



Board of Trustees 2016

President

*Louise Demby, MD, MS, MBA, FSHEA
VA Connecticut Healthcare System*

President Elect

*Sana Cosgrove, MD, MS, FSHEA
Johns Hopkins University School of Medicine*

Vice President

*Keith Kaye, MD, MPH, FSHEA
Wayne State University*

Secretary

*Kurt Stevenson, MD, MPH, FSHEA
The Ohio State University, Wexner Medical Center*

Treasurer

*Eli Perencevich, MD, MS, FSHEA
University of Iowa Carver College of Medicine*

Past President

*Anthony Harris, MD, MPH, FSHEA
University of Maryland School of Medicine*

Councilors

*Deverick Anderson, MD, MPH, FSHEA
Duke University School of Medicine*

*Hilary Babcock, MD, MPH
Washington University School of Medicine*

*Mary Hayden, MD, FSHEA
Rush University Medical Center*

*Silvia Munoz-Price, MD, PhD
Institute for Health and Society/Department of Medicine
Froedtert and the Medical College of Wisconsin*

International Councilor

*Hanan Balkhy, MD, FAAP, MMed
King Abdulaziz Medical City
Saudi Arabia*

Pediatric Infectious Diseases Society Liaison

*Judy Guzman-Cottrill, DO
Oregon Health & Science University*

Community-Based Healthcare Epidemiologist Liaison

*Walter Hellinger, MD, FSHEA
Mayo Clinic Florida*

Executive Director

Eve Humphreys, MBA, CAE

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

Dear Mr. Slavitt,

The Society for Healthcare Epidemiology of America (SHEA) appreciates 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).”

SHEA represents more than 2,000 physicians and other healthcare professionals globally with expertise in antibiotic stewardship, healthcare epidemiology, and infection prevention. 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 and antibiotic misuse.

SHEA respectfully submits comments on the following sections of the proposed rule:

- Quality Assessment and Performance Improvement
- Medical Record Services
- Infection Prevention and Control Programs
- Antibiotic Stewardship Organization and Policies
- Critical Access Hospitals

SHEA thanks CMS for soliciting public comment on the hospital and CAH CoPs. For future inquiries on this submission, please contact Lynne Batshon

at 703-684-0761 or ibatshon@shea-online.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Louise Dembry". The signature is written in a cursive style with a large initial "L".

Louise Dembry, MD, MS, MBA, FSHEA
President, SHEA

Introduction

SHEA applauds CMS' introduction of this proposal to revise the Medicare CoPs for Hospitals and Critical Access Hospitals (CAHs) in an effort to improve the safety of healthcare delivery to patients in these settings. These proposed revisions will bring the CoPs into alignment with advances made in patient safety best practices, and respond to the call to action in the National Action Plan to Prevent Health Care-Associated Infections Road Map to Elimination¹. Most notably, we are pleased to see the proposed addition of an antibiotic stewardship requirement to the Infection Prevention and Control CoP. Antibiotic resistance is one of the most urgent threats to global health we face today. Antibiotic resistance contributes to the rapid spread of multi-drug resistant organisms (MDROs) for which few treatments are available. According to the Centers for Disease Control and Prevention (CDC), at least 2 million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of these infections². The dramatic drop in the development and approval of new antibacterial agents complicates this global health problem and portends a future in which many more infections have no effective treatment option.

Since 2007 when CMS published a comprehensive update of its Interpretive Guidelines for the hospital Infection Prevention and Control CoP, significant progress has been made to reduce healthcare-associated infections across the healthcare continuum, specifically in acute care hospitals. Although the most recent data reported in the CDC HAI Progress Report reflects reductions in healthcare-associated infections, it also shows the need for continued efforts toward improvement in reducing some infections and in some targeted populations. In the HAI Progress Report, CDC reports that every day in a US hospital approximately one in 25 patients has at least one infection contracted during the course of their hospital care³. This number remains unacceptably high. Sustained elimination of healthcare-associated infections requires the continued facility-wide implementation of evidence-based practices, the alignment of financial incentives, the closing of knowledge gaps, and the acquisition of information to assess progress to enable response to emerging threats⁴. CDC also reports research illustrating that when healthcare facilities, care teams, and individual doctors and nurses are aware of infection problems and take specific steps to prevent them, rates of some targeted healthcare-associated infections can decrease by more than 70 percent⁵. Federal regulations requiring infection prevention and control programs as a condition of participation in the Medicare program are a critical component for driving the progress made in preventing the prevalence and transmission of healthcare-associated infections in hospitals settings.

¹U.S. Department of Health and Human Services (HHS). Office of Disease Prevention and Health Promotion. National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination. April 2013.

²"Antibiotic/Antimicrobial Resistance." Centers for Disease Control and Prevention. 14 July 2016. Web. 11 Aug. 2016. <<http://www.cdc.gov/drugresistance/index.html>>.

³"Healthcare-associated Infections (HAI) Progress Report." Centers for Disease Control and Prevention. 03 Mar. 2016. Web. 11 Aug. 2016. <<http://www.cdc.gov/hai/surveillance/progress-report/index.html>>.

⁴ Ibid.

⁵ Ibid.

Many of these healthcare-associated infections are tied to inappropriate or overuse of antibiotics, stressing the importance of both infection prevention and antibiotic stewardship programs complementing each other for sustainable improved standards of care. Antibiotic stewardship programs optimize antibiotic use to achieve the best clinical outcomes while minimizing adverse events and limiting selective pressures that drive the emergence of resistance and may also reduce excessive costs attributable to suboptimal antibiotic use. Antibiotic stewardship must be a fiduciary responsibility for all healthcare institutions across the continuum of care.⁶ Incorporating antibiotic stewardship programs in the hospital CoPs must be done now in order to reach our goal of a 20% reduction nationwide of inappropriate antibiotic use in inpatient settings by 2020, as set forth in the Combating Antibiotic Resistant Bacteria National Action Plan.⁷

Updating the hospital CoPs is a continuation of our sustained efforts to advance the cause of eliminating healthcare-association infections and combatting antibiotic resistance. It is of utmost importance given the threat posed to patient safety today and in the immediate future. Therefore, it is imperative that CMS make every effort to finalize this rule by the end of 2016.

Quality Assessment and Performance Improvement

CMS is proposing to revise the “Quality Assessment and Performance Improvement (QAPI) CoP, published in a final rule in the *Federal Register* January 24, 2003 (68 FR 3435). The QAPI rule establishes the minimum requirements for hospitals in evaluating the quality of services delivered and requirements for implementing quality improvement projects. **SHEA supports CMS’s recommendations to update this section of the QAPI CoPs in recognition of currently available electronic health records technology, and in keeping with the expectations of hospitals to continue to incorporate electronic health records technology as a standard of practice.**

Specifically, CMS is proposing to require that the hospital QAPI program incorporate quality indicator data including patient care data submitted to or received from quality reporting and quality performance programs, including but not limited to data related to hospital readmissions and hospital-acquired conditions.

§482.21 (b)(1) is amended as follows:

⁶ Neil Fishman (2012). Policy Statement on Antimicrobial Stewardship by the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA), and the Pediatric Infectious Diseases Society

(PIDS). *Infection Control & Hospital Epidemiology*, 33, pp 322-327 doi:10.1086/665010

⁷ 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_antibiotic-resistant_bacteria.pdf>

“The program must incorporate quality indicator data including patient care data, and other relevant data such as data submitted to or received from Medicare quality reporting and quality performance programs, including but not limited to data related to hospital readmissions and hospital acquired conditions.”

SHEA agrees that data captured from national quality reporting and quality performance programs should be incorporated in and inform hospitals’ QAPI programs. This should be done in order to improve the validity of national quality reporting and performance measures by examining them from different perspectives, and with an expectation of awareness, and avoidance of, supporting improvement in one area that creates unintended consequences that reduce quality in another. For example, improvements in length of stay could result from sending patients home sooner from acute care hospitals, but could actually increase costs overall if patients require lengthy/costly rehab stays, or if early discharge results in increased readmissions. Data sharing among these programs would allow hospital leaders and key quality improvement contributors at all levels to see all information within the QAPI plan and allow organizations to develop and pursue more optimal plans of action to improve quality of care. This type of data sharing will also facilitate a healthy internal dialogue to streamline identification of the most appropriate quality metrics to the necessary minimum.

However, clinical care databases and quality improvement programs should avoid creating redundancies in data collection to serve different purposes. Data sharing across programs will allow CMS opportunities for examining metrics that are put to multiple uses across the many CMS programs for financial incentives and penalties for hospitals. **We strongly encourage CMS consider use of any quality metric only once for any CMS programs used to determine financial incentives and penalties for hospitals, and review such opportunities in future rulemaking.**

CMS is also encouraging hospitals to use certified health IT systems, including systems to exchange health information to enable real time electronic exchange with other providers, in order to improve patient safety and quality of care. This recommendation is aligned with similar recommendations emphasizing improvements in transparency of medical records (e.g., open notes, documenting adherence to bundles of care, reviewing medical errors, etc.). This supports exchanging information about how providers make decisions and what providers are doing to improve the quality of care for patients. Allowing EHRs to become an avenue for documentation is key.

However limitations remain with the ability for hospitals to adopt EHR systems that can be used for optimal health information exchange among providers locally. In order to meet the expectations of the proposed CoPs, **CMS should strongly encourage EHR vendors to foster collaboration in developing integrated IT solutions** in order to deliver systems capability and support for electronic medical record data capture and exchange between providers and facilities, as well as data-mining and analysis of EHR data for quality improvement activities and reporting. EHR enhancements for quality should be market-driven as hospitals and providers require them and will seek this from

their vendors. Additionally of note is the need for this data exchange to be protected under the Quality and Safety code. EHRs have not been used in the past for this purpose because of the discoverable nature of the medical records.

Medical Record Services

CMS is proposing to revise the “Medical Record Services” CoP in an effort to ensure the requirements for medical record documentation contained in these provisions are clearer regarding the distinctions between inpatient and outpatient status.

On page 39453 in the preamble of the proposed rule at §482.24 “Medical Record Services,” CMS states:

“The Medicare hospital CoPs apply to services being provided to all patients, regardless of insurer, and to both inpatients and outpatients of a hospital.”

Additionally throughout the proposed rule and at §482.42 in the regulatory language, CMS uses the term “hospital-wide” to describe expectations for implementing a variety of proposed CoPs, particularly the new proposed requirements for antibiotic stewardship programs. **SHEA respectfully requests CMS provide clarification on whether “hospital-wide” refers to all populations in the hospital, including pediatrics, inpatient rehabilitative units, and outpatient settings.** Specifically, we ask that CMS provide clarification on whether the antibiotic stewardship standards outlined in §482.42 would apply to these populations. SHEA, in partnership with the Infectious Diseases Society of America (IDSA), elaborates further on these concerns in a separate letter filed jointly to the CMS docket. 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 guidance in other sections of the CoPs.

CMS is proposing to revise the current regulatory language at §482.24(c) to require that the content of the medical record contain information to justify all admissions and continued hospitalizations, support the diagnoses, describe the patient’s progress and responses to medications and services, and document all inpatient stays and outpatient visits to reflect all services provided to the patient. **SHEA supports CMS’ desire to make changes to the provisions in this section so that the requirements are clearer regarding inpatient and outpatient status and improvements to medical record documentation related to each status.** We offer the following remarks on excerpts of these proposed changes below.

At §482.24(c)(4)(ii), CMS proposes the following language:

“(4)(ii) All diagnoses specific to each inpatient stay and outpatient visit.”

Coding of comorbid and complicating conditions could one day be an important contributor to developing a more specific and reliable tool for risk stratification both for standardized infection ratio and antibiotic use reporting. **SHEA supports this language.**

At §482.24(c)(4)(iv), CMS proposes the following language:

“(iv) Documentation of complications, hospital-acquired conditions, healthcare-associated infections, and adverse reactions to drugs and anesthesia.”

The intent of this provision seems to potentially put undue emphasis on documenting that a condition is "hospital-acquired", as opposed to simply stating that a condition is "present". We seek clarification on the type of documentation requirement e.g., is documentation that the patient has a surgical wound infection, or a catheter-related bloodstream infection adequate, or is CMS requiring an additional explicit statement that the above infection is hospital-acquired? This is important, as the clinical definitions used for healthcare-associated infection documentation are frequently different from standard definitions used for healthcare-associated infection surveillance by infection prevention and control programs. Therefore we are seeking clarification on the intended use of such documentation for healthcare-associated infections, as the best course still remains to capture these conditions using standard healthcare-associated infection surveillance, which does not rely on provider documentation for hospital-acquired or healthcare-associated conditions.

At §482.24(c)(4)(vi), CMS proposes the following language:

“(vi) All practitioners’ progress notes and orders, nursing notes, reports of treatment, interventions, responses to interventions, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient’s condition and to reflect all services provided to the patient.”

Hospitals need adequate resources and support to make documentation reasonable for providers, and to avoid unnecessary duplication and burden of documentation. EHR vendors need to assist with this. The needs of clinical care from the EHR compared to the needs of surveillance and quality improvement efforts can be vastly different, and EHR vendors need to work with both clinical, quality, and infection prevention departments to balance these needs. We also take this opportunity to highlight the fact that ensuring the medical record is comprehensive (e.g. must contain all practitioners' progress notes and orders, reports of treatment, interventions, responses to interventions) requires significant time by providers, particularly physicians whose services are cognitive-focused such as those in infectious diseases. Often, the time documenting detailed progress notes that reflect the complex medical decision-making involved in the synthesis of relevant,

disparate information (imaging/lab results, vital signs, patient/family history, etc.) occurs outside the face-to-face encounter with the patient. The critical work goes unrecognized under the current electronic medical coding set. We ask CMS, as it promotes more comprehensive and accurate medical record keeping, to be aware of this issue. Furthermore, our hope is that the result of the agency's proposal, should it be finalized as such, will lead to better quality of the information contained in the medical record and not an increase in redundant information.

At §482.24(c)(4)(vii), CMS proposes the following language:

“(vii) Discharge and transfer summaries with outcomes of all hospitalizations, disposition of cases, and provisions for follow-up care for all inpatient and outpatient visits to reflect the scope of all services received by the patient.”

SHEA agrees that documentation of outcomes, disposition of cases, and provisions for follow-up care in the medical record and discharge summaries is an important element that is often missed and could help facilitate the exchange of healthcare-associated infection information and enhance communication of multi-drug resistant organism (MDRO) status with post-acute care facilities. There is an opportunity to include information regarding exposure to antibiotics, adverse reactions to antibiotics, and relevant microbiology results. This is important because infectious diseases and antibiotic use hold special public health and infection control imperatives and accommodating the inclusion of this information could be helpful. While these opportunities are important, we caution that additional documentation requirements should not move providers away from time spent caring for patients in favor of focus on including documentation in the EHR.

Infection Prevention and Control Programs

CMS is proposing to revise the “Infection Prevention and Control” CoP published in a 1986 final rule (51 FR 22010, 22027), and updated May 2012 (77 FR 29034) to provide further clarity on existing requirements, and to reflect current best practices and state-of-the-art technology for infection prevention and control. **SHEA applauds CMS for making reduction of healthcare-associated infections and antibiotic resistance a priority for improving healthcare quality through the proposed updates to the Infection Control regulations.** We concur with CMS and HHS in that current patient morbidity and mortality rates due to healthcare-associated infections coupled with the growing prevalence of MDROs in the healthcare setting is a major cause for concern. Since the introduction of the Infection Control CoP, a wealth of scientific data have been published and translated into new standards and best practices. Hospital epidemiologists and infection prevention/control medical directors, many of whom are SHEA members, have been major contributors to the research and translation that supports these nationally recognized best practices and standards. We strongly agree the time has come to adopt

these widely recognized practices as a regulatory standard and strongly agree that these standards should be required as a condition of participation in the Medicare program. We are pleased CMS has included in its background information citations to guidelines, guidance, and other literature published by SHEA. We agree that CMS approach the revision of these CoPs with an eye on allowing hospitals flexibility in identifying and adopting guidelines best suited to the needs of their infrastructure and patient populations.

SHEA offers the following comments on selected provisions contained in § 482.42:

“§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

The hospital must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as best practices for improving antibiotic use, where applicable, for reducing the development and transmission of HAIs and antibiotic resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.”

CMS is proposing a change to the title of the “Infection Control” section to “Infection prevention and control and antibiotic stewardship programs” in order to promote cultural changes in hospitals and to emphasize the important role that a hospital should play in combatting antibiotic resistance. CMS is also proposing a change in the introductory paragraph to require that a hospital’s infection prevention and control and antibiotic stewardship programs be active and hospital-wide for the surveillance, prevention, and control of healthcare-associated infections and other infectious diseases, and for the optimization of antibiotic use through stewardship. Finally, CMS is proposing that a program demonstrate adherence to nationally recognized infection prevention and control guidelines for reducing the transmission of infections, as well as best practices for improving antibiotic use, for reducing the development and transmission of healthcare-associated infections and antibiotic-resistant organisms.

SHEA strongly agrees with the goals and objectives of this section of the CoPs and we support their adoption. We also strongly support the inclusion of “antimicrobial stewardship” in the title, and the requirement that an antibiotic stewardship program adhere to nationally recognized guidelines. In adopting these changes, we recommend emphasizing the need for having an infrastructure for hospital-wide implementation of basic infection prevention (e.g., hand hygiene, standard precautions, personal protective equipment use) rather than comprehensive surveillance and implementation of prevention efforts for all healthcare-associated infections at every hospital. Each hospital program

must still perform an appropriate risk assessment to guide allocation of limited resources to specific surveillance and implementation efforts.

CMS is also proposing to introduce the term “surveillance” into the text of the regulation. **We recommend CMS clarify in the preamble of the final rule that the definition of this term also includes dissemination of data throughout the organization.**

Relationships between infection prevention and control programs, and QAPI programs vary from hospital to hospital. **Although SHEA agrees that QAPI programs must incorporate infection control expertise, we ask that CMS not require formal “collaboration” between infection prevention and control programs and QAPI programs by including this term in the text of the regulation.** Individual hospitals should have the flexibility to determine where collaboration should occur to implement specific activities. And SHEA agrees that the infection prevention and control programs may collaborate with the QAPI program when it is appropriate within a hospital’s organization. However it is important to emphasize that infection preventionists/infection control professionals, hospital epidemiologist, and medical directors of infection prevention are the subject matter and implementation experts in this area. If additional resources are needed for implementation of specific interventions, the resources should be directed to infection prevention and control programs rather than to QAPI programs.

We offer the following proposed revisions to this paragraph:

*“The hospital must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as best practices for improving antibiotic use, where applicable, for reducing the development and transmission of HAIs and antibiotic-resistant organisms. ~~Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.~~ **Hospital-wide quality assessment and performance improvement (QAPI) programs should seek the expertise of experts in infection prevention and control as well as antibiotic stewardship in assessing needs and implementing quality improvement interventions.**”*

CMS states at §482.42(a)(1):

“(a) Standard: Infection prevention and control program organization and policies. The hospital must ensure all of the following:
(1) An individual (or individuals), who are qualified through education, training, experience, or certification in infection prevention and control, are appointed by the governing body as the infection preventionist(s)/infection control professional(s) responsible for the infection

prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership.”

SHEA agrees with CMS’ proposal to delete the outdated term, “infection control officer,” and replace it with the term “infection preventionist(s)/infection control professional(s)” consistent with the terminology and definition established by the CDC. We also agree on the need to ensure that the individuals be qualified through education, training, experience, or certification.

CMS states at §482.42(a)(2), §482.42(a)(3), and §482.42(a)(4):

“(2) The hospital infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings.

(3) The infection prevention and control program includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and addresses any infection control issues identified by public health authorities.

(4) The infection prevention and control program reflects the scope and complexity of the hospital services provided.”

SHEA supports the inclusion of this language and emphasize necessity for communication regarding MDRO status throughout care transitions (e.g., inpatient, nursing facility, ambulatory centers, dialysis centers, etc.) to prevent transmission of infections. However we are seeking further clarification in the preamble of the final rule on the intent of the phrase “any infection control issues identified by public health authorities.” It is unclear whether the scope of this phrase extends beyond healthcare-associated infection public health initiatives to emerging community-based infections, such as Zika virus infections, which have minimal impact on hospitals. **SHEA recommends that any public health authority initiatives be aligned with and accommodating of a hospital’s risk assessment and priorities.** Historically public health departments are more involved with hospitals in healthcare-associated infection initiatives at the facility level and any non-urgent initiatives that are considered important by public health should be evaluated in the context of all other initiatives at a particular hospital. SHEA also agrees that in order to implement a successful and sustainable infection prevention and control program, hospitals must have the flexibility to develop programs that reflect the scope and complexity of the needs of their infrastructure and the services provided.

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 is a strong advocate of requiring all healthcare facilities across the continuum to adopt antibiotic stewardship programs.** In pursuit of this goal, SHEA has established important partnerships with many other stakeholders. For this specific proposal contained in this section of the CoPs, SHEA has partnered with IDSA to file joint comments on the antibiotic stewardship program provisions which can be found in a separate letter submitted to the docket. This joint statement also includes commentary on CAHs.

Conclusion

The revision of the infection prevention and control CoPs is an important step in reaching our goals for improving the quality of healthcare delivery in hospitals across the country. SHEA appreciates CMS' leadership in pursuing our national quality improvement goals and we look forward to reviewing the final rule.