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2020-2021

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September 13, 2021

Chiquita Brooks-LaSure

CMS Administrator

Centers for Medicare & Medicaid Services

Attention: CMS-1751-P

7500 Security Blvd.

Baltimore, MD 21244

Re: Comments: CMS-1751-P: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies

Comments submitted electronically via www.regulations.gov.

Dear Administrator Brooks-LaSure,

IDSA 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 including Ebola virus, Zika virus, and most recently SARS-CoV-2.

Our members continue to work vigorously to manage, treat, and oversee the response to the COVID-19 public health emergency (PHE). They are on the front lines of this pandemic, caring for patients, designing, and updating infection prevention and control programs, developing new and innovative diagnostic testing and patient management protocols, collaborating with state and local health departments on communications and mitigation efforts, leading health care facility responses, and conducting research to develop new tools for the prevention, diagnosis, and treatment of COVID-19. It is with this background in mind that we submit our comments to you for consideration.

Comment Solicitation for Impact of Infectious Diseases on Codes and Ratesetting

IDSA would like to thank the Agency for addressing the issues confronting our specialty as our members work tirelessly to treat patients affected by the pandemic, coupled with treating patients with other infectious diseases, while also continuing to be called upon as the experts that lead antimicrobial stewardship programs and infection prevention programs within their hospitals and institutions.

Changes to the conversion factor, coupled with the redistributive effects of the clinical labor updates, will reduce Medicare payments to infectious diseases physicians at a time when our members are providing valuable medical services to patients with COVID-19, while also providing public health services to local communities, state health departments and other public entities.

There are structural problems within the healthcare system and the Medicare Physician Fee Schedule that do not allow for appropriate preparation and distribution of financial resources should another pandemic strike the US. We believe that structural changes are needed to better prepare our healthcare system, networks, and providers for the eventual next public health emergency. As such, IDSA strives to foster policy solutions that aim to bolster the ID work force by ensuring appropriate payment for the expertise and resources needed during times of healthcare crisis. Providing additional reimbursement and resources to the ID physician will also help to attract medical students to careers in ID, as new physicians will know they are valued and compensated appropriately within the healthcare system. While we appreciate that the Medicare Physician Fee Schedule (MPFS) alone cannot resolve all the documented physician workforce shortages, both existing and on the horizon, IDSA urges CMS to consider its policies and proposals with this in mind so as not to exacerbate the infectious disease workforce crisis with policies that undermine the value of the services that ID physicians provide.

In this proposed rule, CMS asks for feedback and comment regarding specific types of services and costs associated with a public health emergency. We appreciate that the Agency has identified issues within the fee schedule that do not account for many of the activities associated with caring for patients during a pandemic. Additionally, we have collaborated with other specialty societies including the Society for Hospital Medicine and the American College of Emergency Physicians on these issues, which included joint meetings with CMS staff and submission of joint comment letters. Finally, the issue as we have described was subsequently taken up by the American Medical Association House of Delegates whereby a resolution was passed in support of creating new payment pathways for the tasks and additional resources needed during an infectious diseases outbreak.

As we have outlined in a previous [comment letter](#) and in meetings with CMS staff, infectious diseases physicians perform tasks associated with treating pandemic patients that are not captured in the fee schedule. IDSA has previously submitted to CMS staff a list of activities, however we reiterate them here.

- Donning and doffing personal protective equipment (PPE) and following new infection control protocols
- Expanded cleaning protocols necessitating slower turnaround time on bed space
- Educating, engaging, and enrolling patients in research and investigational initiatives, including as part of clinical trials, expanded access programs (EAPs), emergency use authorizations (EUAs) and compassionate use (CU) protocols
- Follow-up for persons under investigation
- Monitoring and interpreting the flow of new research and information and triaging education to effectively manage the pandemic
- Constantly revising and updating treatment and management protocols

- Reconciling and adjudicating incongruous or conflicting findings such as understanding asymptomatic transmission during a pandemic
- Supervising other physician specialties deployed to assist in the care of outbreak 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 hospital capacity and supply availability
- Organizing the development of and operating remote treatment 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
- Providing emotional support for staff including educating staff on vaccine safety
- 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 outbreak related data

Modifier as Means to Capture Infectious Disease Outbreak Activities

We believe that creating a modifier that infectious disease physicians and other types of providers could append to current E/M codes may provide a unique solution to ensuring that resources are available for care delivered during circumstances of heightened work. The use of a modifier would provide CMS with two appropriate, useful safeguards (1) CMS could set documentation requirements regarding the existence of the outbreak (e.g., parameters associated with the timeframe that public health officials have declared an infectious disease emergency or reporting associated diagnosis codes); and (2) CMS could set documentation requirements to justify the enhanced services that were provided during the outbreak (e.g., evidence in the medical record that one or more of the aforementioned activities were delivered or influenced care).

We appreciate that the MPFS is not designed to reimburse clinicians for the precise resources dedicated to an individual case, but rather for the “typical” case; however, during an infectious disease outbreak (which could be national, regional, or local), the patients being served no longer represent the “typical” case. And, as we have observed during the COVID-19 outbreak, it is these atypical cases that fill the patient rolls making it difficult to rationalize reimbursing them as “typical” patients. We believe that the establishment of a modifier not only provides CMS with the opportunity to set documentation requirements to ensure that the existence of the outbreak is verifiable and that the “typical” work is performed relative to the “atypical” patient on whom the claim is submitted.

Mechanisms like the temporary inpatient DRG enhancement for COVID-19 cases remain valuable for hospitals reimbursed under the Inpatient Prospective Payment System, but do not capture, nor reimburse for, the heightened work of physicians and their staff during an infectious

disease outbreak. We believe it is in everyone's interest that CMS implement a policy that addresses these spikes in care that can occur across an entire community in a way that considers that different infectious diseases will be involved in different outbreaks. There are, of course other mechanisms that could achieve the same policy goals, but we would add that a mechanism such as a modifier to represent this work would allow the Agency to more narrowly tailor the directing of resources based on cases where the enhanced care is delivered in a way that supports program integrity. We also add that a payment modifier would ensure that physicians, regardless of specialty designation, are receiving reimbursement commensurate with the atypical activities associated with treating patients during an outbreak or pandemic.

We encourage CMS to implement a permanent mechanism to reimburse clinicians for critical activities associated with managing infectious disease outbreaks. Under our proposal, CMS would automatically initiate payment to clinicians (e.g., under the Physician Fee Schedule) for services associated with these unanticipated events, within certain parameters, when they occur. Such a policy would promote certainty for both physicians and CMS; physicians could anticipate receiving additional resources, while CMS would have an established pathway for channeling of those resources.

We do not want to overlook that the CPT Editorial Panel created a CPT® code 99072 to account for the additional supplies, materials, and clinical staff time during a PHE to capture the items that are above and beyond and atypical of routine office visit E/M. However, while we believe this CPT code is of some value, it does not capture the myriad of activities and tasks that are required of an infectious disease physician and other types of physicians during a pandemic. Currently this code is considered bundled and not separately payable under the MPFS. Even if the Agency were to assign a value to this code, it still would not meet the needs of the physician community as it would not account for the services provided during a pandemic.

IDSAs welcome the opportunity to work with CMS on this issue and would welcome an opportunity to meet again to discuss other options and ideas that would create a payment mechanism for physicians treating patients during a pandemic, epidemic, or local outbreak.

Clinical Labor Pricing Update

CMS proposes to update the clinical labor wage data used to calculate practice expense relative values (PE RVUs). While this is necessary to account for increased salaries for clinical labor since the last update in CY 2002, the budget-neutral aspect of the MPFS has created a significant shift in PE RVUs (and Medicare payment) across services and specialties. According to CMS' calculations, ID physicians face an estimated 1% reduction because of this proposal. This is because the primary services delivered by ID physicians – evaluation and management (E/M) in the facility setting – have lost PE RVUs as part of the redistribution.

IDSAs recognize the importance of using updated clinical labor wage data to ensure Medicare payment accuracy; however, we are deeply concerned that the impact – while seemingly small – comes at a time when ID physicians are struggling on the frontlines of the COVID-19 PHE. As noted above, ID physicians continue to go uncompensated for direct and indirect activities associated with caring for COVID-19 patients and directing the clinical aspects of this pandemic.

at the health system level. **We encourage CMS to take every step possible to mitigate the negative impact of this policy on ID physicians, which may include adopting a phased approach to implementation.** Further, we encourage CMS to work with Congress to address the long-standing challenge of mandatory budget-neutrality adjustments, particularly for costs associated with practice expense.

Telehealth and Other Services Involving Communications Technology

Retention of Category 3 Services Through the End of 2023:

IDSAs appreciate the steps the Agency is taking to ensure care is available to beneficiaries during the public health emergency. **Thus, we support the proposal for continued payment through the end of 2023, for services that were placed temporarily on the telehealth list during the PHE.** This extension will allow time for providers and other entities to gather data to then help determine if the services should be added to the telehealth list on a permanent basis.

ID physicians use telehealth technologies to extend their reach to patients in rural and urban underserved areas. We note that 208 million US citizens live in counties with no or below-average access to an infectious diseases physician.¹ Having access to telehealth services, particularly important during a pandemic, can help close this gap. Many of our members have relied upon the use of telehealth to treat patients with COVID-19 or to treat patients with other conditions during the PHE. When the US was under stay-at-home orders, telehealth services were a vital link for many, allowing Medicare beneficiaries to continue care, while keeping their SARS-CoV-2 exposure to a minimum. IDSA would welcome the opportunity to work with the Agency to develop meaningful telehealth policies.

Telehealth and Audio Only for Mental Health Services:

IDSAs appreciate the steps that the Agency has taken to allow for greater access to medical services performed via telehealth and telemedicine technologies. We are in support of the many proposed policies within the rule. **However, we would encourage the Agency to work with Congress to initiate the same geographic flexibilities for other Medicare telehealth services to allow for access to other types of care, not just those services associated with mental health.** We also believe that flexibilities should be available not only for mental health services, but other healthcare services as well. The lack of support in using audio-only to receive care creates a significant barrier to beneficiary access. For many Medicare beneficiaries, using audio-only technology was the only means by which they received care during the pandemic.

Expiration of PHE Flexibilities for Direct Supervision Requirements:

Like our reasoning for supporting the extension of the codes placed temporarily on the Category 3 telehealth list, IDSA supports continuing, beyond the end of the PHE, direct supervision of certain diagnostic tests, physician services and some hospital outpatient services using real-time audio/video technology. Using telehealth technologies allows for an ID physician to reach more patients, and specially patients with no access to ID expertise, by using physician extenders to assist in providing life-saving care over long distances.

¹ Walensky, R.P. et al, *Where is the ID in COVID-19*, Annals of Internal Medicine, October 6, 2020

Split (or Shared) Services:

CMS seeks input on its policy for split (or shared) visits in the facility setting. **IDSA believes that “substantive portion” of patient care under the split/shared services policy should be based on medical decision making and not based on time.** We believe that counting time as the primary driver for determining substantive portion of care is not an accurate or meaningful approach for determining the practitioner who provided the most important components of the overall care, hence who would then submit a claim for that care. We believe that if the physician provides face-to-face time with the patient, documents the pertinent exam findings and assessment summary, while determining the course of treatment, then the physician should submit the claim for the service, even if the non-physician practitioner (NPP) spent “more time” with the patient. We understand that care provided by an NPP is being used to bridge the physician shortage, particularly in ID care and during a pandemic. However, developing a policy that could reduce payments to 85% of the MPFS rate would undermine the resources needed to make this an actual workforce support mechanism. The physician must still oversee the work of the NPP, digesting the NPP’s findings and assessment and then determining the next steps, and thus the payment for the service should remain at 100% of the MPFS.

In addition to our comments above, we also support the AMA RUC’s request for the Agency to collaborate with the CPT/RUC Work Group on E/M to create a proposal to clarify the reporting of split (or shared) visits in the CPT Guidelines. We also support the AMA’s call to not require a modifier for these services as this adds an administrative burden that the revised E/M coding guidelines were created to alleviate.

Monoclonal Antibodies Used to Treat COVID-19:

When the PHE comes to its conclusion, CMS is considering whether it should align payment and coverage for monoclonal antibodies (MABs) used to treat patients with COVID-19 with its approach for other MAB products, which are covered and paid as described in section 1847A. CMS explains how some of the COVID-19 MABs (for example, tocilizumab) were previously approved for other indications (such as rheumatoid arthritis and giant cell arteritis). However, CMS established separate coding and payment rules when these drugs are used to treat COVID-19.

Our members report that administering MABs to treat COVID-19 is significantly more complex when compared to administering MABs for other FDA-approved conditions. For example, providers are not able to use existing infrastructure and infusion suites because these facilities also serve immunosuppressed patients, and the patients receiving COVID-19 MABs are infectious to others. To resolve this, health systems have set up separate areas for these infusions, which has necessitated redirecting and retraining existing clinical staff, and often, hiring new clinical staff, to manage the dedicated infusion suites and rooms for administering MABs for treatment of COVID-19.

In addition, determining the patients that would benefit from COVID-19 MABs relies on a multifaceted set of new and ever evolving criteria, which has required ID, pharmacy, and nursing professionals to establish new clinical workflows to ensure appropriate use of these medications.

Finally, we are concerned about the impact on beneficiary access if CMS aligns payment and coverage for MABs used to treat COVID-19 with payment for MABs used to treat other chronic conditions. While we appreciate the administrative difficulties facing hospital executives, the out-of-pocket costs for these drugs could significantly reduce access – particularly in vulnerable and underserved populations. **Until a long-term solution to the rising costs of drugs, including MABs, and the impact on beneficiary cost-sharing is devised by policymakers, we recommend that the Agency maintain the current payment policy for MABs when used for treatment of COVID-19.**

Quality Payment Program

Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) General Comments

CMS proposes to make available an introductory set of seven MVPs, which would be available for reporting at the individual, group and/or APM Entity level starting with the 2023 performance period. Participating in MIPS through an MVP would be voluntary, although CMS seeks feedback on potentially sunsetting traditional MIPS and making MVPs mandatory starting in 2028. MVP participants would be required to report on four quality measures offered through the MVP, one of which must be an outcome/high priority measure, as opposed to the current requirement of six. They also would be required to select a population health measure from the MVP, which CMS would calculate automatically based on claims data if the participant met the case minimum. For the cost category, each MVP include one to two cost measures, which CMS would score automatically if the MVP participant were attributed enough beneficiaries under each measure. MVP participants also would be required to attest to either one high-weighted improvement activity or two medium-weighted activities offered under the MVP, which is fewer than the 2-4 activities required under the traditional MIPS pathway. Finally, all MVP participants would be required to report on the full set of Promoting Interoperability measures, unless they qualify for an exemption under traditional MIPS rules (e.g., hospital-based clinicians and groups).

IDSAs continue to support the overarching goals of the MVP framework, which are to streamline MIPS reporting, reduce clinician burden, and provide a glidepath to APM participation. However, we have reservations about the initial set of MVPs and question whether the framework goes far enough in terms of fundamentally fixing aspects of the program that have long prevented meaningful participation by our specialty. These concerns are addressed in more detail below.

One of our primary concerns, which the MVP framework does little to resolve, is the ongoing lack of relevant measures available to largely hospital-based cognitive specialists, such as ID physicians. 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 to avoid payment penalties. We remind CMS once again that ID physicians are not “proceduralists,” but rather non-proceduralists/cognitive physicians who provide 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% of 2017 Medicare claims billed by ID physicians were at the facility place of service). Our specialty's unique billing and practice patterns have made it challenging to develop additional quality measures that are feasible to report under a program like MIPS. Since 2013, IDSA has dedicated efforts to develop ID relevant clinical quality measures such as the 72-hour Review of Antibiotic Therapy for Sepsis, Appropriate Use of Anti-methicillin resistant Staphylococcus aureus Antibiotics, and Appropriate Treatment of Initial Clostridium difficile Infection to help fill this gap but have consistently been rejected by CMS when the measures were submitted for the Annual Call for Measures.

Unfortunately, the MVP framework relies on the current inventory of MIPS quality measures and does little to incentivize the development or application of more innovative and meaningful measures. **IDSA reiterates its request that CMS explore the broader use of Medicare inpatient hospital and other facility-level quality reporting programs that could provide our facility-based clinicians with additional opportunities to get credit for clinical actions and outcomes that they are already contributing to within their facilities.** We would also be open to working with CMS on ways to re-specify existing facility-level measures so that those measures may be used for clinician-level accountability. This would not only provide our members with a more meaningful participation pathway but would also promote team-based approaches to care and minimize duplicative reporting.

Another concern we have about the MVP framework is its ongoing reliance on four distinct performance categories whose measures/activities often have little connection to each other or to the MVP's clinical topic. We recognize that CMS is required by statute to measure clinician performance under these four categories, but we believe the statute permits enough flexibility for CMS to think outside the box. For example, all MVP participants, regardless of the MVP's clinical focus, must continue to report on the full set of Promoting Interoperability (PI) measures, unless otherwise eligible for a re-weighting of the category through traditional MIPS scoring rules. Although some of our members qualify for a special status exemption from PI, there are others who do not and who continue to struggle to find relevance in this category's one-size-fits-all measure set. As CMS looks to a future that relies more heavily on digital quality measures, alternative sources of clinical data (such as home monitoring devices and testing kits) and more efficient methods of health information exchange (such as application programming interfaces), we urge the agency to think about ways that the PI category can better recognize these more innovative use cases. We also believe that CMS may, within the limits of the statute, provide clinicians with cross category credit for actions that satisfy the goals of multiple categories, as well as cross-program credit, as discussed earlier. Adopting such policies could help to substantially reduce the reporting burden of the program and allow clinicians to focus on clinical improvement rather than compliance. Finally, there is an ongoing and concerning disconnect between the cost and quality categories. Many of the proposed MVPs rely on existing total cost of care measures, which have no direct tie to the quality measures in the MVP. Even when more focused, episode-based cost measures are available, they often do not measure the same aspect of care as the quality measures in the set, thus producing a distorted and incomprehensible assessment of value.

Given these unresolved concerns, **IDSA opposes CMS' interest in retiring traditional MIPS and making MVPs mandatory by 2028.** It is simply too early to know what the landscape will look like at that time, including data collection capabilities, alternative data sources, and the availability of measures to populate enough MVPs to adequately cover all aspects of clinical practice.

Subgroup Reporting

As part of the MVP framework, CMS also proposes a subgroup reporting option that would be voluntary for the 2023 and 2024 performance years. Starting in 2025, CMS proposes that multispecialty groups would be required to form subgroups to report MVPs. CMS does not anticipate the need to require single specialty groups to form subgroups to report an MVP. Subgroups would inherit the eligibility and special status determinations of the affiliated group (TIN). For example, to participate as a subgroup, the TIN would have to exceed the low-volume threshold at the group level. The subgroup would also inherit any special statuses held by the group, even if the subgroup composition would not meet the criteria.

The intent of the subgroup reporting proposal is to move away from large multispecialty groups reporting on the same set of measures, which may not be relevant or meaningful to all specialists that participate within a multispecialty group. IDSA appreciates CMS' concern that some current group submissions do not accurately reflect the performance of all clinicians within the group, do not provide all clinicians in the group with results that lead to data-driven improvements in quality, and do not provide patients and caregivers the granularity of data needed to make informed decisions. We also agree with CMS that subgroup reporting could provide more direct attribution of quality measure data and results to clinicians than is possible under the current program, which could lead to more valuable, meaningful, and actionable results that contribute to patient care and improvement.

At the same time, we are concerned about the substantial increase in reporting burden that subgroup reporting could cause for practice administrators, as well as clinicians in larger group practices who have traditionally been sheltered from active reporting. **We support CMS' effort to provide clinicians with more freedom to untether from their group practice and choose their own participation pathway. However, we strongly urge CMS to continue to test this model and maintain it as a voluntary option until the agency can ensure that it is feasible for practices to implement and that it results in data that are valid, reliable, and meaningful to patients and clinicians.** As part of this ongoing test period, CMS should also consider implementing subgroup reporting in traditional MIPS for those specialties that do not yet have an applicable MVP but would like the independence to pair with a smaller group of their more personal colleagues to report on more clinically focused measures.

Maintaining a voluntary subgroup reporting option would also allow CMS time to work with stakeholders to address some unresolved issues related to this proposal. For example, would CMS require a multispecialty group to break off into subgroups even if only a single relevant MVP is available to portions of the group? And what would happen to the rest of the group? Would they be required to report through an MVP, or could they report data through traditional MIPS? And if they could participate in traditional MIPS at the group level, would they be

expected to report data across their entire TIN, including the clinicians who are reporting via the subgroup, or would the group only have to report on the portion of the TIN that did not form a subgroup? It is also unclear if CMS intends for subgroups to work like current group reporting, where not every member of the group may contribute to the denominator, depending on the measures selected, or if CMS envisions that every single member of the subgroup should be able to report on the measures selected by the subgroup? It is important that CMS recognize that even in single specialty groups and subgroups, there may be someone who does not provide the same type of care or see the same type of patients than the others.

IDSA also believes that the subgroup reporting option, and MVPs, should be flexible enough so as not to discourage team-based approaches to care. In the rule, CMS discusses potentially limiting clinicians in multi-specialty groups to participate through single-specialty subgroups. **IDSA strongly recommends CMS to NOT require that subgroups be composed of a single specialty for purposes of MVP reporting since this could discourage more coordinated care and exclude clinician types whose primary specialty designation is related to their clinical degree and not to the type of care they provide (such as PAs, NPs, hospitalists, etc.).** Instead, CMS should provide group practices and its members with the flexibility to decide the most clinically appropriate way to organize its clinicians into subgroups for purposes of MIPS value-based assessments. Flexibility is also important since many individual eligible clinicians may practice or be a part of multiple specialties as a part of their scope of practice and some eligible clinicians may have more than one specialty designation in the Provider Enrollment, Chain and Ownership System. Restricting subgroup reporting to single-specialty subgroups would be overly restrictive, complex, and would not necessarily align with the way that care is provided.

Finally, IDSA supports CMS' proposal to allow subgroups to inherit the eligibility and special status determinations of the affiliated group (TIN). A considerable portion of our members meet CMS' definition of facility-based and have historically been exempt from PI. These clinicians should not have to suddenly comply with a category that they have little control over simply because they broke off into a smaller subgroup for purposes of more meaningful participation in MIPS.

New Specialty Measures Set Proposed for Addition and Modifications to Previously Finalized Specialty Measures Sets Proposed for the CY 2022 MIPS Performance Period/2024 MIPS Payment Year and Future Years

IDSA appreciates the opportunity to provide comment on the Infectious Disease (B.18) specialty measure set and would like to take this opportunity to highlight our concerns with the lack of clinically appropriate quality measures within the Merit-based Incentive Payment System (MIPS) that are applicable to many infectious diseases physicians (IDPs). We voice our concerns with consideration of CMS' provisions to implement MVPs in performance year 2023 and visions of sunseting MIPS traditional reporting at a time in the future.

Over the seven years of MIPS, the MIPS quality measures portfolio have not aligned well with ID clinical practice. As stated previously, 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 to avoid payment penalties. The Infectious Disease Specialty Measure Set demonstrates that the current measures available in the MIPS quality measure portfolio are not appropriate to meaningfully evaluate the performance of IDPs and, for example, quality measures on the appropriate use of antimicrobials for the treatment of bacteremia, cellulitis, Clostridium difficile infection, and outpatient parenteral antimicrobial therapy (OPAT) care coordination are much needed.

With the forthcoming implementation of MVPs, utilizing existing MIPS quality measures without the development and implementation of infection specific quality measures will lead to the same outcome, a set of measures that is not broadly relevant to ID physicians' practice patterns. IDSA would greatly appreciate an opportunity to partner with CMS to explore the development of measures to populate future MVPs for infectious diseases conditions that are reportable by multiple specialties within the hospital setting.

Request for Information Regarding the COVID-19 Vaccination by Clinicians Measure

IDSA firmly supports the implementation of the COVID-19 Vaccination by Clinicians measure as the COVID-19 vaccine and its administration to the eligible population is an integral public health tool to reduce morbidity and mortality associated with COVID-19. In response for the RFI questions, please see our comments below.

- *Should the measure assess whether patients completed a COVID-19 vaccination series to capture provision of effective clinical care and why?*

We believe that the assessment of whether patients have completed a COVID-19 vaccination series is appropriate as the data have shown that the COVID-19 vaccines (Pfizer-BioNTech, Moderna, Johnson & Johnson/Janssen) are effective and checking a patient's status and, if appropriate, administering the COVID-19 vaccine is effective clinical care. However, we believe that the focus of this concept should be providing information and education about the efficacy of the vaccine, as opposed to administering the vaccine. Despite the efficacy data, many individuals continue to refuse the vaccine; **physicians should not be penalized based on patient refusal to receive the vaccine that prevents COVID-19.**

- *Given that there are differences in the age ranges for patients eligible to receive the various COVID-19 vaccinations (Moderna and Janssen COVID-19 vaccines are authorized for patients ages 18 years and older; Pfizer-BioNTech COVID-19 vaccine is authorized for patients ages 12 and older; and future COVID-19 vaccines may be approved for other age ranges that are implemented after the publication of the CY 2022 PFS proposed rule), is 18 years and older an appropriate initial age threshold for this measure?*

With the likely complexity of collecting and reporting on the data for the three available vaccines and the varying eligible age ranges for each, we believe a straightforward approach of capturing the 18 years and older age range is an appropriate threshold for this measure.

- *Given the current COVID-19 public health emergency and the intent of the measure, should this measure be mandatory for reporting in a future year?*

Yes, as COVID-19 public health emergency is currently in its fourth surge, IDSA supports that this measure be mandatory for reporting to increase the awareness and accountability of MIPS eligible clinicians to perform effective clinical care.

- *What are the feasibility challenges and barriers to implementing the measure?*

With a new measure, mandatory or voluntary, awareness must be raised to the MIPS eligible clinician community to mitigate challenges in implementation. Additionally, IDSA suggests creating and making available practical clinical quality measure data collection plans that include guidance on how a clinician might actionably meet this measure, e.g., a recommendation may be reminding clinicians to include questions regarding COVID-19 vaccination status when inquiring a patient on additional vaccination statuses including influenza and pneumococcal. A potential feasibility challenge clinicians may encounter is the availability of COVID-19 vaccines in the setting of care they practice. For example, if a patient is in the hospital and is not vaccinated for COVID-19 and has consented to be, will vaccines be available to the clinician to administer?

Improvements Activities Inventory

IDSA appeals yet again to 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 two hundred forty-four 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 respectively. Inconsistently, 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 recommend CMS revise the weighting of “Implementation of an Antibiotic Stewardship Program (ASP) (IA_PSPA_15)” to a high-weight activity.**

Additional Considerations, Reweighting the Promoting Interoperability Performance Category for MIPS Eligible Clinicians in Small Practices

CMS proposes to no longer require an application for physicians and small practices seeking to qualify for the small practice hardship exception and reweighting. Instead, CMS would assign a weight of 0% to the Promoting Interoperability performance category and redistribute its weight

to another performance category or categories in the event no data is submitted for any of the measures for the Promoting Interoperability performance category by or on behalf of a MIPS eligible clinician in a small practice.

IDSA is supportive of this proposal as it reduces administrative burden. In the Proposed Rule, CMS states that it does not intend to keep this policy in the program for the long term. We urge CMS to not prematurely sunset this hardship exemption until the Agency has developed and significantly implemented a robust digital quality measurement (dQM) strategy and have implemented and used a data standard for clinical quality measurement for several years. We believe that establishing these elements will provide clear guidance to CEHRT vendors in developing their products and offerings and may increase CEHRT adoption as it may provide the clinician community reassurances that they will be purchasing a product that is based on and meet mature technological standards.

Calculating the Final Score, Complex Patient Bonus

For CY 2022 MIPS performance period, CMS seeks feedback on several proposals that include implementing a multiplier of four and cap of ten bonus points, a multiplier of two and cap of five bonus points, or implementation of additional options, such as a cap of seven or twenty points.

IDSA is appreciative that CMS continues to review and implement the Complex Patient Bonus and appreciates CMS' efforts to recognize that accounting and adjusting for appropriate risk factors is needed to reliably assess MIPS clinician performance. **In reviewing CMS' proposals, we support the proposal for implementing a multiplier of four and cap of ten bonus points as the rationale provided is logical, supported by the analysis the Agency conducted in developing this proposal.** We encourage CMS to continually update the Complex Patient Bonus analysis with the most current data in subsequent Proposed Rules to inform and adjust this policy accordingly. Finally, to have a better understanding and provide stakeholders more guidance, we ask CMS to specify the goal of the Complex Patient Bonus. For example, is the goal of the bonus to raise the MIPS Total Performance Score of MIPS engaged individuals and groups with the highest complex patient bonus score to the median MIPS Total Performance Score?

We would like to thank the Agency for the opportunity to comment and provide feedback on the 2022 MPFS proposed rule. We would also like to offer our assistance and availability should you have questions or would like to discuss our comments. For additional information or to contact IDSA leadership, please email Kay Moyer, kmoyer@idsociety.org.

Sincerely,



Barbara Alexander
President