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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:

On behalf of the Infectious Diseases Society of America (IDSAs), I thank you for the opportunity to comment on the proposed regulations relating to Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care. IDSAs 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. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, serious health care acquired infections, antibiotic resistant bacterial infections as well as emerging infections such as Middle East Respiratory Syndrome coronavirus (MERS-CoV), Ebola virus disease and Zika virus disease. Our members have undergone extensive training and board certification in both the specialty of Internal Medicine and the subspecialty of Infectious Diseases, and have the specific training, experience, and clinical expertise in recognition, diagnosis and treatment of serious infections that make them the ideal individuals to oversee the many facets of infection prevention programs and antimicrobial stewardship programs that increase quality of care and improve health-care outcomes while reducing unnecessary health care costs. This proposed rule seeks to promote innovation, flexibility, and improve patient care specifically through changes to the Conditions of Participation (CoP) pertaining to the infection prevention programs in hospitals and CAHs as well as by establishing formal antimicrobial stewardship programs in these settings. IDSAs strongly supports these objectives and urges CMS to finalize this rule by the end of the calendar year. We welcome the opportunity to provide input on these proposals.

Infectious Diseases Physician Leadership – A Critical Component for Success

We recognize the ongoing discussion on the need for physician leadership to evolve the health care delivery system to one that is truly patient-centered and value-based with appropriate quality measurement.^{1,2} As physicians lead multidisciplinary teams of health care providers in providing care to patients, their leadership is also essential to the organizational and programmatic changes needed to advance the quality of care and improve resources utilization. IDSA has a history of promoting infectious diseases physician leadership for Infection Prevention & Control Programs (IPCP) and Antimicrobial Stewardship Programs (ASP), as we believe physicians who are most familiar with the diagnosis and treatment of infections are best suited to lead the broad efforts of these activities and ensure that these programs deliver optimal results for patients and public health. We have proposed this to CMS in our comments to the last Hospital and CAH CoP proposed rule pertaining to IPCPs back in 2011.³ As well, we have promoted ID-physician leadership of IPCP in our comments on the CoP rules pertaining to IPCPs for Home Health Agencies.⁴ In response to this latest proposed rule from CMS, we reiterate our rationale for ID physician leadership of IPCPs and ASPs, suggesting that this is a critical component to success in making real progress to address the spread of health care associated infections, the threat of new and emerging diseases such as Ebola and Zika virus disease, and the crisis of antimicrobial resistance.

Infection Prevention & Control Program Organization and Policies

CMS proposes substantive changes to the Conditions of Participation related to hospital Infection Prevention & Control Programs (IPCP). For example, the agency has proposed a requirement that hospitals demonstrate adherence to nationally recognized infection prevention and control guidelines for reducing the development and transmission of HAIs and antibiotic-resistant organisms. As well, the agency has proposed introducing the term “surveillance” into the text of the regulation as well as replacing the term “infection control officer” with “infection preventionist/infection control professional.” The agency seeks to adjust the scope of the IPCP by proposing a focus on “transmission of infection.” Finally, CMS has included language in this proposed rule that indicates its intent to elevate the importance of preventing HAIs to hospital leadership and governing bodies, by specifying points of accountability for the governing body, calling for the involvement of medical staff leadership, and coordination with a facility’s Quality Assurance Performance Improvement (QAPI) programs.

¹ Jarousse LA. (2015) “Developing Physician Leaders.” Hosp & Health Networks. April 14, 2015. Available at <http://www.hhnmag.com/articles/2974-hospitals-find-health-it-help-in-their-own-backyards>

² Angood p, Birk S. “The Value of Physician Leadership.” PEJ. May:June 2014. Available at <http://csms.org/wp-content/uploads/2015/04/The-Value-of-Physician-Leadership.pdf>

³ IDSA Comments on Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation, Proposed Rule, [CMS-3244-P]. Available at [http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Access_to_Quality_Healthcare/Comments/COP%20Proposed%20Rule_Final.pdf#search=%22infection control condition of participation%22](http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Access_to_Quality_Healthcare/Comments/COP%20Proposed%20Rule_Final.pdf#search=%22infection%20control%20condition%20of%20participation%22)

⁴ IDSA Comments on Comments on Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies [CMS-3819-P]. Available at [http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Access_and_Reimbursement/2014/IDSA_HH_CoP_FINAL.pdf#search=%22infection control condition of participation%22](http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Access_and_Reimbursement/2014/IDSA_HH_CoP_FINAL.pdf#search=%22infection%20control%20condition%20of%20participation%22)

IDSA Comments – Changes to Infection Prevention & Control Condition of Participation

IDSA is supportive of the agency’s proposal to require hospitals to demonstrate adherence to nationally recognized infection prevention and control guidelines and that hospitals be encouraged to adapt appropriate best practices for reducing HAIs and MDROs. We appreciate the mention of the guidance that IDSA and SHEA promulgate related to infection prevention & control and we agree with CMS that allowing hospitals the flexibility in choosing which guideline to follow will facilitate adaptation and integration.

IDSA appreciates the agency’s efforts to revise the Condition of Participation with updated terms that reflect current jargon, such as “infection preventionist/infection control professional.” We respectfully suggest that, along with adopting current terms, CMS also recognize current practice of IPCP in many hospitals under the leadership of infectious diseases physicians, typically holding the title of “Medical Director – Infection Prevention & Control” or a similar title. The CDC definition for “infection control professional,” which appears in the Interpretive Guidelines for the Medicare Conditions of Participation and which is referred to in the rule, does not specify one whose primary training is in medicine, commensurate with that of a physician. It is helpful that CMS has proposed that appropriately designated infection control professionals be qualified “through education, training, experience, certification, or through specialty boards in adult or pediatric infectious diseases.” IDSA believes that the language in the Condition of Participation as well as the language in the Interpretive Guidelines should accurately recognize infectious diseases physicians as infection control professionals by virtue of their professional training. Under the leadership of infectious diseases physicians, IPCP teams focus on the promotion of health care worker vaccinations, hand hygiene, contact isolation, and environmental cleaning across health care settings. In the event of outbreaks, these teams respond rapidly to identify the source and ensure procedural compliance to prevent transmission of communicable disease to patients and health care workers. It is our position that the leadership required to engage the medical staff of a facility and, when necessary, to liaise with outside public health entities, rests with the infectious diseases physician. **Therefore, we ask CMS to include language in the final rule and in the Interpretative Guidelines that recognizes infectious diseases physicians when defining the newly proposed term of “Infection control professional.”**

Furthermore, IDSA supports the agency’s proposal to require hospitals to seek out and consider the recommendations of medical staff leadership when appointing infection control professionals. We believe that the medical staff leadership will recognize that infection prevention and control programs, like antimicrobial stewardship programs, depend on aligning physician behavior to meet critical objectives in HAI reduction and prevention. Ideally, with an infectious diseases physician designated as the infection control professional leading the IPCP, we believe that effective physician-to-physician peer interactions are critical to enabling the success of IP&C programs and achieving a hospital-wide culture of safety and quality.

IDSA supports the agency’s efforts to adjust the scope of a hospital’s IPCP to one that focuses on “transmission of infection.” This aligns well with the clinical practice of infectious diseases physicians who tend to the individual patient’s needs but also then assess the potential for transmission from patient to the broader population, through care transitions across the health care system. As well, infectious diseases physicians who lead IPCPs often interact with local public health authorities to coordinate appropriate measures and other planning with a focus on preventing the transmission of infection.

The Infection Preventionist/Infection Control Professional Responsibilities

CMS proposes to add a requirement that would make the infection preventionist/infection control professional(s) responsible for the following within a hospital:

- Development and implementation of hospital-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.
- All documentation, written or electronic, of the prevention and control program, and its surveillance, prevention, and control activities, specifying that the word “documentation” would “encompass both collecting and maintaining pertinent information in a systematic fashion.”
- Communicate and collaborate with the hospital’s QAPI program on all infection prevention and control issues as well as communicate and collaborate with the antimicrobial stewardship program
- Take a direct role in the 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 infection prevention and control guidelines, policies, and procedures.
- Preventing and controlling HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.

IDSA appreciates the agency’s comprehensive revisions to the current Conditions of Participation which have resulted in proposed changes intended to bolster infection prevention efforts across hospitals. We support much of what CMS has proposed as we believe these revisions will strengthen infection prevention and control efforts to improve patient safety and public health. Further, the proposed revisions align well with our position that IPCPs are best led by infectious diseases physicians, given the breadth of responsibility assigned to the infection control professional. We propose the following suggested edits to CMS for consideration in the final rule and the Interpretive Guidelines:

- We envision that the designated infection control professional would oversee the competency-based training and be accountable for the effectiveness of the training program; therefore, we suggest that CMS finalize in the rule language that reflects this activity. Our concern with the currently proposed language is that this may be interpreted as the infection control professional being required to personally deliver the competency-based training.
- With regards to the ICP being “responsible for preventing and controlling HAIs,” we ask CMS to consider instead that the ICP “be responsible for the effectiveness of the IPCP through the auditing of adherence to infection prevention and control policies and procedures by hospital personnel.”

Medical Record Services

CMS has proposed changing the requirement for hospitals related to medical records. Specifically, the agency is proposing that the medical record “must contain all practitioners’ progress notes and orders,

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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.” Furthermore, CMS would require that the medical record “must document 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... so that the content of the medical record would contain final diagnoses with completion of medical records within 30 days following all inpatient stays, and within 7 days following all outpatient visits.”

IDSA supports the agency's efforts to ensure the patient's medical record accurately reflects the patient's condition and all services provided to the patient. We 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, much of 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. This critical work goes unrecognized under the current E/M coding set and 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.

IDSA appreciates the opportunity to provide comments in response to the agency's proposed rule on the Conditions of Participation that apply to acute care hospitals and CAHs. We commend CMS for its efforts to update these conditions with specific language that promotes accountability for IPCPs and ASPs, laying the foundation for physician leadership of these activities. We believe these practices will result in optimal outcomes for patients and public health. We ask that CMS carefully consider our comments in finalizing the CoP rule and we look forward to further interaction with the agency to ensure that the Interpretive Guidelines support this movement towards accountable leadership for IPCP and ASPs. We feel that it is important that all stakeholders maintain the momentum behind this proposed rule and move expeditiously move towards finalizing the rule by the end of this calendar year. Please feel free to contact Andrés Rodríguez, Director of Practice & Payment Policy at IDSA, (arodriguez@idsociety.org or 703-408-4015).

Sincerely,



Johan S. Bakken, MD, PhD, FIDSA
President