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September 25, 2019

RE: Medicare Program; CMS 1715-P, CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion

Submitted electronically via <a href="http://www.regulations.gov">http://www.regulations.gov</a>

Dear Administrator Verma:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide comments on the proposed rule for the 2020 Medicare Physician Fee Schedule (MPFS). IDSA represents nearly 12,000 infectious diseases (ID) physicians, scientists and other healthcare professionals devoted to patient care, prevention, public health, education, and research in infectious diseases. Our members care for patients of all ages with serious infections, including treating meningitis, pneumonia, tuberculosis, HIV/AIDS, healthcare-associated infections, antibiotic-resistant bacterial infections, as well infectious disease outbreaks and emerging infections such as the Middle East Respiratory Syndrome coronavirus (MERS-CoV), Ebola virus and Zika virus. We are providing comments on specific proposed regulations related to Evaluation & Management coding, other provisions of the proposed rule and proposals related to the Quality Payment Program.

#### **Changes to Evaluation & Management Services**

Last year the Centers for Medicare & Medicaid Services (CMS) spent a considerable amount of time and resources working on revising the code structure and payment for office/outpatient evaluation & management (E/M) services reported with CPT® codes 99201-99215. The goals of CMS in the revision process were to reduce physician administrative burden while putting the patient first. To that end, CMS finalized, for implementation in 2021, a code structure that would have collapsed the five codes used to describe an encounter with a new patient to two codes and used the same approach for established patient encounters (again, from five codes to two codes). This revised code structure and subsequent reduced payment levels were met with great resistance from the physician community. Since that proposed revision, the Agency has

carefully listened to the physician community regarding issues with the office/outpatient visit E/M code set. IDSA participated in discussions and worked collaboratively with other medical specialty societies to assist in developing an alternative E/M code structure that would serve the goals of the Agency while also meeting the needs of the physician community and Medicare beneficiaries.

IDSA would like to commend Administrator Verma and the CMS staff for engaging with the physician community regarding the revision of the E/M service codes for office visits. We are pleased to see positive changes within the office visit E/M code set. These positive changes are a step in the right direction in valuing cognitive care provided by ID physicians; however, we would like to see the Agency continue to work with other stakeholders and us to ensure that the entire E/M code set, including inpatient, emergency department visits, nursing home care and others are valued in a fair and equitable manner taking into account the different services and resources required in each setting. We believe that reviewing all E/M codes needs to be done in order to capture the complexity, expertise and skills required to perform the work of the cognitive physician, particularly in the inpatient setting.

Even though the office visit E/M code set has been revised and revalued, the documentation burden remains quite high for ID physicians, as many ID physicians work in the inpatient setting where the documentation burden remains unchanged. One issue is when the revised E/M codes are implemented in 2021, there will be different sets of documentation guidelines based on siteof-service (office vs. all others). This could lead to confusion and increased administrative burden. Additionally, there will still be "note bloat" and "copy and paste" issues for not only ID physicians, but also for any physician who reports E/M codes other than the revised office visits codes. We request that CMS staff meet with IDSA and other groups within the physician community to create a collaborative, step-wise approach to reviewing and possibly revising the entire E/M code set. We also suggest CMS align efforts to revise the E/M code set, to reduce documentation burden, with other stakeholders such as the Office of the National Coordinator (ONC). ONC may consider requiring EHR vendors to provide an attestation mechanism for data review with the documentation process so that physicians are not compelled to copy and paste all the records they have electronically reviewed. We believe that EHR vendors should also help with reducing the documentation burden. We perceive this to be an opportunity for the Agency and ONC to work collaboratively in developing synergistic documentation and administrative certification requirements within the EHR. IDSA is seeking opportunities to collaborate with EHR vendors in developing appropriate documentation guidelines for our specialty. We would also welcome the opportunity to work with CMS and others to build a better reporting system for all healthcare encounters.

#### Payment for Evaluation and Management (E/M) Services

IDSA supports the proposed work values and times for the revised office visit E/M codes. We also appreciate the work of the AMA CPT° Editorial Panel for ushering through the CPT code changes that CMS has proposed. We also support the value and associated time for the new prolonged service code that may be used in conjunction with Level 5 new and established patient visits. IDSA was among the more than 50 specialties that participated in the RUC survey to

value the revised codes. The RUC survey for the revised E/M codes had a historical number of responses. IDSA supported the findings of the RUC survey.

IDSA understands the considerable complexities and resources needed in undertaking to revise and to revalue the E/M code set. We are also keenly aware of the complex issues that surround the issue of E/M services included in global surgical packages. IDSA agrees with the Agency that there is a fundamental difference between a typical outpatient follow-up E/M visit and post-operative follow-up visit; therefore, any bundled visits (global E/M visits) must only be those appropriate for the level of service delivered. The work involved in a post-operative visit is different than the work of an office E/M service and therefore, the post-operative visit should be valued differently. We support CMS' efforts to determine the number and type of E/M visits bundled into the global surgical packages. We recommend that CMS continue to study the complex issue of the global surgical package and to work with all stakeholders to develop a fair and equitable solution.

#### **Single Add-on Code to Indicate Patient Complexity:**

IDSA supports the proposed add-on code GPC1X to report the care associated with a patient's single, serious, or complex chronic condition. In the past, we have asked the Agency to consider using Hierarchical Conditions Category (HCC) scores to capture the complexity of care at the patient level. Currently, we view the complexity add-on code as a reasonable proxy. We thank the Agency for creating the complex add-on code to capture the work of complex patient care. Our Society has worked tirelessly to promote the importance of allowing for additional resources when patient complexity warrants more physician time and cognitive expertise to deliver care. We also support the code descriptor as written such that the code is tied to patient complexity, and therefore is patient-specific and not specialty-specific. However, the code descriptor and the CMS language within the rule do not provide guidance as to the definition or documentation requirements of *serious* or *complex*. We ask that the CMS provide clarification as to the documentation requirements needed to report the complex care code. The following is an infectious diseases clinical example of the type of patient for which we think the complex add-on code may be used to capture the additional time and resources needed to treat a complex patient.

A 45-year-old man with prosthetic aortic valve endocarditis due to *Staphylococcus* aureus requiring aortic valve replacement with a mechanical valve. The patient has comorbidities of hypertension and chronic hepatitis C. He is treated with two intravenous antibiotics (cefazolin and gentamicin) and one oral antibiotic, rifampin for six weeks post-surgery. He already has renal dysfunction after his initial infection and subsequent surgery so peak and trough gentamicin levels must be carefully followed to avoid further renal failure; liver function tests must be closely monitored due to the potential of rifampin to cause transaminitis. The rifampin may also interact with the warfarin he is taking, requiring close monitoring of INR and may also interact with his antihypertensive medications requiring close attention to his blood pressure. All these comorbidities are managed by the ID physician while the patient is administered antibiotics at home and during weekly clinic visits.

The above clinical example highlights the simultaneous, interacting conditions observed in many Medicare patients. Many Medicare patients take multiple medications that add an additional layer of complexity to their care. Finally, as the example highlights, patient care provided by an ID physician often involves multiple organ systems further highlighting the complexity of care involved with treating patients with infectious diseases. ID physicians similarly provide complex care to patients living with HIV and patients with chronic prosthetic joint infections both of whom commonly have complex cardiac and respiratory co-morbidities that must be considered.

### Practice Expense for Revised E/M codes: Removal of Equipment Item ED021 (computer, desktop, with monitor)

IDSA respectfully disagrees with the Agency proposal to remove equipment item ED021 (computer, desktop, monitor) as a direct practice expense for the revised E/M office visit codes. The computer, as a proxy for a laptop, is used during direct patient care to review relevant medical history, laboratory tests, review X-rays and other diagnostic tests as well as previous chart notes. The computer is then used to record the current visit notes including history, physical exam, and documentation of care recommendations. During a patient encounter, the computer is being used for a single patient and cannot be used with another patient simultaneously, nor can it be used with multiple patients. Therefore, by definition, this is considered a direct practice expense. IDSA asks the Agency to retain equipment item ED021 (computer, desktop, with monitor) as a direct practice expense. Alternatively, the Agency may consider adding a laptop equipment item with a separate ED code to then include in the practice expense for office visit/outpatient E/M visits.

# Comment Solicitation on Opportunities for Bundled Payments under the Physician Fee Schedule (PFS)

Citing several examples of bundled payment models that are being tested by the Innovation Center, CMS is seeking comment on "opportunities to expand the concept of bundling to recognize efficiencies among physicians' services paid under the PFS" and seeks ideas that can be applied "within the statutory framework of the PFS." We note that CMS existing bundled payment programs have proven problematic given their application of population-based quality measures that are often not meaningful to the providers in the bundled payment, as well as challenges with appropriate physician attribution. In addition, ID physicians are specifically concerned that CMS bundled payment programs fail to account for the efforts of ID physicians in leading the establishment of important system-wide and facility-level programs (e.g., antimicrobial stewardship programs, infection control and prevention) that serve as a foundation for high-quality care. At present, there are no reportable codes and associated RVUs to account for this work, making it even more difficult for ID physicians to meaningfully contribute in the suggested bundles that would be limited to the PFS. We urge CMS to reconsider moving forward with new bundled payment models until all the associated complexities of such models have been thoroughly studied and addressed.

We also believe that ID physicians, and the care they provide, should be included in the development bundled payment programs since nearly any health care interaction (surgery, illness, hospitalization) could lead to an infection, thereby requiring the services of ID physicians.

There are numerous studies, some supported through IDSA, which prove the value that ID physicians provide when involved in the care of patients with severe infections, as compared to patients with severe infections whose care does not involve an ID physician. 1,2,3,4,5,6 This "value" is reported in outcome measures which include decreased mortality, decreased length-of-stay, decreased hospital readmissions and lower costs. We suggest that the development of bundled payments under the PFS must always consider the resources needed when ID physicians are involved in the care of a Medicare patient.

#### **Care Management Services**

In an effort to increase beneficiary access to care management services, CMS proposes to: 1) increase payment for Transitional Care Management (TCM) services and revise its requirements to allow TCM codes to be billed concurrently with certain other services; 2) establish and make payment for a set of G-codes for certain chronic care management (CCM) services and adjust billing requirements related to typical plan care elements; and, 3) establish separate coding and payment for Principal Care Management (PCM) services. IDSA supports CMS care management proposals and urges the agency to finalize them.

We believe it is prudent to proceed with new G-codes to immediately improve beneficiary access to these services. Additionally, IDSA is particularly pleased with CMS PCM proposals, as they help to recognize the important role ID physicians and other specialized practitioners have in the management of chronic diseases. ID physicians routinely manage chronic illnesses, including patients with HIV, *Clostridioides difficile* and other infections. Again, we support the care management proposals of CMS and urge the Agency to finalize these policies.

#### **Review and Verification of Medical Record Documentation**

Following significant input from stakeholders and expanding on its previously finalized policy, CMS proposes to "establish a general principle to allow the physician, the PA, or the APRN who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team." CMS specifically states that this would apply to all Medicare-

Schmitt et al. Infectious Diseases Specialty Intervention Is Associated with Decreased Mortality and Lower Healthcare Costs. Clinical Infectious Diseases, Volume 58, Issue 1, 1 January 2014, Pages 22–28, https://doi.org/10.1093/cid/cit610

<sup>&</sup>lt;sup>2</sup> Schmitt et al. Early Infectious Diseases Specialty Intervention Is Associated with Shorter Hospital Stays and Lower Readmission Rates: A Retrospective Cohort Study. Clinical Infectious Diseases, ciy494, https://doi.org/10.1093/cid/ciy494

<sup>&</sup>lt;sup>3</sup> 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. Clinical Infectious Diseases 2015; 60:1451–61

<sup>&</sup>lt;sup>4</sup> Hamandi B, Husain S, Humar A, Papadimitropoulis EA. Impact of Infectious Disease Consultation on the Clinical and Economic Outcomes of Solid Organ Transplant Recipients Admitted for Infectious Complications. Clinical Infectious Diseases 2014; 59: 1074-1082

<sup>&</sup>lt;sup>5</sup> Spec A, Olsen MA, Raval K, Powderly WG. Impact of Infectious Diseases Consultation on Mortality of Cryptococcal Infection in Patients Without HIV. Clinical Infectious Diseases, Volume 64, Issue 5, 1 March 2017, Pages 558–564, <a href="https://doi.org/10.1093/cid/ciw786">https://doi.org/10.1093/cid/ciw786</a>

<sup>&</sup>lt;sup>6</sup> Burnham JP et al. Infectious Diseases Consultation Reduces 30-Day and 1-Year All-Cause Mortality for Multidrug-Resistant Organism Infections. Open Forum Infectious Diseases, Volume 5, Issue 3, 1 March 2018, ofy026, <a href="https://doi.org/10.1093/ofid/ofy026">https://doi.org/10.1093/ofid/ofy026</a>

covered services paid under the Medicare Physician Fee Schedule. We appreciate the additional clarification and support of this proposal.

#### Comment Solicitation on Consent for Communication Technology-Based Services

CMS seeks comment on whether a single advance beneficiary consent could be obtained for several communication technology-based services, in which the practitioner would make sure the beneficiary is aware that utilization of these services would result in a cost-sharing obligation. We wholly support a single advance beneficiary consent for communication technology-based services, allowing practices to seek beneficiary consent for communication technology-based services. In response to CMS' question about the appropriate interval of time or number of services for which consent could be obtained, it seems reasonable that beneficiary consent should cover any combination of communication technology-based services that the physician and beneficiary agree may be necessary and that span a period of one-year from the date beneficiary consent is obtained. We do not believe any additional program integrity efforts will be necessary outside of the current audit programs.

#### Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy

As a result of the passage of the 21st Century Cures Act, a separate benefit was created to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously through a pump that is an item of durable medical equipment (DME) in the beneficiary home, beginning January 1, 2021. Prior to the furnishing of home infusion therapy to an individual, the law stipulates that the physician who establishes the therapy plan for the individual shall provide notification of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy. As such, CMS solicits comments regarding the appropriate form, manner and frequency that any physician must use to provide notification of the treatment options available to their patient for the furnishing of infusion therapy under Medicare Part B. CMS also invites comments on any additional interpretations of this notification requirement.

As stated in our comments on the Home Infusion Therapy Requirements outlined in CMS CY 2020 Home Health Prospective Payment System (HH PPS) proposed rule, we are concerned that CMS failed to adequately consider the provision of Outpatient Parenteral Antimicrobial Therapy (OPAT) by ID physicians under the benefit. As a result, we are challenged in our ability to answer CMS questions because the underlying policy that CMS has proposed for the permanent home infusion therapy benefit is flawed. In fact, if CMS finalizes the permanent home infusion benefit as proposed, it is unlikely that OPAT will be accessible by beneficiaries at all, thus eliminating an option a physician could share with this subset of patients.

We shared in our HH PPS comments that most ID physicians in clinical practice use OPAT, which allows patients to be discharged from the hospital to complete their antimicrobial course of therapy at home, rather than remain as an inpatient or be transferred to a post-acute care (PAC) facility. ID physicians actively oversee care transitions associated with OPAT, providing monitoring and longitudinal support to ensure patients are effectively and safely treated. This ID

oversight is particularly important as there is a complex and sometimes fragmented healthcare home delivery process that involves pharmacy operations, DME supplies, home health professional services, safety-based laboratory testing, and other physician services.

We remain concerned with CMS proposed policies for the permanent home infusion therapy benefit, and specifically the CMS definition of "infusion drug administration calendar day," which will inappropriately limit beneficiary access to OPAT. This is because CMS states that "it is necessary for the qualified home infusion therapy supplier to be in the patient's home, on occasions when the drug is being administered in order to provide an accurate assessment to the physician responsible for ordering the home infusion drug and services." This statement does not reflect the standard-of-care for the majority of OPAT cases whereby recipients can be adequately trained to perform the OPAT infusion without requiring a skilled professional to be present.

Moreover, there are OPAT cases requiring multiple infusions per day (depending on the pharmacokinetics of the antimicrobial selected for therapy) that, under CMS policy, would require a skilled professional to make multiple visits to a patient home in the same day. If finalized, home infusion providers will find these cases less desirable, and ID physicians could be forced to order a more expensive drug with once-a-day dosing, or prescribe a less preferred drug for treatment of the infection, which would limit the number of skilled visits but eliminate the cost-savings potential for OPAT given the increased drug costs.

We urge CMS to review our comments on the Home Health proposed rule for 2020 and finalize policies that will ensure beneficiary access to lifesaving, high quality and cost-effective OPAT services.

# Medicare Enrollment of Opioid Treatment Programs and Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm

We are concerned that CMS enrollment policies concerning improper prescribing are duplicative of current safety mechanisms, create an unnecessary administrative burden for clinicians, and continue to "second guess" the clinical judgment of physicians. More importantly, these policies do not ensure access to innovative care and treatment regimens for certain beneficiary populations. For example, what may be considered excessive prescribing for the general population could be clinically appropriate depending on a patient's individual circumstances, particularly in certain diseases and conditions. Indeed, many "off-label" uses of Part B and Part D drugs are clinically appropriate and represent the standard-of -are.

Moreover, the CMS proposal to add a new revocation and denial reason that would permit CMS to revoke or deny, as applicable, a physician's enrollment if he or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. This rule is a significant overreach by the Agency. First, the factors CMS would consider in making a revocation or denial decision are not automatic indicators of patient harm. As proposed, CMS could revoke or deny enrollment to a clinician based on a single administrative or monetary penalty. Further, including "any other information that CMS deems relevant to its determination" as a factor

provides overly broad authority to CMS in making enrollment decisions. Importantly, CMS provides no information on how it would even apply these factors (i.e., what is the standard on which CMS will decide if there are enough grounds to revoke or deny enrollment based on patient harm?).

A Medicare enrollment revocation or denial – and its extension to other federal health programs (e.g., Medicaid) – based on uncertain evidence of patient harm is irresponsible. It would cause devastating and unnecessary financial damage to a physician's practice and, more importantly, negatively impact beneficiary access to care. IDSA opposes these policies and urges CMS to withdraw them.

#### **MIPS Value Pathways**

IDSA appreciates the efforts of CMS to develop a more cohesive MIPS participation experience for clinicians by way of the MIPS Value Pathways (MVPs). CMS states the four guiding principles that would be used to define MVPs are as follows:

- 1. MVPs should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to the selection of measures and activities, simplify scoring, and lead to enough comparative data.
- 2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care.
- 3. MVPs should include measures that encourage performance improvements in high priority areas.
- 4. MVPs should reduce barriers to alternative payment model (APM) participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

IDSA is generally supportive of these guiding principles, as they aim to ensure the measurement is impactful to patient care as well as to reduce reporting burden by decreasing the total number of measures and activities required to be reported across all four performance categories. With current MIPS reporting requirements, an eligible clinician is required to report on six quality measures, up to four improvement activities (IAs), and must report on at least six promoting interoperability (PI) measures and attest to three PI statements to satisfactorily participate in MIPS. Although IDSA is supportive of the MVP initiative, CMS should move away from arbitrary minimum requirements and recognize that each MVP will be unique and should include only as many measures as are relevant to the episode and meaningful to both the clinician and patient.

IDSA also has concerns with using currently available MIPS quality measures to build MVPs as there is a lack of meaningful quality measures for ID physicians. Historically, quality measures available in the Physician Quality Reporting System (PQRS) have not aligned well with ID clinical practice and continue to be misaligned with the transition to the Quality Payment

Program (QPP). Aside from Human Immunodeficiency Virus (HIV) Hepatitis C virus (HCV) quality measures, which are only meaningful to a small proportion of ID physicians in the outpatient setting who focus on these disease areas (as opposed to General ID), there are very few ID-specific measures upon which ID physicians can report avoiding payment penalties. As previously stated in past IDSA comment letters, ID physicians are not "proceduralists" but rather cognitive specialists, providing most of their services using Evaluation & Management (E/M) codes. Across all ID physicians in clinical practice, many E/M codes billed are for services provided in the inpatient setting (e.g., 78 percent of 2017 Medicare claims billed by ID physicians were at the facility place of service).

ID physicians are integrally involved in population health through their leadership in developing and managing infection control and prevention and antimicrobial stewardship programs respectively. In developing MVPs, CMS recommends the use of administrative claims-based population health level quality measures, but as with the currently available MIPS quality measures, there are few reporting opportunities that are relevant to an ID physician's work at the population health level. According to the Measure and Activities Explorer tool available on the QPP website, the All-Cause Hospital Readmission is the only administrative claims quality measure available that may have relevance to ID physicians. As with the facility-based measurement option for eligible clinicians, CMS should explore the use of measures within the CMS hospital and other facility-level quality reporting programs to incorporate cross-cutting, outcome measures that are applicable to a wide variety of eligible clinicians and do not require active clinician quality data submission.

We would like to express our interest in collaborating with CMS to develop MVPs regarding topics such as but not limited to antibiotic resistance, infection control and prevention, antimicrobial stewardship, HIV, and Hepatitis C.

#### **Quality Performance Category**

Overall, IDSA is concerned about the limited number of ID-specific quality measures available for MIPS reporting, as well as the ongoing removal of specialty-focused measures – including those focused on ID quality – through CMS' Meaningful Measures Framework. For the 2020 performance period and future years, CMS proposes to remove 55 previously finalized quality measures (including 1 measure from the CMS Web Interface). However, the removal of these measures – including the designation of key ID measures as "topped out" – is contrary to the stated goals of this initiative. When specialty-focused measures are removed, the MIPS program becomes less relevant to specialists and the patient populations they serve, eliminates opportunities to improve care in key conditions identified by specialty societies, increases burden by forcing specialists to report measures that do not apply, and fails to provide meaningful information to change behavior in areas where specialists have control. It also creates barriers to future engagement in APMs, as specialists will have few opportunities to demonstrate their value in the diagnosis, treatment, and management of key conditions.

"Topped Out" Measures. IDSA strongly urges CMS to reconsider the topped-out designation for Quality ID #407 Appropriate Treatment of Methicillin-Susceptible Staphylococcus aureus

(MSSA) Bacteremia. Although this measure is considered standard-of-care, we believe that it is inappropriate to consider removing a quality measure that promotes the appropriate use of antibiotics at a time when antimicrobial resistance is a global health emergency. Additionally, 2019 is the first year that this measure has had a benchmark. We believe it is too early to categorize the performance of this measure to be "unvarying." In the upcoming 2020 MIPS performance year, revisions to the measure were approved to include patients that are diagnosed with *S. aureus* bacteremia rather than only sepsis due to MSSA. This patient population expansion may allow for a more accurate measure of performance for the appropriate treatment of MSSA bacteremia.

In addition, for measures that are not reported frequently enough to establish a benchmark, CMS should incent their reporting by offering bonus points rather than eliminate the measures altogether.

Regarding special circumstances for topped-out status exemption, IDSA would like to suggest for consideration the use of recommendations developed by global and national health organizations such as the World Health Organization Ten Threats to Global Health list and the Centers for Diseases Control and Prevention Antibiotic Resistance Threats report to identify high priority areas that would be exempt for topped-out designation. Doing so may lead to better alignment of clinical focus to improve patient lives.

### **Cost Performance Category**

IDSA appreciates CMS transparency in sharing its thought process for considering the weight of the cost performance category for performance years 2020 and 2021. IDSA is concerned with increasing the weight of the cost performance category, as many of the cost measures have flawed methodologies or have resulted in low-reliability rates when testing was conducted. Additionally, CMS contractor work is still ongoing to develop episode-based cost measures in the MACRA Episode-Based Cost Measures – Clinical subcommittee Wave 3 project. IDSA has concerns regarding the hastily conducted field testing for the MACRA Episode-Based Cost Measures – Clinical subcommittee Wave 1 project that resulted in inadequate clinician feedback. Further, only three of the 18 measures proposed for the 2020 MIPS performance year received NQF endorsement. Additionally, among the Wave 1 episode-based cost measures that have been implemented into MIPS, only three were endorsed by NQF. The remaining five measures were not endorsed by NQF due to lack of scientific acceptability. Lastly, for the MACRA Episode-Based Cost Measures Clinical Subcommittee Wave 2, none of the 10 measures have been reviewed by NQF yet. Holding eligible clinicians accountable for the cost-of-care for Medicare patients that have not been rigorously tested and reviewed by NQF is unreasonable. <u>IDSA urges</u> CMS to work with legislators to extend the deadline for weighting the cost performance category to 30 percent. We would also suggest that CMS extensively use trials and testing periods for all newly developed episode-based cost measures to ensure high reliability and validity. Finally, we would like to note that IDSA members are actively involved in building episode-based cost measures, as we currently have four physicians who are a part of the Wave 3 Sepsis group. IDSA welcomes further opportunities to collaborate with CMS in the development of episode-based cost measures.

#### **Improvement Activities Performance Category**

Despite clarification in its proposed rule that Improvement Activities (IAs) requiring "significant investment of time and resources should be high-weighted," CMS failed to increase the weight for "Implementation of an Antibiotic Stewardship Program (ASP) (IA\_PSPA\_15)" as requested by IDSA. We continue to believe this IA should be designated as "high-weight" due to the extensive amount of effort and cross-disciplinary resources that are required to implement an ASP, not to mention the enormous importance of this activity for public health. To calculate the significant investment of time and resources to sustain an ASP, Doernberg et al surveyed two hundred forty-four members of IDSA, SHEA, and PIDS and developed a full-time equivalent (FTE)-to-bed ratio that can be used as a starting point to resource effective hospital ASPs. Using these data, the authors proposed that an ASP at a 100-500 bed hospital requires 0.4 physician FTEs with 501-1000 and >1000 bed hospitals requiring 0.6 FTEs and 1.0 FTEs respectively.<sup>7</sup>

Ironically, CMS has designated "Completion of CDC Training on Antibiotic Stewardship (IA\_PSPA\_23)," as a high-weighted IA. However, this IA is only one component of implementing an ASP (IA\_PSPA\_15). As previously noted, this discrepancy promotes a confusing and inconsistent message to participating clinicians and beneficiaries about the significance of efforts to combat antimicrobial resistance. Decreasing antimicrobial resistance has been identified as a national strategic priority. We again urge CMS to revise the weighting of "Implementation of an Antibiotic Stewardship Program (ASP) (IA\_PSPA\_15)" to a high-weight activity.

As the QPP enters its fourth year, we appreciate the Agency removing barriers and facilitating easier participation in MIPS. We look forward to furthering dialogue with CMS on how the program can evolve towards more relevant quality measurement focused on meaningful health outcomes.

We appreciate the time and effort that CMS has put into the proposed revisions for the 2020 MPFS and QPP. If you have any questions, please contact Kay Moyer, Program Officer, Clinical Affairs on 703-721-8493 or kmoyer@idsociety.org.

Sincerely,

Cynthia L. Sears, MD, FIDSA

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President, IDSA

<sup>&</sup>lt;sup>7</sup> Sarah B Doernberg, Lilian M Abbo, Steven D Burdette, Neil O Fishman, Edward L Goodman, Gary R Kravitz, James E Leggett, Rebekah W Moehring, Jason G Newland, Philip A Robinson, Emily S Spivak, Pranita D Tamma, Henry F Chambers, Essential Resources and Strategies for Antibiotic Stewardship Programs in the Acute Care Setting, Clinical Infectious Diseases, Volume 67, Issue 8, 15 October 2018, Pages 1168–1174, <a href="https://doi.org/10.1093/cid/ciy255">https://doi.org/10.1093/cid/ciy255</a>