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September 6, 2016

Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: 42 CFR Medicare Program; Revisions to Payment Policies under the
Physician Fee Schedule and Other Revisions to Part B for CY 2017
[CMS-1654-P]

Submitted electronically via Regulations.gov

Dear Mr. Slavitt:

The Infectious Diseases Society of America (IDSociety) appreciates the opportunity to provide comments on the Medicare Physician Fee Schedule (MPFS) proposed rule for calendar year 2017. IDSociety 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, 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, and Zika virus diseases.

IDSociety 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, and many lead the "on-the-ground" efforts to combat healthcare associated infections and antimicrobial resistance. The specialty of infectious diseases is unique in that it is the only specialty whose training emphasizes the linkage between individual patient care and the impact on the larger patient population. This "bedside-to-population" system-based awareness is what distinguishes the critical role of the ID physician within the healthcare system, especially as it applies to quality improvement that is related to healthcare associated infections. It is with this perspective that we offer our comments on the proposed rule related to the MPFS.

Medicare Telehealth Services:

Critical Care Evaluation & Management (E/M)

IDSA supports the agency’s proposed inclusion of critical care E/M services to the approved list of telehealth services. IDSA has long been a proponent of the use of telehealth to treat patients with infectious diseases, and we believe the addition of critical care services to the approved telehealth services list will provide Medicare beneficiaries who live in remote areas access to infectious diseases physician expertise when this access might have previously been unavailable. With the announcement of the Center for Medicare & Medicare Innovation’s (CMMI) Frontier Community Health Integration Project, CMMI intends to study the use of telehealth services in critical access hospitals (CAHs). Under the demonstration project, CMS will pay participating CAHs 101% of the costs associated with fringe benefits, overhead, salaries, and the depreciation value of used telemedicine equipment, instead of a fixed facility fee as is the current telehealth policy. **We believe the addition of critical care telehealth services to the approved telehealth services list will prove to be a valuable addition, especially for those CAHs participating in this recently announced demonstration project.** IDSA appreciates the agency’s expansion of telehealth under demonstration projects as this shows stakeholders that the agency is willing to test models of alternative care and to test whether expansion of the telehealth benefit provides increased access to essential medical services for Medicare beneficiaries.

IDSA believes our physicians provide valuable consultative services particularly in the instances of patients with critical needs such as those suffering from septic shock, patients on ventilators or those patients suffering from other critical infectious diseases. **It is under these circumstances when an infectious disease consult cannot wait until a patient is transferred to a facility that has access to an infectious disease physician.** At a time when the prevalence of infections in intensive care patients and the use of antibiotics in intensive care units (ICUs) is high, access to timely, appropriate, and highly skilled infectious disease critical care is of the utmost importance. In a recent prevalence study, 51% of 13,796 patients in 1,265 ICUs across 75 countries were infected and 71% were under antibiotic treatment.¹ Timely access to appropriate treatment, enabled by telemedicine, by an infectious disease physician during these critical moments can change the outcome for the patient and provide antimicrobial stewardship in areas of intensive antibiotic usage.

CMS proposes to make payment using new HCPCS G codes, *Telehealth Consultations for a Patient Requiring Critical Care Services, initial and subsequent, (GTTT1 and GTTT2)*, to describe critical care consultations furnished via telehealth. While IDSA supports the addition of critical care services to the telehealth services list, **we do not support the development of HCPCS G codes to report those services.** We believe the creation of new G codes will serve to distinguish telehealth as a distinct service rather than as a *tool to deliver a service*. It has been our understanding that telehealth services are medical care that is delivered using telehealth technologies, but the care is exactly the same as if the care were provided in person. The Medicare Claims Processing Manual (MCPM) states that telehealth is the use of telecommunications which “**may substitute for an in-person encounter** for professional consultations, office visits, office psychiatry services and a limited number of other physician fee

¹ Vincent, J. et al. *International Study of the Prevalence and Outcomes of Infection in Intensive Care Units*, Journal of the American Medical Association, 2009; 302:2323-9.

schedule services”.² This statement from the MCPM indicates that a telehealth service should be no different than an in-person visit, except that it is provided via telehealth technologies. The creation of G codes to indicate *telehealth critical care delivered via telehealth* undermines the basic premise of what telehealth services actually are. As CMS notes in the proposed rule “a practitioner who furnishes a telehealth service to an eligible telehealth individual should **be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system.**” IDSA believes that this statement is indicative of what a telehealth service is and should be, and therefore, we do not support the creation of HCPCS G codes for critical care telehealth services. However, we do support the addition of critical services to the telehealth services list, but suggest that the existing CPT[®] codes 99291 and 99292 be used to report these valuable services.^{3,4}

Place of Service (POS) Code for Telehealth Services

IDSA supports CMS’s proposal for the creation and use of a Place of Service (POS) code to indicate that a service was provided via telehealth. Largely driven by requests from other payers, CMS proposes how a POS code for telehealth would be used under the PFS (if one were created by the POS Workgroup within CMS) with the expectation that, if such a code were available, it would be used as early as January 1, 2017. CMS proposes that the physicians or practitioners furnishing telehealth services would be required to report the telehealth POS code to indicate that the billed service is furnished as a telehealth service from a distant site. **We understand CMS’s intent with creating a new telehealth POS code, and believe that the creation of this code will lead to more accurate data collection regarding telehealth services.** IDSA supports the creation of the POS code only if the new POS code is not tied to limitations of payment based on the POS designation. Further, we only offer support for this new POS code as long as it is NOT a new form of the Metropolitan Service Area (MSA) limitation currently in place for payment for payment of telehealth services. In support of this proposal, IDSA suggests CMS provide educational materials, through provider calls and MedLearn Matters articles to support and educate providers on the appropriate use of the new POS code.

Non-Face-To-Face Prolonged Evaluation & Management (E/M) Services

IDSA is pleased CMS has proposed payment for prolonged services associated with non-face-to-face patient care. CMS has proposed to cover CPT[®] codes 99358 (prolonged E/M service before or after direct patient care, first hour) and 99359 (prolonged E/M service before or after direct patient care, each additional 30 minutes). CMS will require the non-face-to-face prolonged service be provided on the same day, and by the same physician as the companion E/M code. We appreciate the agency’s efforts to provide payment for non-face-to-face cover, however, we are concerned with the requirement that the prolonged service must be provided on the same day as the companion E/M code. There are often times when an ID physician may provide prolonged care on a different date than the companion E/M code. The CPT[®] code book

² Medicare Claims Processing Manual, Chapter 12 Physicians/Non-Physician Practitioners: Section 190.3, List of Medicare Telehealth Services.

³ 99291 – *Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes*, 99292 - *Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)*.

⁴ CPT is copyright of the American Medical Association, 2016.

provides guidance which notes that the prolonged service “may be reported on a different date than the primary service to which it is related...but that the prolonged service “must relate to a service or patient where (face-to-face) patient care has occurred or will occur and relate to ongoing patient management”.⁵ As such, **IDSA believes CMS should follow previously published CPT guidelines on the use of the non-face-to-face prolonged services codes to avoid confusion, and to allow for the prolonged services CPT codes to be used as intended.**

We appreciate the agency’s efforts to recognize the value of cognitive care outside of a direct face-to-face patient interaction. CMS has shown its support for cognitive care through the development of the transitional care management and chronic care management concepts. IDSA has supported the agency’s development and subsequent Medicare reimbursement for these valuable non-face-to-face services. **Further, in our efforts to advocate for improved recognition of the value of cognitive care, IDSA has submitted an application to the American Medical Association (AMA) CPT® Editorial Panel for the development of new CPT® codes for review of electronic health records (EHR).** If approved by the Panel, the new CPT® codes will be used to report the considerable time, cognitive effort, and intensity used by physicians when reviewing electronic health record data for patients with multiple comorbidities, complications, and/or extended inpatient stays. This service will be provided as a non-face-to-face (indirect) service, and may be provided either prior to or after a direct (face-to-face) patient care E/M service. The review of EHR records may be performed directly in the EHR database/format or it may be the printed version of an EHR record.

We believe EHR review is an auditable service such that physicians will be able to prove their time associated with service, as EHRs have the capability of recording the time a physician spends accessing and reviewing each patient’s EHR. The codes we have requested of the AMA will be based on 15 minute increments, with the initial code reported for the first 15 minutes and the add-on code reported for each additional 15 minutes. We believe that the existing CPT codes associated with the non-face-to-face prolonged services do not meet the needs of our providers, such that the time threshold is nearly impossible to reach; and the current CPT codes do not describe extended and extensive EHR review. We look forward to advancing this concept and if CMS should have any questions about this, we would welcome a dialogue with the agency.

We note that the American College of Physicians (ACP) has proposed, in its comment letter, that the Agency consider the creation of G-codes (GZZZ1: Prolonged evaluation and management service before and/or after direct patient care; first 15 minutes; and GZZZ2: each additional 15 minutes) to recognize non-face-to-face care involved in prolonged E/M. Whereas they describe this G code in the context of a situation where the physician has identified and must manage a “new problem or exacerbation of an existing problem before and/or after direct patient care,” **we suggest that this proposal creates a G code for the exact work that the Agency proposes to recognize with CPT® codes 99358 & 99359, but for 15 minute increments.** With this, IDSA asks the agency to consider the creation of the G codes, as ACP has brought forth, in lieu of covering 99358 & 99359. We believe the creation of the G codes would allow for physicians to be compensated for non-face-to-face care in a more meaningful increment of time and will help to alleviate confusion that may result from establishing payment policy that does not conform to the CPT® code description.

⁵ CPT Professional Edition 2016, published by the American Medical Association, 2016, page 33.

Improving Payment Accuracy for Primary Care, Care Management, and Patient Centered Services

As members of the Cognitive Care Alliance, we are aware of a separate comment letter being submitted from that consortium of cognitive medical specialty societies; however we would like to reiterate the importance of payment accuracy for cognitive care. IDSA advocates for appropriate reimbursement for cognitive care associated with a myriad of complex diseases that ID physicians diagnose and treat on a daily basis. As we have asserted in previous comment letters, the current Medicare Physician Fee Schedule is flawed in large part due to inherent biases in the valuation process that favor procedures, imaging, and laboratory services over cognitive services. **IDSA supports exploration and studies of alternative valuation models for evaluation and management services with the aim of improving the valuation of physician services that involve complex medical decision-making.** Furthermore, we believe it is imperative that any 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. Therefore, we are hopeful that any studies CMS commissions on the work of cognitive physicians will be the result of a thorough, transparent process that attracts physicians knowledgeable in work valuation that appropriately accounts for complex medical-decision making.

Valuation of the Global Surgical Codes

IDSA supports the premise under which CMS has proposed to revalue the pre and post-operative E/M services associated with surgical services. The study and data collection of these services will provide a better understanding of the work, time, and intensity involved in pre and post-operative E/M services, and as such will assist in a better understanding of the differences between this type of care and cognitive care. IDSA is working as part of the Cognitive Care Alliance (CCA) whose goal is to improve payment accuracy for inpatient and outpatient E/M services. Infectious disease physicians are cognitive care specialists by nature and rely on appropriate payment and valuation of E/M services. As such, we echo the sentiments of the comment letter submitted by the CCA. IDSA believes that in order to improve the accuracy and validity of the physician fee schedule, CMS's payment policies must be based on a well-constructed, valid and representative knowledge-base. Therefore, we have similarly proposed that CMS commit to developing an evidence base from which E/M services can be redefined and valued to more accurately describe and value the work performed by cognitive physicians. We also believe CMS should work with the specialties most greatly affected by revaluation of E/M services, and IDSA would welcome the opportunity to work with the Agency in this regard.

Proposed Expansion of the Diabetes Prevention Program (DPP) Model:

The agency proposes to expand the duration and scope of the Diabetes Prevention Model (DPP) which CMS will rename as the Medicare Diabetes Prevention Program (MDPP). We understand CMS will engage in additional rulemaking in order to establish specific requirements of the MDPP, which is set to begin on January 1, 2018.

IDSA would like to specifically comment on the agency's intent to designate the MDPP as an additional preventative service. CMS has proposed to use its waiver authority in this instance because the United States Preventative Services Task Force (USPTSF) has not granted MDPP a recommendation grade of A or B which is typically required for Medicare coverage. CMS further explains that under its waiver authority, it will use the recommendations of the Community Preventive Services Task Force (CPSTF) which endorse the use of diabetes prevention programs. **IDSA believes CMS should use this same waiver authority to cover all Advisory Committee on Immunization Practices (ACIP) recommended vaccines for Medicare beneficiaries.** CMS has noted in years past that it cannot cover all recommended vaccines for adults since CMS is limited by statute to cover only preventive services that have received a grade A or B from the USPTF. However, the Affordable Care Act required coverage for all ACIP recommended vaccines for beneficiaries who are covered under private or exchanged-sponsored health insurance policies. This has led to a two-tiered coverage system whereby some Medicare beneficiaries have received some of the ACIP recommended vaccines (influenza and pneumococcal), while other Medicare beneficiaries have mandated coverage and therefore receive all ACIP recommended vaccines.

The ACIP is a Centers for Disease Control and Prevention (CDC) convened expert panel whose purpose is to “provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian populations of the United States”.^[1] It is our understanding of its work that the ACIP uses evidenced-based research to make recommendations on the vaccines the U.S. population should be given. ACIP also uses other standards and concepts to formulate vaccine policy recommendations including:^[2]

- Review of data on the morbidity and mortality associated with a particular disease.
- Review of scientific literature (both published and unpublished) on the safety, efficacy, effectiveness, cost-effectiveness, and acceptability of the immunizing agent.
- Consideration of the quality and quantity of all relevant data.
- **“Following specific rules of evidence, such as those followed by the USPTF to judge the quality of the data and to make decisions regarding the nature and the strength of recommendations”.**
- Other considerations include clinical trial results, and information provided on packaging labels, equity in access to the vaccine, recommendations of professional liaison organizations, and feasibility of incorporating the vaccine into existing vaccine regimes and programs.

We believe that the ACIP is similar to the USPTF just as the CPSTF is similar to the USPTF. It appears to IDSA that ACIP meets or exceeds the requirements for a waiver based on the

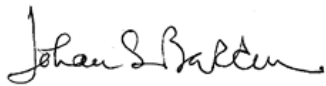
^[1] ACIP Charter, updated April 20, 2016. <https://www.cdc.gov/vaccines/acip/committee/charter.html> Accessed on August 4th, 2016.

^[2] Smith, J. C. *The Structure, Role, and Procedures of the U.S. Advisory Committee on Immunization Practices (ACIP)*. Vaccine 285 (2010) A68-A75.

rationale the agency presents in the rule for what it intends to do for the MDPP. We look forward to working with CMS on this important issue.

IDSAs appreciate the efforts of CMS to promote improved payment accuracy and patient safety as set forth in the MPFS proposed rule. We look forward to further engagement with CMS and other stakeholders as we work toward meeting the goals of this proposed rule. If you have any questions, please feel free to contact Andrés Rodríguez, Director of 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 prominent initial "J".

Johan S. Bakken, MD, PhD, FIDSA
President