June 27, 2014

Marilyn B. Tavenner, RN, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1607-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers
(File Code: CMS-1607-P)

Dear Administrator Tavenner,

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide comments on the FY 2015 Inpatient Prospective Payment System (IPPS) proposed rule. IDSA represents more than 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education and research in the area of infectious diseases (ID). The Society’s members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the United States and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, surgical infections, those with cancer or transplants who have life-threatening infections caused by unusual or drug-resistant microorganisms, people living with HIV and AIDS, and new and emerging infections, such as severe acute respiratory syndrome (SARS) and H1N1 influenza.

IDSA members are committed to improving the quality and safety of patient care in hospitals and health systems across the nation. A significant portion of our members in clinical practice are hospital-based. In this setting, ID specialists work in collaboration with other healthcare personnel to develop and implement evidence-based practices to prevent and control healthcare-associated infections (HAIs). Since HAIs and their measured improvement figure prominently in CMS’ quality and reimbursement programs, our comments focus primarily on the Hospital Value-Based Purchasing (VBP) Program, the Inpatient Quality Reporting (IQR) Program and the Hospital-Acquired Condition Payment Policy; however we do highlight how other proposed changes in the rule link to broader infection-related issues.
Proposed Add-On Payments for New Services and Technologies

IDSA does not take a position on whether any specific product should receive New Technology Add-On Payments (NTAP). Recognizing that CMS may occasionally be asked to consider granting NTAP for new antibiotics, IDSA is pleased to offer information regarding the types of data we believe CMS should consider in these cases.

In recent years, the U.S. has experienced an alarming decline in antibiotic research and development (R&D), coupled with surging rates of antibiotic resistance, which have had a devastating impact on patients. This public health crisis has been well documented by the Centers for Disease Control and Prevention, the World Health Organization, and multiple other government entities and non-government experts, including IDSA with our 2004 Bad Bugs, No Drugs report and our 2011 Combating Antimicrobial Resistance: Policy Recommendations to Save Lives report. We are on the very real, very frightening precipice of a post-antibiotic era. An IDSA report issued in April 2013 identified only seven new drugs in the development pipeline for the treatment of serious infections caused by multidrug-resistant Gram-negative bacilli. There is no guarantee that even one of these drugs will make it to the market, given the failure rate of bringing drugs at this stage to market is very high.

Economic, regulatory and scientific challenges have caused many companies to abandon antibiotic R&D. Antibiotics are typically priced low compared to other new drugs, used for a short duration and held in reserve to protect their utility, making them far less economically viable investments for companies than other types of drugs used over years to treat chronic diseases. A lack of feasible clinical trial guidance is one serious regulatory hurdle to antibiotic R&D that the Food and Drug Administration (FDA) has recently taken steps to address. For example, FDA has recognized that in most instances, it is necessary to base approval of a new antibiotic on non-inferiority trials instead of requiring superiority trials.

Superiority clinical trials are often not appropriate or feasible for the study of new antibiotics. First, it is unethical to knowingly administer placebo to patients with serious or life-threatening infections. Second, superiority studies that compare a new, experimental antibiotic to another drug already on the market can be problematic as well. For some infections caused by highly resistant pathogens, there may be no appropriate comparator. Even when a comparator exists, ethical issues still make superiority trials highly problematic in some cases. Third, primary outcomes in clinical trial designs whether superiority or non-inferiority are efficacy based and do not take into account other important factors such as toxicity, adverse events, route or frequency of administration and need for monitoring that can confer meaningful clinical benefit and enhance utility.

An experimental antibiotic that is active against bacteria that are resistant to a comparator antibiotic should have superior efficacy to that of the comparator antibiotic when treating patients infected with those resistant bacteria. However, it would be unethical to use an antibiotic to which bacteria are resistant as a comparator. Thus, comparator antibiotics (or combinations of antibiotics) used in clinical trials are specifically selected to be active against almost all bacteria likely to infect patients enrolled in the study. In such a design in which both comparator and experimental antibiotic are active, it is highly unlikely that one regimen is going
to be superior in efficacy to the other. Such studies pose an unacceptable risk of failing to show that the experimental drug is superior to the comparator drug, even if the experimental drug is, in fact, highly effective.

Since superiority studies cannot be conducted for most serious infections, the best pathway to approval for many new antibiotics is a “non-inferiority” clinical trial, which seeks to determine if the experimental drug is similar in efficacy to a standard drug already on the market. Recently, the FDA has demonstrated increased willingness to consider approval of new antibiotics of proven efficacy and shown to have to achieve well-defined and statistically validated non-inferiority margins. We encourage CMS to take a similar approach when determining whether a new antibiotic should receive NTAP. We also encourage CMS to consider carefully-analyzed and peer-reviewed safety, utilization and economics data when such data are available to support an NTAP payment for a new antibiotic. This could increase the types of information that would be considered for drugs for which superiority trials are inappropriate and/or infeasible.

Furthermore, IDSA encourages CMS to anticipate the economic model that antibiotic manufacturers may adopt in light of the current payment system (i.e. IPPS) and the evolving payment system (VBP Program). As noted above, manufacturers of antibiotics intended for limited use must ensure their economic model is viable. Under the current NTAP program, Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed Medicare’s payment); or (2) 50 percent of the difference between the full DRG payment and the hospital’s estimated cost for the case. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS-DRG payment plus 50 percent of the estimated costs of the new technology. We ask CMS to consider the implications of the NTAP policy on antibiotics that fall under the current IPPS and, in particular, the VBP Program for which the inclusion of the MRSA bacteremia measure and the C-difficile measure are proposed. IDSA is concerned that current payment policy will be inadequate and place further financial pressure on hospitals. While we recognize and appreciate that the intent of the NTAP program is to strike a balance between timely payment that recognizes value in innovative technologies and limiting Medicare spending, CMS must consider the evolving payment paradigm facing inpatient facilities (IQR, HAC, and VBP) and ensure that these various policies do not have competing goals. For example, insufficient add-on payments could discourage high quality care and contradict the goals of value-based purchasing. If hospitals are to be penalized under the VBP for infections that could have been prevented by more appropriate antibiotic use (e.g., measures related to MRSA bacteremia and C. diff), then payment for those antibiotics need to be sufficient enough to ensure access and encourage appropriate use.

Also related to the NTAP program, we understand that data is collected over a two-year period, and is used to recalibrate the MS-DRG payments to the hospital. From the proposed rule, one can conclude that this data collection is optimized when new technologies are associated with procedures described by ICD-9-CM codes. IDSA encourages CMS to incorporate any learning from the recent accounting/tracking challenges that hospitals face when accounting for NTAP-eligible oral medications given in the inpatient setting in future NTAP data collection guidance.
IDSA urges CMS to bear in mind the urgent public health need for new antibiotics, the infeasibility of conducting superiority trials for some of the most needed antibiotics, and the need for economic incentives for antibiotic R&D when reviewing any NTAP application for a new antibiotic that treats serious or life-threatening infections, particularly multi-resistant Gram-negative infections for which few alternatives exist. The life-saving potential of these drugs is tremendous and perhaps the only option for patients infected with these multidrug-resistant pathogens.

IDSA believes it is critical that CMS maintain an ongoing dialogue with the FDA as well as non-government experts in antibiotic resistance and antibiotic drug development in order to more fully understand the highly complex issues regarding the type of data available for the study and approval of new antibiotics. IDSA would be happy to serve as a resource for this important effort.

**Hospital Value-Based Purchasing (VBP) Program**

IDSA supports the proposed inclusion of two infection-related quality measures in the FY 2017 Hospital Value-Based Purchasing Program. The first, Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia (NQF #1716), is the risk-adjusted outcome measure monitoring hospital onset of MRSA bloodstream infection events (using MRSA bacteremia SIR). The second, for *Clostridium difficile* Infection (NQF #1717), is a risk-adjusted outcome measure monitoring hospital onset of *C. difficile* infection events (using *C. difficile* SIR). Both measures are reported via CDC’s National Healthcare Safety Network (NHSN). We share with CMS the concern of the seriousness of these types of infections and we feel that by tying performance for these measures to the Value-Based Purchasing Program, it will further incent hospitals to employ appropriate infection control & prevention (IC&P) programs and antimicrobial stewardship (AS) programs.

IDSA has long been a proponent of such programmatic activity, advocating for infectious diseases specialists to lead such programs. Specifically, we have most recently approached CMS to consider including antimicrobial stewardship (AS) as a Medicare Hospital Condition of Participation. There is a sizable body of literature to justify establishing AS programs as a means to specifically reduce *C. difficile* infection and healthcare costs and, more broadly, reduce antimicrobial resistance, which is a huge concern at the national level. In our view, AS supports the achievement of the specific infection-related quality measures that are part of the IQR/VBP programs.

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Hospital Inpatient Quality Reporting (IQR) Program
As noted above, a significant portion of infectious diseases specialists are hospital-based. Therefore, we assess the proposed changes to the IPPS rule with regards to how they may directly or indirectly impact the clinical care that ID specialists provide. Furthermore, as the possibility of allowing hospital-based physicians to tie their reporting for the Physician Quality Reporting System to the performance metrics of their institution continues to be explored, our interest in infection-related quality measurement at the facility-level increases.

Currently, there are 57 quality measures under the IQR program from which FY2016 payments will be determined. For 2017, CMS proposes to remove or suspend up to 20 measures, mainly due to the measures being “topped out.” Of the 20 proposed, 10 will be retained as voluntary electronic clinical quality measures, which hospitals may choose to report on in order to satisfactorily demonstrate meaningful use of EHR technology, under the Medicare Hospital EHR program.

Of the measures that CMS is proposing to retire, the SCIP-Inf 3: Prophylactic Antibiotic Discontinuation within 24 hours After Surgery End Time (NQF #0529) is the one measure of particular interest to IDSA. We believe this measure should not be retired despite its “topped out” status. Specifically, we request that CMS consider maintaining this measure for reporting (versus payment) purposes within the IQR program. IDSA’s strong advocacy for antimicrobial stewardship (AS) has been mentioned above. We view this particular measure to be in alignment with AS principles. Although performance on this measure is currently high, if it is completely retired, there will no longer be a consistent mechanism to track whether adherence to this practice has declined to an “unacceptable” point where its re-adoption is necessary. Given the national concern related to antibiotic resistance and that many hospitals do not yet have formal AS programs in place, we ask CMS to consider retaining this measure within the IQR program.

With respect to the quality measure that reports influenza vaccination coverage among healthcare personnel (NQF #0431), IDSA appreciates the effort that CMS has made to clarify to facilities the reporting requirements, whereby facilities should collect and report a single vaccination count for each healthcare facility by CMS Certification Number (CCN). We agree that this alleviates the burden of having to report by inpatient vs. outpatient setting, and we think that this will facilitate consumer (patient) interpretation when these percentages are publicly reported at the facility level.

Hospital-Acquired Condition (HAC) Reduction Program
The HAC Reduction Program includes 11 categories of hospital-acquired conditions that result in a payment penalty for hospitals who report applicable cases. IDSA appreciates CMS’ maintenance of the program in the current state, with no proposed additional new measures. We remain concerned about the HAC payment policy’s “all-or-nothing” approach, which still does not include adequate case-mix adjustments or provide a mechanism to flag cases where an infection occurred despite adherence to evidence-based guidelines. For many conditions on the HAC list, occurrence rates cannot be reduced to zero or near zero even when the evidence-based guidelines are followed. Some medical conditions, such as a compromised immune system,
simply put patients at higher risk of a HAC than other medical conditions. While IDSA fully supports efforts to minimize HACs, it is inappropriate for CMS to deny payment for such complications without taking into consideration whether a patient did, in fact, receive optimal evidence-based care. We strongly encourage CMS to more carefully evaluate this program and its potential for unintended consequences and to explore how information learned from present-on-admission coding could be used to better understand and prevent HACs before it considers the inclusion of any additional categories of HACs.

We look forward to the completion of the NQF review process of the AHRQ PSI-90 composite measure, as well as the CLABSI and CAUTI measures. We understand that if there are any significant changes to these measures that CMS will issue a notice-and-comment rulemaking prior to modifying the reporting requirements.

IDSA applauds the efforts of CMS to promote improved patient safety and better quality of care in inpatient hospital settings, while also aiming to reduce any unnecessary reporting burdens and achieve operational efficiency. We welcome further discussion with CMS and other stakeholders on how quality measurement in the IQR/VBP program can promote infection control and antimicrobial stewardship in the context of a broad effort to address antibiotic resistance. If you have any questions, please feel free to contact Andres Rodriguez, Director for Practice & Payment Policy, at 703-299-5146 or arodriguez@idsociety.org.

Sincerely,

Barbara E. Murray, MD, FIDSA
President