physician-led antibiotic stewardship program, we would like to describe a model for "tele-stewardship" that is currently employed on a limited basis in some parts of the country. We believe implementation of an ID-physician led, telestewardship program, where telehealth technology is employed to administer antibiotic stewardship programs, will serve as a viable solution to many rural and critical access hospitals (CAHs) in complying with the CoPs. The basic configuration for this model requires secure, data encrypted digital connectivity, where an infectious diseases physician (located remotely) can communicate with the physician and/or pharmacists at the CAH (originating site) on a regular basis as needed by the facility.

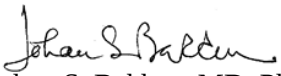
Ideally, antibiotic stewardship programs that are administered via telehealth should allow an ID specialist:

- **Access to the facility antibiogram** – this facility-specific document provides useful information to an ID specialist that will inform the practice of antibiotic stewardship.
- **Access to, and interaction with, the facility pharmacy and therapeutics (P&T) committee** – the P&T committee will make decisions on antibiotic usage that will be pertinent to the ID specialist providing stewardship services. The P&T committee may also benefit from access to the ID specialist.
- **Access and ability to review a patient's medical record** – The EHR will hold pertinent data that will inform antibiotic stewardship recommendations.
- **Access and interaction with personnel** to deliver educational programs in support of the antibiotic stewardship program.
- **Access to patients** when applicable to antibiotic stewardship functions.

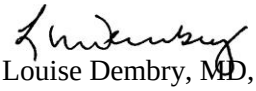
We will look to promote this model to facilities that face challenges in implementing ASPs and ask that CMS consider this model for inclusion in Interpretive Guidelines.

Once again, we commend the agency's efforts to promote innovation, flexibility, and improvement in patient care and safety in this proposed rule. More specifically, we welcome the proposed changes that will establish ASPs in acute care hospitals and CAHs and we urge CMS to carefully consider all comments and move to finalize these proposals. Our societies stand ready to engage CMS and other stakeholders in order to maintain the momentum towards establishing ASPs across our health care system and assist the agency with updating the Interpretive Guidelines. Please feel free to contact Andrés Rodríguez (arodriguez@idsociety.org or 703-299-5146) IDSA's Director of Practice & Payment Policy or Lynne Batshon (lbatshon@shea-online.org or 703-684-0761), SHEA's Director of Policy & Practice.

Sincerely,



Johan S. Bakken, MD, PhD, FIDSA
President, IDSA



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