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September 6, 2022

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 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies

Comments submitted electronically via www.regulations.gov.

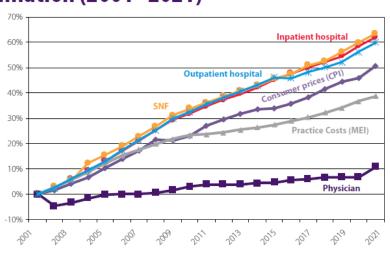
Dear Administrator Brooks-LaSure,

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 careassociated infections, and antibiotic-resistant bacterial infections, as well responding to infectious disease pandemics and outbreaks including Ebola virus, Zika virus, and most recently SARS-CoV-2 and Monkeypox.

Our members continue to work vigorously to manage, treat, and oversee the response to the COVID-19 public health emergency (PHE), while also leading response efforts for the monkeypox PHE. They are on the front lines of these crises, 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 such as vaccination campaigns, leading health care facility responses, and conducting research to develop new tools for the prevention, diagnosis, and treatment of COVID-19 and monkeypox. This work enhances patient safety and provides essential expertise and partnership to public health, primary care and other medical specialties, allowing a wide array of medical services to be provided safely. In addition to these emergency responses, ID physicians exercise constant vigilance to recognize clinical presentations of emerging infectious diseases and manage increasingly complex patient populations, as medical advances like transplantation and cancer care carry significant risks of complicated infections. It is with this background in mind that we submit our comments to you for consideration.

Proposed Conversion Factor and Impact on Infectious Diseases Physicians

Along with the rest of the physician and health care professional community, IDSA remains deeply concerned about the steep reduction in the Medicare PFS conversion factor for CY 2023, particularly amidst the ongoing COVID-19 PHE, the newly declared Monkeypox PHE, and the period of historic rates of inflation. As proposed, the reduction is nearly -4.5%. As a reminder, the conversion factor was also reduced in CY 2022 (-0.80%) and CY 2021 (-3.3%). More importantly, since the inception of the Resource-Based Relative Value Scale (RBRVS), the conversion factor has remained relatively flat (see graphic prepared by the American Medical Association (AMA), also shown below).



Medicare pay updates compared to inflation (2001–2021)

On the surface, CMS' proposed rule appears to increase payments to ID physicians (5%), the result of proposed changes in certain E/M service values. However, this relatively modest increase will be reduced by more than half with the expiration of the 3% payment update provided by Congress for CY 2022. In fact, based on CMS' own assumptions, any increase for ID physicians would only materialize for those in *facility* settings (+6%, reduced by 3%), while those in office settings would take a hit (-2%, further reduced by 3%). CMS is keenly aware that physicians in the employ of hospitals and health systems are often paid a salary that is, in part, based on relative value unit (RVU) generation. Notably, however, entities like Sulllivan Kotter, who provide compensation and benchmarking data and work with hospitals and health system to establish compensation models, are known to have recommended against improving payments to employed physicians based on increased RVUs for E/M services. It may fall outside of CMS' statutory and regulatory authority to take action; however we remind the agency that its assumptions are far from a true reflection of the reimbursements received by Medicare-enrolled physicians caring for beneficiaries.

We also note that in CY 2021, under CMS' policies that improved E/M values for the office and outpatient settings, ID physicians took a steep hit (-4%) that was only partially mitigated due to Congressional action. Under these same policies, other physician specialties whose work is dominated by the delivery of E/M services primarily in outpatient settings (e.g., rheumatology, endocrinology) realized astonishing boosts in their specialty pools, upwards of +15% in some cases. ID physicians are among the lowest compensated physicians despite many years of specialty (usually 3 years of internal medicine or pediatrics) and subspecialty (usually 2-3 years of fellowship) training. This, together with the increasing burden of college

Sources: Federal Register, Medicare Trustees' Reports and U.S. Bureau of Labor Statistics

and medical school debt, has led to problems in the recruitment of residents into the specialty. Continuing to undervalue the work and expertise of ID physicians will only make matters worse.

It is not a question of *whether* there will be another infectious diseases outbreak, it is a question of *when*, how often and how many simultaneous outbreaks will need to be managed. As a country, we are wholly unprepared to manage another large-scale outbreak – let alone multiple outbreaks – given the inadequate ID physician workforce. Even outside of public health emergencies, medical care is growing increasingly complex, and many new medical advances are significantly increasing the number of immunocompromised patients. ID physicians are essential to manage highly complex patients undergoing transplantation, cancer care, other surgeries and autoimmune conditions. Infection prevention expertise is increasingly critical in health care facilities. CMS has already recognized antimicrobial stewardship as essential to ensure optimal antimicrobial use, improve patient outcomes and reduce resistance, but we must invest in the experts necessary to lead these programs to protect our precious antimicrobial arsenal. ID physicians are, unacceptably, underrepresented in medicine, and we contend this is largely the result of CMS' flawed payment policies that grossly devalue their expertise. CMS must increase payments for the work of ID physicians, starting with the establishment of policies to address infectious disease outbreaks and by maintaining the historic relatively between inpatient and office/outpatient E/M RVUs. These are discussed in more detail below. Failure to do so threatens the future of the workforce for infectious disease and public health specialties. Moreover, it jeopardizes the entire medical spectrum, since infections are common complications of medical advancements (such as for cancer, transplantation and advanced surgical procedures), and ID specialists are needed to respond to outbreaks.

Evaluation and Management (E/M) Visits: Hospital Inpatient and Observation Care

CMS began an effort in 2018 to ensure accuracy in the valuation of E/M services. As a result, RVUs for office and outpatient E/M services were increased in CY 2021. Similarly, as outlined in this proposed rule, RVUs for certain inpatient, observation, and other E/M services are proposed to be updated in CY 2023.

As the agency is aware, ID physicians—unlike other physician cognitive specialties whose work is dominated by the delivery of outpatient E/M services (e.g., rheumatology, endocrinology)—primarily deliver care in the inpatient setting. Therefore, when CMS improved the office and outpatient E/M services in CY 2021, and subsequently applied a statutory budget neutrality adjustment, the ID specialty absorbed a -4.0% cut on top of already low compensation relative to other physician specialties. Because ID physicians viewed the overarching effort as incredibly important to cognitive care and delivery, and a precursor for improvements in the E/M services ID physicians deliver in the inpatient setting, they lauded CMS' proposals and urged them to finalize the increases. The expectation was that the inpatient and observation E/M services would improve commensurate to the office and outpatient E/M services, allowing ID physicians to finally realize – similar to their cognitive specialty colleagues in CY 2021 – a meaningful increase in value for the services they deliver most.

Unfortunately, CMS' proposed revisions to the values for inpatient and observation E/M visits are woefully inadequate relative to the increases provided for office and outpatient E/M services, and contravene IDSA's request this spring that CMS apply an equitable approach that maintains the longstanding relativity across the inpatient and office and outpatient E/M codes (see Table 1 below). We further explained that inpatient care is inherently more complex—involving sicker patients, higher risk of adverse outcomes and a higher level of medical decision-making.

CPT Code	2023 wRVU	Cf. 2022	IDSA Request	
Initial Visits				
CPT 99221	1.63	- 15.1% (1.92)	1.92	
CPT 99222	2.60	0% (2.61)	2.79	
CPT 99223	3.50	- 9.3% (3.86)	4.25	
Same Day Discharge				
CPT 99234	2.00	-21.9% (2.56)	2.00	
CPT 99235	3.24	0% (3.24)	3.24	
CPT 99236	4.30	+2.4% (4.20)	4.30	

Table 1: CY 2023 Proposed Inpatient & Observation Work RVUs

As part of its proposed justification for the stagnant increases to the inpatient E/M services, CMS responded by saying "...practitioners furnishing visits in the office setting face particular uncertainties in their estimates of illness and treatment courses, and the office settings have fewer resources close at hand," and that "...those practicing in institutional settings generally have ready availability of diagnostic equipment (for example, imaging and other advanced services), allowing for more immediate access to clinical information and reducing the amount of time needed to manage a given case," while also suggesting "[t]he challenge of coordinating and gathering these types of care and information in the office setting may add additional time and complexity to the case management."

With all due respect, physicians furnishing inpatient E/M services face considerable uncertainties in estimates of illness and treatment courses—more so than the office setting, given the inpatient setting has a predominance of more seriously ill, extraordinarily complex patients with multiple comorbidities that can frequently lead to numerous complications that change the trajectory of a patient's care. Inpatient consultations involve rapidly changing clinical presentations that require the expertise of and coordination among many different subspecialties, as well as interpretation of many different diagnostic testing modalities (e.g., radiology, cultures, pathology). This culminates in recommendations for therapy, along with ongoing, evolving management during the patient's hospitalization and post-discharge by the ID-led care team. Multiple co-morbidities can each impact a patient's susceptibility to infection as well as their ability to tolerate treatments, and the ID physician routinely has to balance a wide array of complex health factors that can inform diagnosis and complicate treatment. To demonstrate this, we provide the following clinical vignettes:

- A patient with recent bilateral total knee arthroplasties, cardiovascular disease and diabetes presents with fever and pain in his low back, right knee and right hip. An ID consultation is requested to review the case, conduct a thorough history and physical examination, and interpret the significance of positive blood cultures. The ID physician consultant must choose appropriate diagnostic testing and surgical intervention, assess antimicrobial susceptibility and make a therapeutic decision, and a transition from inpatient to outpatient parenteral antibiotic therapy (OPAT). Coordination is required with orthopedic surgery, hospital medicine, pharmacy, physical therapy and case management. Extensive patient and family education are required during hospitalization and post-discharge to appropriately monitor antimicrobial therapy, prevent spread or worsening of infection, promote wound care and identify potential emerging complications of both the infection and the treatment (intravenous line complications and antimicrobial adverse effects). The ID physician is often the first and only physician to interact with and care for the patient post-discharge.
- A recent lung transplant recipient with a history of serious infections presents with tachycardia and hypotension. Urinalysis shows pyuria; CT imaging shows bilateral pulmonary nodules and hepatic nodules. An ID consultation is requested. The ID physician consultant orders further diagnostic evaluation to determine antibiotic choice and duration of therapy. Extensive testing required includes blood and respiratory cultures, blood chemistries, serologies, acute phase reactants, and

potentially the need for biopsy – all of which will require ID physician expertise to interpret and manage. Given the need for immunosuppression to prevent organ rejection, extremely close monitoring is required to rapidly identify potential additional infections. The patient's history of serious infections may limit antimicrobial therapy options, heightening the need for complex clinical decision-making, including combination therapy approaches. Coordination is required with the pulmonary transplantation team. Extensive patient and family education are required during hospitalization and post-discharge.

• A patient with prostate cancer diabetes and COPD is admitted for a severe urinary tract infection. He is treated with antibiotics and initially improves, but develops fever and abdominal pain. An ID consultation is requested. The patient requires interpretation of microbiologic studies of stool, urine, and blood, as well as imaging findings. Pre-existing co-morbidities need to be factored into interpretation and clinical decision-making, potentially increasing risks and limiting treatment options. Coordination is required with urology, general surgery, pathology, radiology, pharmacy, and case management. Extensive patient and family education are required during hospitalization and post-discharge.

CMS' response demonstrates that the agency failed to adequately consider or value the higher degree of medical complexity and severity that are routinely encountered in an inpatient setting compared to an outpatient setting. In fact, the severity of a patient's illness or condition and the complexity of care they require are among the most typical triggers of a hospital admission. In other words, and as we've shared previously, **inpatient care is inherently more complex than outpatient care**.

In addition, in contrast to CMS' assertion, not all institutions have the full and extensive on-site diagnostic testing services necessary to meet the full needs of their patients. Depending on specific patient needs, ID physicians must coordinate with their hospital laboratories, commercial reference laboratories, or public health laboratories (sometimes all of the above for a single patient, as multiple tests are often necessary to rule out certain infections and make conclusive diagnoses). During an outbreak, an ID physician may be required to spend multiple hours per patient collaborating with the state health department and public health laboratory in order to access diagnostic testing and treatment for a single patient—as is the case with the current monkeypox PHE and for which there is no compensation. The severity of illness in the inpatient setting can require more extensive diagnostic testing, monitoring of treatment, and coordination between medical teams including physician coordination between medical and interdisciplinary teams.

CMS' response to our request is even more insulting given the E/M codes reported by physicians in the office setting, and for which CMS finalized weighty increases, are <u>exactly the same codes physicians report</u> <u>in the hospital outpatient</u> setting. If CMS truly believes that patients in an inpatient setting are <u>less</u> complex to manage because of readily available resources, it stands to reason the agency would have taken its usual approach: establishing G codes for the hospital outpatient setting to account for the aforementioned "site of care" differences, thus ensuring accuracy in the value these services.

As we have shared in the past, and allude to above, inappropriately valued inpatient E/M services have led to a large compensation disparity between the physicians who primarily use these codes and many other specialties. We are concerned that these disparities limit workforce recruitment and retention and access to care, negating efforts to improve health outcomes, pandemic preparedness and health equity. For example, in 2021, only 70% of infectious diseases physician training programs were able to fill their slots,¹ and nearly 80% of counties in the U.S. do not have a single infectious diseases physician.² The proposed inpatient E/M values yield the real possibility of worsening beneficiary access to ID physician expertise even further.

¹ https://www.nrmp.org/wp-content/uploads/2022/03/2022-SMS-Results-Data-FINAL.pdf

² https://www.acpjournals.org/doi/10.7326/m20-2684

There is no question that more severe and complex patients typically seen in hospitals require a higher level of medical expertise and medical decision-making as compared to patients typically seen in outpatient settings. This expertise cannot be replaced or duplicated by other physicians or advance practice providers in hospitals, regardless of the supposed resources that are "close at hand."

ID physicians have been on the frontlines of the COVID-19 PHE and now the monkeypox PHE. Our members are central to our nation's preparedness for future health emergencies and integral to modern medical care. To stabilize, and potentially increase, the ID workforce, we request that CMS restore relatively across its E/M codes sets by finalizing the IDSA requested RVUs as outlined in Table 1 above. At a minimum, CMS should maintain the current values (CY 2022) for CPT codes 99221, 99223 and CPT 99234 for CY 2023.

Outbreak Activation

Shortly after the onset of the COVID-19 pandemic, IDSA and its partnering organizations highlighted concerns with Medicare's payment systems, and specifically the Medicare Physician Fee Schedule, that do not allow for appropriate preparation and distribution of financial resources to physicians for their *individual contributions* in addressing infectious diseases outbreaks. In prior comments (here and here), we outlined the tasks that physicians perform associated with treating patients in an outbreak situation that are not captured in the fee schedule, and urged CMS to consider establishing a modifier so ID physicians and other eligible clinicians could identify, and be compensated for, heightened work during an outbreak. We referred to this proposed policy as "outbreak activation" coding and payment.

Two years later, CMS has yet to take action on this proposal, although it has acknowledged the impact of infectious diseases on codes and rate setting. Failure to direct resources to individual clinicians, particularly those on the frontlines of infectious diseases outbreaks such as COVID-19 and now monkeypox, is a dangerous precedent. Other Medicare providers have received, and continue to receive, enhanced reimbursement to address pandemic-related expenses. For example, inpatient hospitals receive a 20% payment enhancement for COVID-19 related care.

IDSA urges CMS to establish coding and payment that would direct resources to individual clinicians who are leading the diagnosis, treatment and ongoing management of infectious diseases outbreaks. Absent a specific payment policy, at a <u>minimum</u>, CMS should establish an "outbreak activation" modifier so that it can track those instances where providers are providing an enhanced level of service specific to an infectious diseases outbreak.

Telehealth

Even before the COVID-19 pandemic, ID physicians adopted telehealth technologies to extend their reach to patients in rural and urban underserved areas. As we shared above, nearly 80% of counties – with more than 208 million US citizens – do not have a single ID physician.² Having access to telehealth services can help close this gap. Many of our members have relied upon the use of telehealth to treat patients with COVID-19, and now monkeypox, as well as other ongoing conditions our patients continue to face during the PHEs, such as HIV and viral hepatitis. IDSA greatly appreciates the steps CMS has taken to allow for greater access to medical services performed via telehealth and telemedicine technologies, and would welcome the opportunity to assist CMS in further developing meaningful telehealth policies.

Requests to Add Services to the Medicare Telehealth Services List for CY 2023

IDSA is disappointed that CMS is not proposing to keep the telephone E/M services on the Medicare Telehealth Services List after the 151-day post-PHE extension period. Audio-only technology is often the only means by which some Medicare beneficiaries will be able to access health care, even absent a pandemic. CMS is aware that broadband internet is limited or non-existent in many areas of the country, making access to audio-visual technology nearly impossible. In our experience, some Medicare beneficiaries find audio-visual technologies difficult to use, while others simply feel uncomfortable using it. This is particularly true for those with certain health conditions and prefer the increased privacy afforded via audio-only care. Moreover, we recognize that the telephone E/M codes were not added to the telehealth list on a Category 3 basis, because the agency defines telehealth services as having a simultaneous audio/video connection and does not view these services as equivalent to those delivered face-to-face. We urge CMS to continue working with Congress to ensure that CMS has the authority to cover telephone E/M services after the PHE concludes. Not only is it important for these services to be covered, but also, they must be reimbursed adequately. Decreasing reimbursement for these services undervalues the physician work involved and, for beneficiaries without video or broadband access, will present a significant barrier to access to care.

Additionally, we remind CMS that, in the CY 2022 PFS, it revised the regulatory definition of "interactive telecommunications system" to permit use of audio-only communications technology for purposes of diagnosis, evaluation, or treatment of a mental health disorder when provided to beneficiaries located in their home. We recognize this policy complemented a change in statute that lifted geographic and originating site requirements for furnishing telehealth services in this specific case. It seems reasonable that CMS could expand audio-only access more broadly, even if Congress has yet to include a beneficiary's home among the list of originating sites, and in the spirit of reducing inequities and expanding access to care. However, if CMS believes it lacks the authority to do so, we urge the Agency to work with Congress to expand access to audio-only telehealth for the provisions of E/M service for evaluation, management and treatment of other conditions.

Other Services Proposed for Addition to the Medicare Telehealth Services List

CMS proposes to create HCPCS codes for prolonged evaluation and management (E/M) services furnished in inpatient or observation care, nursing facility, and home or residence settings services (GXXX1, GXXX2, and GXXX3, respectively). As these prolonged services codes are similar to services already on the Medicare Telehealth Services List, CMS proposes to add these services to the Medicare Telehealth Services List on a Category 1 basis. **IDSA strongly supports this proposal.**

Services Proposed for Removal from the Medicare Telehealth Services List after 151 Days Following the End of the PHE

To align with the CAA, 2022, which extended several telehealth flexibilities implemented during the PHE for COVID-19 for an additional 151 days after the end of the PHE, CMS proposes to continue to include on the Medicare Telehealth Services List the services that are set to be removed from the list when the PHE ends for an additional 151 days following the end of the PHE. *IDSA supports this proposal, particularly for the inpatient hospital, observation and other E/M services. Further, we strongly urge CMS to permanently add these services to the Medicare Telehealth Services List on a Category I basis.*

Expiration of PHE Flexibilities for Direct Supervision Requirements

We are disappointed that CMS did not propose to make the temporary exception to allow immediate availability for direct supervision through virtual presence permanent, and urges CMS to reconsider this proposal – particularly when it is used in the provision of ID services. We recognize virtual presence may not be appropriate in all health care situations, and appreciate CMS' cautious approach. However, virtual presence allows ID physicians to extend their reach to patients, especially where ID care is not available,

by using physician extenders to assist in providing life-saving care over long distances. In the case of ID care, we urge CMS to make this exception permanent.

Quality Payment Program

MIPS Value Pathways (MVPs)

In this rule, CMS re-confirms that MVPs will be available for voluntary reporting beginning with the CY 2023 MIPS performance period, and that it intends for MVPs to become the only method to participate in MIPS in future years, although it has not yet finalized the timing for the sunset of traditional MIPS. CMS believes that MVPs can improve value, reduce burden, inform patient choice in selecting clinicians, and reduce barriers to participation in Alternative Payment Models (APMs). CMS also believes that MVPs will produce data that can better assist patients in comparing clinician performance and in selecting clinicians.

IDSA continues to support the overarching goals of the MVP framework, namely to streamline MIPS reporting, reduce clinician burden, and provide a glidepath to APM participation. However, we continue to have reservations about the manner in which MVP are being implemented 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.

As IDSA expressed last year, one of our biggest concerns is that the MVP framework does little to resolve 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 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 these measures have consistently been rejected by CMS when 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 use 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 respecify existing facility-level measures so that those measures could 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 ongoing concern we have about the MVP framework is its failure to break down the siloes between the programs' four performance categories. 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 and move beyond EHR functionalities. 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 reward credit across federal quality programs, 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 total cost of care measures, which have no direct tie to the quality measures in the MVP and fail to provide actionable data for clinicians to improve their care. 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.

Finally, although IDSA appreciates the intent of subgroup reporting, we are very 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 larger group 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 subgroup reporting as a voluntary option would also give CMS time to work with stakeholders to address some unresolved issues related to this proposal, such as how to determine which groups are eligible to form subgroups.**

In terms of scoring subgroups on administrative claims and cost measures, CMS proposes to evaluate clinicians in subgroups using measures in the cost performance category, and the population health measures and outcomes-based administrative claims measures in the quality performance category, based on their affiliated group's performance score, if available. IDSA requests that CMS reconsider this proposal and instead apply a scoring hierarchy that provides subgroups the higher of their subgroup or group score rather than defaulting to the group score. This will help to ensure that performance scores produced by MVPs are actionable and meaningful both the clinicians in the subgroup and patients making medical decisions.

MIPS Performance Threshold

Under statute, beginning with the 2022 performance year, CMS is required to set the MIPS performance threshold at the mean or median of the final scores for all MIPS eligible clinicians with respect to a prior period specified by CMS. In this rule, CMS proposes to rely on the mean final score from the CY 2019 MIPS payment year, which is 75 points, for the 2023 performance year.

IDSA supports CMS' decision to set the performance threshold at 75 points and appreciates CMS selecting the lowest possible threshold permissible under statute. At a time when practices are still dealing with COVID-19 staffing shortages and other strains on resources, it is important that CMS not increase the threshold and maintain stability in the program to the greatest extent possible.

Complex Patient Bonus

CMS previously finalized a complex patient bonus for MIPS eligible clinicians, groups, APM Entities, and virtual groups that submit data for at least one MIPS performance category during the applicable performance period, which is added to the final score. CMS also previously established facility-based measurement for certain MIPS eligible clinicians, which allows CMS to apply measures used for the inpatient setting for purposes of the MIPS quality and cost performance period, a facility-based MIPS eligible clinician would be eligible to receive the complex patient bonus even if they do not submit data for at least one MIPS performance category. Since many of our members practice in the inpatient setting and often face the challenges of seeing medically complex patients, IDSA strongly supports CMS' proposal to allow facility-based clinicians to receive the complex patient bonus.

Quality Category

Data Completeness Criteria

CMS proposes to raise the data completeness criteria from 70 percent to 75 percent for the CY 2024 and CY 2025 performance periods, which represents the minimum percentage of applicable patients that a clinician or group must report on for each measure. **IDSA urges CMS not to increase the data completeness threshold for the CY 2024 and CY 2025 performance periods.** Although CMS suggests it is feasible for eligible clinicians and groups to comply with a higher data completeness threshold, this conclusion is based on 2017 performance year data when clinicians had the option to submit only one quality measure on one patient for one single day. Additionally, our largely facility-based members often provide services across multiple sites that might not all participate in MIPS or use the same EHR. Even among those who practice in a single facility, they might not have direct control over their EHRs or the ability to obtain data in a timely or complete manner.

Infectious Disease Specialty Set

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 as the Agency implements MVPs in the upcoming performance year with intentions of sunsetting the MIPS traditional reporting option in the future.

Over the eight years of MIPS, the MIPS quality measures portfolio has not aligned well with IDP clinical practice. The majority of IDPs predominately treat adult patients in the hospital setting and aside from Human Immunodeficiency Virus (HIV) and Hepatitis C virus (HCV) quality measures, which are meaningful to a subset of IDPs in the outpatient setting who focus on these disease areas, there are very few ID specific measures on which IDPs 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 OPAT care coordination are much needed.

Further reiterating the lack of relevant quality measures to IDPs within the MIPS program, an analysis of the latest available <u>2020 QPP Experience Public Use File Data</u> found that the six most reported MIPS quality measures by IDPs for the 2020 MIPS performance year were areas of general clinical practice that did not accurately evaluate value of an IDP. The six most reported MIPS quality measures by IDPs for the 2020 MIPS performance 2.

Table 2: Top 6 Reported MIPS Quality Measures by Infectious Diseases Physicians for MIPS Performance Year 2020

	MIPS Quality Number	Measure Title
1.	#236	Controlling High Blood Pressure
2.	#1	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)
3.	#110	Preventive Care and Screening: Influenza Immunization
4.	#134	Preventive Care and Screening: Screening for Depression and Follow-Up
		Plan
5.	#318	Falls: Screening for Future Fall Risk

Based on the aforementioned factors, we recommend CMS to create a separate specialty measure set for HIV providers and sunset the Infectious Disease Specialty Measure Set. We propose the HIV provider measure set to include the following HIV, HCV, and STI measures.

	MIPS Quality Number	Measure Title	
1.	#205	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia,	
		Gonorrhea, and	
2.	#338	HIV Viral Load Suppression	
3.	#340	HIV Medical Visit Frequency	
4.	#400	One-Time Screening for Hepatitis C Virus (HCV) for all Patients	
5.	#401	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients	
		with Cirrhosis	
6.	#475	HIV Screening	

Table 3: Proposed Quality Measures for HIV Provider Specialty Measure Set

The proposed HIV provider specialty measure set is aligned with the <u>Core Quality Measures Collaborative</u> <u>HIV & Hepatitis C core set of measures</u> which seeks to "set as a parsimonious group of scientifically sound measures that efficiently promote a patient-centered assessment of quality and should be prioritized for adoption in value-based purchasing and Alternate Payment Models."

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 IDPs' 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.**

Improvement Activity Category

CMS proposes a to add a new improvement activity to MIPS starting in 2023, titled "COVID-19 Vaccination Achievement for Practice Staff." This medium-weighted activity requires an attestation that the clinician's practice has maintained or achieved a rate of 100% of office staff that is fully COVID-19 vaccinated according to the Center for Disease Control and Prevention's definition of fully vaccinated.

IDSA fully supports the intent of the "COVID-19 Vaccination Achievement for Practice Staff" IA and understands that high vaccinations rates are needed to end the COVID-19 public health emergency. However, we have concerns with the feasibility of achieving the 100% vaccination rate for reporting clinicians. With the United States Supreme Court ruling that the Occupational Safety and Health Administration (OSHA) does not have the authority to enforce COVID-19 vaccination mandates regulations as well as piecemeal state and local policies, it would prove difficult to achieve 100% compliance if federal, state, and local regulations and policies may not allow it. IDSA recommends allowing for an exception to allow for MIPS participating clinicians to report and succeed on this IA.

We would like to thank the Agency for the opportunity to comment and provide feedback on the 2023 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 Dana Wollins or Amanda Jezek (dwollins@idsociety.org; ajezek@idsociety.org).

Sincerely,

Daniel P. McQuillen, MD, MHS, FIDSA IDSA President