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Submitted via: <http://www.regulations.gov>

Andy Slavitt, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Attention: CMS-1631-FC

Re: Comments on Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 [CMS-1631-FC]

Dear Mr. Slavitt,

The Infectious Diseases Society of America (IDSAs) appreciates the opportunity to provide comments on the CY 2016 Physician Fee Schedule (PFS) final rule. 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) and Ebola virus disease.

IDSAs members are committed to improving the quality and safety of patient care in a manner that aligns reimbursement with value-based principles. This PFS final rule outlines changes to the Physician Quality Reporting System (PQRS), the Quality and Resource Use Reports (QRURs) and the Value-Based Payment Modifier (VM), and the Physician Compare Website, among other Part B related issues. The finalized changes for the PQRS program from this rule, as well as changes in the measure specifications, are particularly concerning to IDSAs as our members will find it even more challenging to comply with reporting requirements, which will lead to payment penalties in subsequent years. Below, we submit our specific comments on these changes and explain the negative impact that they will have on our members.

The ID Specialist in Clinical Practice – Challenges to Quality Reporting

As stated in our [comment letter](#) on the Medicare PFS proposed rule, we feel it is important to describe the clinical practice of our members to provide context to the issues related to the PQRS program. ID specialists are not “proceduralists” but rather are cognitive specialists, providing most of their services using Evaluation & Management (E/M) codes. Across all ID specialists in clinical practice, the overwhelming majority of E/M codes billed are for services provided in the inpatient setting. Within the inpatient setting, ID specialist involvement in the care of patients with severe infections has been well-documented to produce decreased mortality, reduced length-of-stay, fewer readmissions, and/or lower costs.^{1,2,3} The importance of highlighting the inpatient focus of ID specialty care is particularly significant when considering quality measurement and reporting under PQRS. Per this final rule, CMS maintains the requirement that all eligible professionals (EPs) must report 9 measures across 3 quality domains for at least 50% of the Medicare Part B fee-for-service (FFS) patients, with at least one measure contained in the PQRS cross-cutting measure set. Those that fail to meet this 9-over-3 threshold or that fail to report on one cross-cutting measure will be subject to the Measures Applicability Validation (MAV) process and ultimately a -2% payment adjustment in 2018. As we have previously stated in prior comment letters, we believe the MAV process will represent additional administrative burden for our members as they attempt to comply with a quality reporting system that is particularly challenging for hospital-based EPs.

For 2015, our members could report on the one PQRS measure that applies to inpatient E/M visits and is **reasonably relevant** for an ID specialist to perform – CMS Measure #130/NQF 0419: Documentation of Current Medications in the Medical Record. This measure was particularly helpful for our members to comply with the PQRS program as it was included in the cross-cutting measure set. This means that for most of our members, they could report on measure #130 for at least 50% of their Medicare Part B FFS patients, be subjected to the MAV process, and be deemed compliant with the PQRS program, thereby possibly avoiding a payment penalty in 2017. For 2016, we note in the recently released [measure specification guidance](#) that the inpatient face-to-face encounters are no longer applicable for measure #130. In fact, the only measures that apply to inpatient face-to-face encounters are CMS Measure #001: Diabetes: Hemoglobin A1c Poor Control and CMS Measure #47: Care Plan.^{4,5} The Diabetes measure is not appropriate for an ID specialist to report upon. The Care Plan measure is difficult to consider as appropriate for ID specialists, given their consultative role. It is important to note that in the inpatient setting, ID specialists are called on to provide services by the attending physician in cases where patients are thought to be suffering from an infection. In thinking about a patient who has been admitted to a hospital in an inpatient status, one might imagine that the attending physician would cover advance care planning with the patient and family in the initial face-to-face encounter. As measure #47 applies to inpatient face-to-face encounters under the PQRS program, this same patient (and her/his family) may likely be asked whether s/he has completed her/his advance care planning by every specialist called by the attending to provide a consult on the case, as the specialists will want to report on a cross-cutting measure to satisfy PQRS and avoid a payment penalty. In envisioning the possible repeated inquiries regarding care planning driven by “check the box” quality reporting, it is difficult to see how this might enhance the patient experience and lead to higher patient satisfaction.

¹ Schmitt S, McQuillen DP, Nahass R, et al. Infectious diseases specialty intervention is associated with decreased mortality and lower healthcare costs. *Clin Infect Dis* 2014; 58:22–8.

² Hamandi B, Husain S, Humar A, Papadimitropoulos EA. Impact of Infectious Disease Consultation on the Clinical and Economic Outcomes of Solid Organ Transplant Recipients Admitted for Infectious Complications. *Clin Infect Dis* 2014; 59: 1074-1082

³ Bai AD, Showler A, Burry L, et al. Impact of infectious disease consultation on quality of care, mortality, and length of stay in *Staphylococcus aureus* bacteremia: results from a large multicenter cohort study. *Clin Infect Dis* 2015; 60:1451–61

⁴ CMS Measure #001: Diabetes: Hemoglobin A1c Poor Control - Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period

⁵ CMS Measure #47: Care Plan - Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan

IDSA seeks to facilitate PQRS participation for our members. We appreciate CMS' inclusion of the Appropriate Treatment of MSSA Bacteremia (CMS Measure #407) in the PQRS program, a measure for which IDSA is the steward. IDSA continues to develop measures that are specific to the clinical practice of ID specialists. However, it will be some time before we can establish a portfolio of relevant measures from which the quality of care of ID specialists can be appropriately measured. In the meantime, we seek to provide guidance for our members to comply with PQRS, using available measures. With the recent changes to measure #130, our members are now left unable to report on a cross-cutting measure that is **reasonably relevant** to their practice. We ask CMS to change the measure specifications for measure #130 to how it was specified for the 2015 reporting period in order to allow our members the chance to avoid a payment penalty in 2018.

Improving Payment Accuracy for Primary Care and Care Management Services

In the proposed rule, CMS recognized that the “current E/M office/outpatient visit CPT codes were designed with an overall orientation toward episodic treatment,... these E/M codes may not reflect all the services and resources involved...” CMS proposed to use add-on codes that would capture “the different resources (particularly cognitive work) involved in delivering broad-based, ongoing treatment, beyond those resources already incorporated.” We applaud the agency for proposing to address the deficiencies in the existing evaluation and management (E/M) services. We reiterate our belief that the deficiencies of the current E/M valuation apply not just to office/outpatient visits but to all cognitive work captured by the E/M code set, including the inpatient and other sites of service. We reiterate the need for consideration of the complexity of medical decision-making on the part of many cognitive specialists and primary care physicians involved in the treatment of acute and chronic conditions. As CMS did not finalize any concepts from the proposed rule, we urge CMS to consider undertaking new research that explores alternative valuation models in order to better identify and quantify the inputs that accurately capture the elements of complex medical decision-making. Such research should take into account the evolving health care delivery models with growing reliance on team-based care, and should consider patient risk-adjustment as a component to determining complexity. We urge CMS to commit to underwriting this research by hiring an expert contractor to work with stakeholders to develop a comprehensive understanding of E/M. Furthermore, we believe it is imperative that any research into an alternative valuation process include direct involvement of physicians and other healthcare providers who are the purveyors of the very medical services that are to be valued. IDSA is hopeful that CMS will step forward to fund this needed research and, as ID is one of the specialties with the highest percentage of billing as E/M codes, we will be pleased to serve as a resource for the agency in its efforts to ensure accurate code definitions and valuations for Evaluation & Management services.

Provisions Related to the Medicare Access and CHIP Reauthorization Act (MACRA) – Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs)

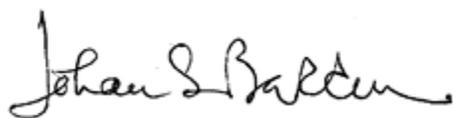
In the proposed rule, CMS sought preliminary feedback on strategies for implementing both the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) provisions of MACRA. Subsequently, CMS issued a “Request for Information Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models,” to which IDSA provided a [response](#). As CMS considers all comments that may inform their implementation of MACRA, we restate how critical it is that CMS recognize a wide range of activities and payment models that are relevant to physicians in different specialties and practicing in a variety of settings and avoid a one-size-fits-all approach that limits

meaningful participation by specialists in federal quality programs, as currently is the case for ID specialists with the PQRS program. We would like to take this opportunity to highlight, yet again, one provision within MACRA that allows the Secretary certain flexibility for weighting performance categories and activities under MIPS in cases where “there are not sufficient measures and activities... applicable and available to each type of eligible professional involved.” CMS should consider exercising its discretion as granted within MACRA to allow for weighting adjustments across the performance categories for various subsets of eligible professionals (those in large group practices versus solo practitioners, those who are hospital-based versus outpatient-focused). For the many ID specialists who bill an overwhelming percentage (80+%) of their services in the inpatient setting, the ability to perform in the MIPS program could prove challenging, and therefore shifting more weighting onto Clinical Practice Improvement Activities may be more meaningful. For this reason, we ask that CMS consider an adjustment of weighting across the MIPS performance categories for this subset of EPs.

With respect to Clinical Practice Improvement Activities under MIPS, we detailed in our comment letter to the proposed rule and we highlight here what we believe are viable concepts for consideration – ID specialist leadership of Infection Prevention Programs, Antimicrobial Stewardship Teams, and Outpatient Parenteral Antimicrobial Therapy (OPAT) Programs. Regarding APMs, we again ask that CMS consider how concepts such as the Patient Centered Specialty Practice within a “Medical Neighborhood” can be used as the foundation on which to develop alternative payment models. IDSA views the passage of MACRA as a new opportunity to create effective quality measurement programs tied to value-based payment that take into account team-based care and diverse practice patterns. We look forward to working with CMS and other stakeholders to achieve this objective.

IDSA appreciates the efforts of CMS to promote improved patient safety and better quality of care as set forth in this PFS final rule. If you have any questions, please feel free to contact Andrés Rodríguez, Director for Practice & Payment Policy, at 703-299-5146 or arodriguez@idsociety.org.

Respectfully,

A handwritten signature in black ink that reads "Johan S. Bakken". The signature is written in a cursive style with a large initial 'J'.

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