



IDSAs

Infectious Diseases Society of America

2019-2020 BOARD OF DIRECTORS

President
Thomas M. File, Jr., MD, MSc, FIDSA
SUMMA HEALTH
AKRON, OH

President-Elect
Barbara D. Alexander, MD, MHS, FIDSA
DUKE UNIVERSITY
DURHAM, NC

Vice President
Daniel P. McQuillen, MD, FIDSA
BETH ISRAEL LAHEY HEALTH
LAHEY HOSPITAL & MEDICAL CENTER
BURLINGTON, MA

Secretary
Angela M. Caliendo, MD, PhD, FIDSA
ALPERT MEDICAL SCHOOL OF BROWN UNIVERSITY
RHODE ISLAND HOSPITAL
PROVIDENCE, RI

Treasurer
Helen W. Boucher, MD, FIDSA
TUFTS MEDICAL CENTER
BOSTON, MA

Immediate Past President
Cynthia L. Sears, MD, FIDSA
JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE
BALTIMORE, MD

Jeffrey S. Duchin, MD, FIDSA
PUBLIC HEALTH – SEATTLE & KING COUNTY
UNIVERSITY OF WASHINGTON, SEATTLE
SEATTLE, WA

Victoria J. Fraser, MD, FIDSA
WASHINGTON UNIVERSITY SCHOOL OF MEDICINE
ST. LOUIS, MO

Kimberly E. Hanson, MD
UNIVERSITY OF UTAH
SALT LAKE CITY, UT

John B. Lynch, III, MD, MPH
HARBORVIEW MEDICAL CENTER
UNIVERSITY OF WASHINGTON
SEATTLE, WA

Ann T. MacIntyre, DO, MHS, FIDSA
PRIVATE PRACTICE
MIAMI, FL

Jeanne Marrazzo, MD, MPH, FIDSA
UNIVERSITY OF ALABAMA AT BIRMINGHAM
SCHOOL OF MEDICINE
BIRMINGHAM, AL

Wendy Armstrong, MD, FIDSA
EMORY UNIVERSITY
ATLANTA, GA

Susan J. Rehm, MD, FIDSA
CLEVELAND CLINIC
CLEVELAND, OH

Tina Q. Tan, MD, FIDSA
NORTHWESTERN UNIVERSITY
FEINBERG SCHOOL OF MEDICINE
CHICAGO, IL

Chief Executive Officer
Christopher D. Busky, CAE

IDSAs Headquarters
1300 Wilson Boulevard
Suite 300
Arlington, VA 22209
TEL: (703) 299-0200
FAX: (703) 299-0204
EMAIL ADDRESS:
info@idsociety.org
WEBSITE:
www.idsociety.org

October 1, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-8016

Re: Comments: **CMS-1734-P** CY2021 Payment Policies Under the Physician Fee Schedule and Quality Payment Program

Dear Administrator Verma,

IDSAs represents more than 12,000 infectious diseases (ID) physicians, scientists and other health care 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 meningitis, pneumonia, tuberculosis, HIV/AIDS, health care-associated infections, and antibiotic-resistant bacterial infections, as well responding to infectious disease outbreaks and emerging infections such as the Ebola virus, Zika virus, and SARS-CoV-2. Over the past many months, our members continue to work vigorously to manage, treat, and oversee the response to the COVID-19 public health emergency (PHE).

With this proposed rule and the interim-final rules, IDSAs thanks the Agency for working with us and other medical specialty societies to help respond to and prepare for pandemics now and in the future. As ID physicians and other health care professionals on the frontlines of the COVID-19 pandemic, we thank you for your commitment and dedication to protecting public health and safety during these unprecedented times. We appreciate your swift action to support the clinician community with waivers and additional flexibilities to care for patients during this public health crisis. It is within this context that we provide our comments for the Medicare Physician Fee Schedule (MPFS) 2021 Proposed Rule.

Impact of Evaluation and Management Changes on the Physician Fee Schedule

Beginning January 1, 2021, CMS will implement its previously finalized revisions to office/outpatient evaluation and management (E/M) services and make payment for services associated with complex patient care through a new “add-on” code (i.e., GPC1X). The sum of these policies, along with other proposals outlined in this rule, will result in a 10.61 percent reduction to the CY 2021 MPFS conversion factor, including a 4 percent reduction in payments to ID physicians, in order for the agency to meet its statutory budget neutrality requirements.

IDSAs participated in and supported the process to update the office/outpatient E/M service values, as well as to revise the associated documentation requirements, anticipating CMS would soon work with the physician community to similarly update and revise the inpatient E/M service codes, which ID physicians primarily bill. While we continue to support prompt implementation of the new E/M values, the 4 percent reduction comes at a time when ID physicians are working tirelessly on the front-lines of the COVID-19 PHE, leading and coordinating pandemic-centered activities within their respective facilities and clinical practices. This reduction adds to existing financial pressure on a specialty already experiencing a decrease over the past decade in trainee applicants thereby threatening to further decrease critical access for Medicare beneficiaries.

In stark contrast, Medicare hospitals will realize a positive payment update of 2.4 percent, as well as a 20 percent increase in DRG weighting for their inpatients with confirmed COVID-19 diagnoses. These same hospitals have increased ID physicians’ workload while, in many cases, reducing physician pay, further exacerbating the negative financial impact on ID physicians.

We encourage CMS to work with Congress to mitigate the reduction in Medicare payments to ID physicians due to budget neutrality requirements concurrent with its implementation of the revised office/outpatient E/M service values. Additionally, we offer below a proposed mechanism that can be taken by CMS now to improve payment to ID and other front-line physicians for COVID-19 related activities.

Professional Services Claims-based Payment Enhancement for Activities Associated with a Pandemic

IDSAs sincerely appreciate the actions CMS and HHS have taken to address the ongoing COVID-19 pandemic as well as the ongoing conversations the Agency has been willing to have about what more can be done to ensure that clinicians have the resources to confront the pandemic and, eventually, engage in a swift recovery post-PHE. IDSAs believe a long-term policy that ensures additional resources can be made quickly available when future epidemics arise will be crucial to improving our collective response to infectious disease outbreaks. In the meantime, however, we believe that short term solutions are warranted to address needs in the current PHE.

We previously provided CMS with a proposal concept—a professional services claims-based payment enhancement—that would quickly channel resources to health care practitioners on the frontlines of the COVID-19 pandemic. The proposal, now supported by additional specialty organizations including the Society of Hospital Medicine and the American College of

Emergency Physicians, is intended to help achieve the policy goal of recognizing the enhanced, non-separately reimbursable work performed by physicians during the COVID-19 PHE by providing a 20% reimbursement enhancement for professional claims (without regard to specialty designation) submitted with dates-of-service during the PHE where the ICD-10 codes meet the criteria established for COVID-19 testing and treatment coverage under the [HRSA COVID-19 Uninsured Program](#).

Implementation of this proposal would direct resources to the physicians that are performing patient care services that require enhanced direct and indirect work to effectively treat patients with COVID-19 and perform additional, critical activities associated with managing a pandemic.

Examples of such direct activities include:

- Donning and doffing personal protective equipment (PPE) and following new infection control protocols
- Increased time for patient/family communication and communicating between provider service lines
- Expanded cleaning protocols necessitating slower turnaround time on bed space
- Increased time for conducting procedures and interventions with patients with known or suspected COVID-19 infection
- Follow-up for patients under investigation

Examples of indirect activities include:

- Monitoring the flow of new research and information
- Studying constantly changing treatment and management protocols
- Reconciling and adjudicating incongruous or conflicting findings such as understanding asymptomatic transmission during this pandemic or any other
- Supervising other physician specialties that were deployed to assist in the care of COVID-19 patients
- Leading, managing, and advising groups of staff dedicated to evaluating, implementing, and interpreting testing platforms, exposure management, PPE procurement, and associated activities during a pandemic, including contingency functioning related to supplies staff and limited physical capacity
- Daily contingency planning related to ICU and ventilator capacity
- Setting up and operating remote locations such as tents and triage areas
- Creating and managing protocols for isolation of infected or exposed patients and staff
- Crafting visitor and staffing policies
- Triage education ongoing for COVID-19 split flow
- Management of other work processes not associated with direct patient care but that is required and necessary to effectively manage a pandemic
- Providing emotional support for staff

Other activities may include:

- Planning to safely resume elective procedures, including developing protocols for distancing, testing, sanitation, hygiene and availability and distribution of personal protective equipment
- Advising local schools on safe reopening
- Collaborating with state and local health departments on public messaging to reduce transmission
- Providing advice and preparing alternative housing for providers isolating from their families
- Capturing and reporting COVID-19 related data

Setting the payment enhancement at 20%, the policy would be consistent with (a) the level set for Modifier ~22 (for enhanced *procedural* services), and (b) [20% MS-DRG weight increase](#) under the IPPS for hospital admissions for patient with COVID-19 diagnoses.

The enhancement could be administered via the usual claims process. The payments for such activities should be retroactive to include services provided during the entirety of the declared PHE.

IDSA appeals to CMS to implement this COVID-19 professional services claims-based payment enhancement as quickly as possible to address the ongoing needs of the COVID-19 pandemic. Recognizing that there are often limited rulemaking vehicles in which to implement policies, IDSA therefore recommends that CMS issue this policy with the status of “interim final with comment” packaged inside the CY 2021 Medicare Physician Fee Schedule Final Rule.

We believe it is important to highlight that this request is specifically designed to focus on efforts that are *not* recognized under the current statutory and agency-established guidelines for *The CARES Act* Provider Relief Fund General Distributions. As you are well aware, the General Distributions of the Provider Relief Fund have been intended to provide support for “healthcare-related expenses or lost revenue attributable to the coronavirus,” but not for the increased level of effort demanded by delivering care in this environment. In addition, HHS has made efforts via Targeted Distributions to aid *facilities*, but we are not aware of instances in which that assistance has been passed on to the physician practices providing services in the hospitals that received the Targeted Distributions. In fact, we have been provided accounts that highlight the opposite- that the assistance provided to hospitals in the form of Targeted Distributions is affirmatively not making its way to the physicians affiliated with those hospital recipients.

Visit Complexity Add-on Code GPC1X

IDSA continues to support the implementation of GPC1X to report care associated with a patient’s single, serious, or complex chronic condition. 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.

Healthcare Common Procedure Coding System (HCPCS) add-on code GPC1X was designed to recognize the resources inherent in engaging the patient in a continuous and active collaborative plan of care related to an identified health condition, the management of which requires the direction of a physician with specialized clinical knowledge, skill and experience. Such collaborative care includes patient education, expectations and responsibilities, shared decision-making around therapeutic goals, and shared commitments to achieve those goals.

The GPC1X add-on code captures the additional patient-based work “intensity” arising from three input categories not included in the existing outpatient E/M service codes: (1) the **clinical complexity of the care provided** by an ID physician in the context of patient characteristics; (2) the **nature of the physician-patient relationship** developed and maintained, in many cases indefinitely; and (3) the **responsibility** assumed by physicians to continually update and maintain their knowledge-base required to deliver cognitively intense services.

In addition, the GPC1X captures the work associated with the continuous and comprehensive care of a single condition or a cluster of conditions which our physicians are most often called upon to treat.

Finally, GPC1X addresses the issue of maintaining cognitive care expertise, an input that outpatient E/M codes have never captured. The need to constantly update and revise the clinical knowledge-base for ID physicians, particularly during a pandemic, is a characteristic of the clinical competencies required for the type of outpatient E/M care provided to our patients.

Given the above, IDSA supports the implementation of code GPC1X, without delay on January 1, 2021. Further, and consistent with our comments above, we request CMS allow reporting of the GPC1X add-on code in conjunction with inpatient E/M codes until such time those services are revalued in a future MPFS rulemaking.

The Agency has asked for comments on when GPC1X may be reported within the context of specialty care. The following is a real-world clinical case example of the type of patient for which we believe the add-on code would be used by an ID physician in the office/outpatient setting.

A 67-year-old man with history of diabetes, atrial fibrillation and hypertension develops a foot ulcer- and is eventually diagnosed with osteomyelitis with MRSA and a multi-drug resistant *Proteus*. Patient is treated with a six-week course of intravenous antibiotics (vancomycin and ertapenem). The patient requires wound care, and a wound vacuum is placed. During the six-week antibiotic treatment course the patient requires close monitoring of his creatinine, vancomycin levels and INR, as the antibiotics cause a change in the steady dose of Coumadin he has been taking for his atrial fibrillation. The patient requires weekly wound vacuum changes and, while on the antibiotics, subsequently develops *Clostridioides difficile* infection.

The ID physician in this example not only monitors the patient’s weekly blood count, creatinine and vancomycin levels, but also coordinates care with the primary care physician and cardiologist to adjust the Coumadin dose. Further, the ID physician

coordinates care with the podiatrist regarding wound care and the use of the wound vacuum. On development of *Clostridioides difficile* infection, oral vancomycin is started, and the infectious diseases physician must now monitor the patient via phone calls every two days, check his potassium level and other electrolyte levels and arrange for supplementation via the IV route as needed. This care is administrated in the outpatient setting in order to avoid hospitalization, which both the clinical team and the patient wish to avoid unless necessary.

To deliver this care the ID physician spends approximately 20 minutes, three times per week for two weeks, and subsequently about 30 minutes weekly until the patient finishes the course of IV antibiotics.

The above clinical example highlights the simultaneous, interacting clinical needs and conditions observed among many Medicare patients, who may also be taking multiple medications that add an additional layer of complexity to their care. Providing this care often requires an ID physician to reconcile drug-to-drug interactions, manage and collaborate with other health care practitioners, all the while managing the needs and expectations of the patient, further highlighting the complexity of care involved in treating patients with an infectious disease and multiple co-morbidities.

Telehealth and Other Services Involving Communication Services

Coding and Payment for Virtual Services:

In recent years, CMS has established separate coding and payment for several services that use telecommunications technology but are not considered Medicare telehealth services. For example, CMS established Communication Technology-Based Services (CTBS), which includes virtual check-ins, remote evaluation of images and Interprofessional Internet Consultations. CMS also created six non-face-to-face codes to describe and reimburse for "patient-initiated digital communications that require a clinical decision that otherwise typically would have been provided in the office," also known as e-Visits. We greatly appreciate CMS' efforts to improve access to virtual care services through CTBS and e-Visits.

In this rule, CMS seeks comment on any impediments that contribute to health care provider burden and that may result in practitioners being reluctant to bill for CTBS. We note that CMS addressed a key administrative burden last year associated with beneficiary consent when it permitted a single consent to be obtained for multiple CTBS or interprofessional consultation services, which must be renewed annually. Thus far, we have not heard concerns from our members regarding the use of these codes or issues with the current consent policy. However, it would be helpful if CMS provided data on specialty-specific uptake of CTBS and e-Visits, both before and after the COVID-19 PHE, to determine if there are access challenges in specific specialties, including ID. At that point, IDSA can work with CMS to improve outreach and education efforts in this area.

CMS is also seeking comment on physicians' services that use evolving technology to improve patient care that may not be fully recognized by current MPFS coding and payment. IDSA would be interested in exploring possible coding and payment for virtual care services that improve patient care, but do not necessarily involve *direct* patient care. As ID physicians, we often provide consultative services (using virtual and other platforms) to hospitals and other facilities to help them improve activities that have a direct impact on patient care and outcomes, such as antimicrobial stewardship, and infection control and prevention. Our role in improving these facility-level processes are currently unreimbursed, because there is no mechanism for Medicare payment (i.e., there are no billing codes and payment amounts assigned for population-level care). We welcome the opportunity to discuss how to correct this deficiency.

Furnishing Telehealth Visits in Inpatient and Nursing Facility Settings and Critical Care Consultations:

Disappointingly, CMS did not propose to remove the frequency limit on subsequent inpatient hospital visits, which is currently set at 3 days. In general, we believe that frequency limitations usurp clinician judgement and expertise in favor of arbitrary controls that hinder access to medically necessary care. In the case of ID, subsequent inpatient hospital visits may be warranted at intervals outside of these parameters, particularly where patients have been diagnosed, or are in the process of being diagnosed, with complex infectious diseases. As such, we urge CMS to reconsider its policy and remove subsequent inpatient hospital visits limitations, allowing clinicians to make care decisions based on clinical needs of their patients.

Continuation of Payment for Audio-only Visits:

IDSA is grateful for the additional regulatory flexibilities that allow physicians and other health care practitioners to conduct audio-only telephone E/M visits during the COVID-19 public health emergency (PHE). This provided patients, especially seniors and the immune-compromised, with another mechanism to access medically necessary care and treatment while adhering to CDC guidance to shelter in place, thus mitigating the spread of the SARS-CoV-2 virus.

ID physicians, along with other medical specialties, are leading efforts to address the ongoing pandemic. However, given the distribution of ID physicians in the US is geographically skewed¹, nearly two thirds of all Americans live in the 90% of US counties with limited or no access to their expertise. While Medicare telehealth has improved access to ID care and treatment overall, the availability of audio-only visits has helped ID physicians significantly expand their capacity during the pandemic, providing care and treatment for greater numbers of patients with, or suspected of having, COVID-19.

Beyond COVID-19, our patient population includes those with some of the most complex and devastating illnesses, including HIV/AIDS, hepatitis and other communicable diseases. It is well established that these patients face greater challenges accessing health care due to a variety of social determinants, including homelessness and economic instability. Many of our patients do

¹ <https://www.acpjournals.org/doi/10.7326/M20-2684>

not have access to broadband internet, “smart phones” or other technology, while others live in crowded locations (e.g., YMCAs, public shelters) with limited or no privacy. Due to these and other challenging circumstances, an audio-only visit may be the only way to provide care.

As such, IDSA strongly recommends that CMS establish policies making audio-only telephone E/M visits a permanent fixture in the Medicare program. In addition, we urge CMS to make payment for these visits at the same rate as in-person visits. We submit that the physician effort in providing audio-only visits is no less than when providing in-person visits, which is demonstrated in the clinical examples below:

Clinical Example #1

A 72-year-old man who lives in rural Ohio is diagnosed by bronchoalveolar lavage with pulmonary blastomycosis. He is started on itraconazole by a local physician. Shortly after, the patient is hospitalized with increasing shortness of breath. He is thought to have pulmonary edema due to heart failure and is diuresed in the hospital. However, the treating physicians thought it might be worsening of his blastomycosis and refers him to the Infectious Diseases Clinic upon discharge. The patient did not present in-person due to COVID-19 restrictions and did not have reliable broadband internet service at home for a video visit. Phone conversation with the patient revealed a very unwell man: exhausted, dehydrated, dry mouth and weak. The ID physician consulting on the case suspected that his heart failure may have been due to high itraconazole levels. Without seeing the patient, in-person or by video, the ID physician tells the patient to go to a local laboratory to assess his itraconazole levels, the result of which revealed toxic levels. The ID physician reduces his dose and makes sure he is in the therapeutic, but not toxic, range. Over time, the patient can wean off the diuretic and beta-blocker that had been started in the hospital, which was not needed now that he does not have toxic itraconazole levels. These unnecessary medications were making the patient feel exhausted, dehydrated, and weak. The patient completes his course of treatment for blastomycosis and feels like his normal self after stopping the unnecessary medications for heart failure.

Clinical Example #2

An 87-year-old Spanish-speaking gentleman with significant medical conditions (HIV, CKD, diabetes, recent chemotherapy for diffuse large B cell lymphoma, limitations to vision, limitations to manual dexterity) has relied on phone visits since the start of the pandemic. Living on his own and with limited digital literacy, he does not feel able to do video visits without help. Without phone visits he would be required to visit the clinic, which would potentially expose him to the SARS-CoV-2 virus.

Clinical Example #3

A 65-year-old English-speaking gentleman with significant medical comorbidities (HIV, hepatitis B, renal cell carcinoma) has a phone but intermittently can't afford the additional cost of data speeds or data amounts to support video visits. He has relied on phone visits since the start of the pandemic in order to stay engaged in care.

Clinical Example #4

A 70-year-old Somali-speaking woman with chronic hepatitis B and a recurrence of lymphoma is being considered for immunosuppressive therapy with Rituxan. She elects for her first visit with the ID physician to be conducted using audio-visual telemedicine, as she had recently had COVID-19 and recently had a stroke. Unfortunately, she is unable to figure out the video interface and so a phone visit is necessary. This was an incredibly complex medical situation with a high risk of hepatitis B flare and fulminant hepatitis if put on chemotherapy without hepatitis B therapy. She did not tolerate the first month of hepatitis B antivirals. Conducting patient care using audio only option was crucial to her care.

Again, we encourage CMS to establish permanent coverage of audio-only telephone E/M visits at a payment rate equal to in-person visits. As demonstrated in the clinical examples above, the physician work, time and intensity of an audio-only visit is equivalent to that of an in-person visit. Moreover, physicians must still access and navigate patient information in their electronic health record (EHR) systems and query clinical decision support and other tools during the visit, just as they would in the office setting. As such, audio-only and in-person visits should be reimbursed equally. We submit that differences in payment should be related to medical complexity, time and other relevant factors – not the mode of delivery.

Quality Payment Program

MIPS Value Pathways Guiding Principles:

IDSAs appreciate CMS' decision to delay the implementation of MIPS Value Pathways until the 2022 MIPS performance period or later due to the COVID-19 PHE. IDSA continues to support the overarching goal of MVPs which is, as stated on the [Quality Payment Program website](#), "to move away from siloed activities and measures and move toward an aligned set of measure options more relevant to a clinician's scope of practice that is meaningful to patient care."

Responding to CMS commentary on the proposed changes for the MVP Guiding Principles, IDSA is encouraged that CMS is exploring options to reduce clinician quality reporting burden, however we have reservations about the potential for overreliance on administrative claims-based population health measures. While IDSA recognizes the need to have quality measures that can be used to compare performance across many, if not all, medical specialties, and appreciates that administrative claims-based measures could substantially reduce reporting burden for clinicians, we remind CMS of the limitations of claims data and challenges related to appropriate attribution and risk adjustment in the absence of clinical data. IDSA suggests that CMS consider the use of population health measures that incorporate both administrative and clinical data to account for clinical circumstances that cannot be captured by administrative claims-based data alone.

IDSAs are supportive of CMS' plans to enhance comparative performance data by allowing subgroup reporting that comprehensively reflects the services provided by multispecialty groups.

We believe that subgroup reporting could reveal meaningful performance data for specific physicians and specialties within a multispecialty group in a manner that is not possible under the current program. While supportive of subgroup reporting, IDSAs suggest that extensive testing be conducted to ensure that the enhanced data present valid, reliable, and accurate information to patients and multispecialty groups before publicly releasing it to consumers or using it for accountability purposes. Furthermore, we suggest that CMS should also consider implementing subgroup reporting in traditional MIPS group reporting as many specialties may not have applicable MVPs soon.

Lastly, CMS specifies in the proposed rule that MVPs should support the transition to digital quality measures (dQMs). IDSA fully supports CMS' efforts to transition to dQMs, as leveraging technology can lead to a reduction in reporting burden, compliance, and documentation. In developing the specific steps to fully transition to dQMs, IDSA urges CMS to be cognizant of the current state of dQMs in all settings of care and the required resources in the form of staff, expertise, finances, time to implement, and more to bridge the digital divide to the future state of dQMs. Additionally, to build trust among the physicians and other health care professions that would potentially rely on this system of dQMs, buy-in should be sought from stakeholders who would be involved in dQMs such as electronic health record, data analytics and other technology companies; standard setting bodies; and the health care industry in order to ensure coordination and avoid disparate requirements that health care professionals may be required to satisfy, which could be an unintended consequence.

MVP Process for Developing and Evaluating MVP Candidates:

IDSA appreciates the opportunity to provide comments on the process for developing and evaluating MVP candidates. IDSA supports CMS' goal of creating a process that is transparent and would like to share our desire to partner with CMS to be involved in the entire development lifecycle of an infectious diseases MVP. Engagement of IDSA in the entire development process, from conceptualization to implementation in MIPS, would lead to a more transparent, meaningful MVP for ID clinicians and patients.

We would also like to share our concerns with the "Utilization of Measures and Activities across Performance Categories" MVP evaluation criterion that states, "MVPs should include measures and activities from the Quality, Cost, and Improvement Activities performance categories." Historically, quality measures available in the Physician Quality Reporting System (PQRS) have not aligned well with ID clinical practice and continue to be misaligned in the Quality Payment Program (QPP). Aside from Human Immunodeficiency Virus (HIV) and Hepatitis C virus (HCV) quality measures, which are meaningful to only 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 on which ID physicians can report in order to avoid payment penalties. As 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). Utilizing existing MIPS quality measures will lead to the

same outcome as the Infectious Disease Specialty Measure Set, a set of measures that is not broadly relevant to ID physicians according to their practice patterns. Furthermore, MIPS offers very few cost measures that are applicable to an ID physician's practice pattern, thus, severely impeding the development of a meaningful MVP. IDSA suggests CMS explore the re-specification of measures within the CMS inpatient hospital and other facility-level quality reporting programs for use in clinician-level quality reporting programs, namely MVPs and MIPS, to incorporate cross-cutting, outcome measures that are applicable to a wide variety of eligible clinicians, often encourage team-based approaches to care, and do not require active clinician quality data submission.

MIPS Cost Performance Category:

IDSA continues to encourage CMS to work with legislators to extend the deadline for weighting the cost performance category to 30 percent. In that spirit, we also encourage CMS to maintain a Cost Performance Category weight of 15% and withdraw its proposal to increase the Cost Performance Category weight to 20% given ongoing issues with current QPP cost measures and the lack of applicable cost measures to many specialties.

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. Additionally, field testing for Wave 3 episode-based cost measures (Asthma/Chronic Obstructive Pulmonary Disease (COPD), Colon and Rectal Resection, Diabetes, Melanoma Resection, Sepsis) recently concluded on September 18, 2020. Delays in reweighting the cost performance category would better serve the health care clinician community as more time would allow for familiarization and understanding of these highly complex measures as well as understand the full implications.

MIPS Improvement Activities:

IDSA appreciates CMS' efforts to quickly implement the COVID-19 Clinical Trials (IA_ERP_3) Improvement Activity (IA) during this PHE and fully supports the provisions to allow for flexible nominations of future IAs in instances of public health emergencies.

We continue to urge CMS to increase the weight of "Implementation of an Antibiotic Stewardship Program (ASP) (IA_PSPA_15)" to a "high-weight" IA as it requires significant investment of time and resources. 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 as well 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 244 members of IDSA, the Society for Healthcare Epidemiology of America, and the Pediatric Infectious Diseases Society 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 respectively².^[7] Inconsistently, CMS has

² Doernberg S.B, et al, 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, <https://doi.org/10.1093/cid/ciy255>

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.

Calculating the Final Score – Complex Patient Bonus:

CMS proposes for the CY 2020 MIPS performance period that the calculated complex patient bonus using the existing formula be doubled but be limited to ten points. IDSA is supportive of this policy and appreciates CMS’ efforts to recognize that practicing medicine during a pandemic is increasingly complex and efforts such as quality reporting, even under normal circumstances, is extremely difficult with the top priority being patient care.

Laboratory Services Payment Reduction

The proposed 5% cut to independent laboratory services in 2021 Medicare PFS further limits the ability of clinical laboratories to develop, innovate, and offer critical diagnostic tests following previous cuts to reimbursement in 2019 and 2020. From 2018-2020, most infectious diseases diagnostic tests received successive 10% reductions (for a 30% or greater reduction overall). These rates do not reflect market-based payments as intended by Congress and will derail critical advances in point-of-care (POC) testing. Specifically, high quality POC testing provides crucial support in patient care by spurring appropriate antibiotic use (or withholding antibiotics if a viral infection is diagnosed) and further assists in limiting growth in antibiotic resistance. IDSA proposes the following concepts to alleviate payment reductions to vital laboratory services;

- CMS should survey for variance within market segments to better understand utilization in different regions of the country and within laboratory types including reference laboratories, physician office-based laboratories, and independent laboratories.
- CMS and Congress should work collaboratively to develop a comprehensive solution to ensure that Medicare reimbursement truly reflects the market;
- Address the flawed methodology for calculating fees within the Clinical Laboratory Fee Schedule. The current method reduces patient access to rapid and accurate testing due to fewer laboratories offering these tests which may be particularly detrimental to patients in rural and underserved areas;
- Utilize existing program integrity and program administration authorities to improve data accuracy through a statistical survey method that is less burdensome on providers and reflects the full range of health care sites and their associated services and relative costs;
- Expand Medicare’s determination of “medically necessary” services to include multiplex tests that are essential to rapid diagnosis for infectious diseases patient care. This will ultimately reduce test turnaround time, length of hospital stays, disease transmission, and

healthcare costs while enhancing the appropriate use of antibiotics that will also enhance patient outcomes and reduce antimicrobial resistance.

Thank you for the opportunity to provide comments on the 2021 MPFS Proposed Rule as we continue to work through solving the current pandemic crisis. If you would like to discuss the issues we have outlined, have questions or would like to meet in person, please contact Kay Moyer on 703-721-8493 or via email at kmoyer@idsociety.org.

Sincerely,

A handwritten signature in cursive script that reads "Thomas File". The signature is written in black ink and is positioned below the word "Sincerely,".

Thomas File, MD, MSc, FIDSA