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September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure,

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the calendar year (CY) 2025 Medicare Physician Fee Schedule (PFS) Proposed Rule. On behalf of IDSA, which represents more than 13,000 physicians, scientists, public health practitioners and other clinicians specializing in infectious diseases (ID) prevention, care, research and education, thank you for your focus on reforming physician payment and for recognizing the importance of ID services provided to Medicare patients.

IDSA strongly supports and urges the Centers for Medicare and Medicaid Services (CMS) to finalize its proposal for a new Healthcare Common Procedure Coding System (HCPCS) add-on code to describe intensity and complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease performed by a physician with specialized training in infectious diseases. IDSA members care for patients with a wide variety of serious infectious diseases, including COVID-19, antimicrobial-resistant infections, HIV, viral hepatitis and infections associated with cancer care, solid organ transplantation and injection drug use. Our members also lead hospital programs charged with antimicrobial stewardship, infection prevention and control, and emergency preparedness and response. We are pleased to support several components of the CY 2025 Medicare PFS Proposed Rule as well as offer suggestions to strengthen some provisions, as detailed below.

HCPCS Infectious Disease Add-On Code

IDSA enthusiastically supports and urges CMS to finalize its proposal for a new HCPCS add-on code to describe intensity and complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease performed by a physician with specialized training in infectious diseases. Under CMS' proposal, the new HCPCS GIDXX

code could be appended to hospital and inpatient evaluation and management (E/M) services to describe service elements, including disease transmission risk assessment and mitigation, public health investigation, analysis and testing, and complex antimicrobial therapy counseling and treatment.

IDSA has long advocated for such a proposal that **recognizes the value of ID care** to the Medicare population. ID care is unique because it touches so many aspects of health care and core hospital functions. For example, ID care is essential for patients undergoing cancer treatment and organ transplantation, given their high risk of serious infection. ID physicians prevent, diagnose and treat serious infections associated with surgeries, including hip and knee replacements and cesarean sections. Access to ID expertise is critical to restoring and maintaining the health of all immunocompromised Medicare and Medicaid patients.[1]

The new add-on code reflects a similar proposal that IDSA suggested to CMS earlier this year to create a mechanism to appropriately value complex ID services that are not adequately captured and valued in existing codes. **The establishment of this new add-on code and relative value for ID care is essential to the sustainability of our specialty, providing both a foundation for ID physicians to begin to receive more accurate reimbursement that reflects the work they do and important data that can be used to improve "benchmarks" in current population-based models to inform the development of new value-based care models for ID care.**

The new add-on code, as proposed by CMS, describes three main elements:

1) Disease transmission risk assessment and mitigation;
2) Public health investigation, analysis and testing;
3) Complex antimicrobial therapy counseling and treatment.

IDSA agrees with the three elements and their associated activities. However, we urge CMS to clarify that an ID physician may append this add-on code to hospital inpatient and observation services for performing one, or any combination, of these elements. It would be infeasible to require that an ID physician perform all three elements and their associated activities in a single instance. Similar to the G2211 add-on code for complex care, we understand that GIDXX is intended to reflect the *inherent complexity* of the work described. **As such, we urge CMS to also clarify that no *additional* documentation requirements are being established; the ID physician's medical record documentation should sufficiently demonstrate the inherent complexity. IDSA would also like to clarify whether only ID physicians are able to bill this add-on code or if other physicians are able to do so as well.**

As noted above, IDSA continues to work on additional coding and payment options that would address other ID-led care and treatment services that are not captured in existing codes and that have led to chronic under-reimbursement – or non-reimbursement – for essential services, including outpatient

[1] Steven Schmitt, Daniel P. McQuillen, Ronald Nahass, Lawrence Martinelli, Michael Rubin, Kay Schwebke, Russell Petrak, J. Trees Ritter, David Chansolme, Thomas Slama, Edward M. Drozd, Shamonda F. Braithwaite, Michael Johnsrud, Eric Hammelman, Infectious Diseases Specialty Intervention Is Associated With Decreased Mortality and Lower Healthcare Costs, *Clinical Infectious Diseases*, vol. 58, issue 1, 1 January 2014, p. 22–28, https://doi.org/10.1093/cid/cit610

parenteral antibiotic therapy (OPAT). IDSA will share additional proposals with CMS in time for future rulemaking.

Again, IDSA appreciates and strongly supports the implementation of the new add-on code, HCPCS GIDXX, and associated relative values, and urges CMS to finalize it for CY 2025.

Conversion Factor

IDSA remains concerned about the steep reduction in the Medicare PFS conversion factor proposed for CY 2025. As proposed, the CY 2025 proposed PFS conversion factor is $32.36, a decrease of approximately 2.8% from the CY 2024 PFS conversion factor of $33.29. This stems from the following:

- The 0.00% update adjustment factor as established in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA);
- The expiration of the 2.93% increase provided by Congress for CY 2024 in the Consolidated Appropriations Act, 2024;
- A budget neutrality adjustment of 0.5% stemming from CMS' proposals.

Unfortunately, these cuts coincide with ongoing growth in the cost to practice medicine as CMS projects the increase in the Medicare Economic Index (MEI) for 2025 will be 3.6%. Physician practices cannot continue to absorb increasing costs while their payment rates dwindle. Both the Medicare Physician Payment Advisory Commission and the Medicare Trustees have issued warnings about access to care problems for America's seniors and persons with disabilities if the gap between what Medicare pays physicians and what it costs to provide high-quality care continues to grow.[2]

To address these concerns, IDSA advises that CMS work with Congress on solutions to the PFS challenges such as the lack of inflationary update, budget neutrality threshold, practice expense updates and quality program reforms. IDSA is actively supporting bipartisan efforts in Congress to prevent any reimbursement cuts to physicians for 2025 and engaging with Congress to inform broader PFS reform efforts. Adjusting physician reimbursement rates to better reflect inflation is helpful for all but does not address specific concerns for specialties that have been the most chronically undervalued, including ID physicians. IDSA appreciates and strongly supports CMS' proposal to establish coding and payment for inpatient ID care reflecting its inherent complexity and urges CMS to continue working with IDSA to ensure the new add-on code achieves its goals and to develop additional policies, such as new coding and payment for the initiation and oversight of OPAT, in future rulemaking.

<u>Physician Fee Schedule Provisions</u>

Practice Expense

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[2] *Medicare trustees warn of payment issue's impact on access to care* (no date) *American Medical Association*. Available at: https://www.ama-assn.org/press-center/press-releases/medicare-trustees-warn-payment-issue-s-impact-access-care (Accessed: 29 July 2024).

IDSA appreciates and agrees with CMS' proposal to, once again, delay incorporating the 2017-based MEI in PFS rate setting for CY 2025 as it awaits data from the American Medical Association (AMA) Physician Practice Information (PPI) Survey effort, which is currently underway.

However, we continue to be concerned about the pace at which CMS has made updates to direct practice expenses (PEs), including clinical labor, supplies and equipment. CMS delayed updating these direct PE inputs by two decades, causing significant shifts in payment across codes and specialties. Considering the high rate of inflation and growing practice costs, these updates must occur on a more regular and frequent basis, not less than every 5 years. We appreciate that CMS discusses plans to update its PE methodology and incorporate more routine updates to these costs, as often as every 4 years. **IDSA urges CMS to share more about these methodology improvements, including CMS' contact with the RAND Corp. to analyze and develop alternative methods for measuring practice expenses for implementation of updates to payment under the PFS, including an analysis of updated PPI data. CMS should provide updates to the physician community on these efforts on a dedicated CMS webpage, as often as possible, and preferably more often than PFS notice-and-comment rulemaking.**

Potentially Misvalued Services Under the PFS

COVID Immunization Administration (CPT Code 90480)

CMS is proposing the RUC-recommended work RVU of 0.25 for CPT code 90480 (Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, single dose). CMS is also proposing the RUC-recommended direct PE inputs for CPT code 90480 without refinement. IDSA supports this RUC-recommended work RVU.

RSV Monoclonal Antibody Administration (CPT Codes 96380 and 96381)

CMS is proposing the RUC-recommended work RVU of 0.24 for CPT code 96380 (Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional) and the RUC-recommended work RVU of 0.17 for CPT code 96381 (Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection). CMS understands that these are interim work recommendations from the RUC, and that the RUC intends to conduct a more complete review at a future RUC meeting, which we would then consider in future rulemaking. CMS is also proposing the direct PE inputs as recommended by the RUC for both codes. IDSA supports these changes but recommends that the RUC does conduct a more complete review for these codes.

Telemedicine

CMS does not propose to adopt 16 of 17 new telemedicine codes established by the AMA CPT Editorial Panel. CMS will continue to pay for office and outpatient E/M as telehealth services under their current

authority, bearing in mind that geographic and site of service restrictions that were in place prior to the COVID-19 public health emergency (PHE) will again be in effect starting Jan. 1, 2025. IDSA understands that CMS cannot adopt these codes due to the language used within the codes under the Medicare active status as they are currently proposed.

Non-Chemotherapy Administration

IDSA appreciates and supports CMS' proposals to update its Medicare Claims Processing Manual, Chapter 12, Section 30.5, to include language currently consistent with CPT code definitions for the complex non-chemotherapy infusion code series stating that the administration of infusion for particular kinds of drugs and biologics can be considered complex and may be appropriately reported using the chemotherapy administration CPT codes 96401-96549. ID physicians that operate infusion suites in outpatient settings, including their offices, frequently administer highly complex biologics and monoclonal antibodies for ID and other conditions. MACs have inappropriately directed ID practices to "down code" these services as "therapeutic" despite the level of effort involved in managing these drug administration services to patients. **We urge CMS to finalize these manual changes and to monitor MAC adherence to the revised policy. This new language will result in more accurate payments for non-chemotherapy administration and will improve patient access.**

Medicare Telehealth Services

Requests for Changes to the Medicare Telehealth Services List

CMS notes that services identified with provisional status will remain on the list on a provisional basis until CMS conducts a comprehensive review of all provisional codes. CMS proposes to add individual counseling for preexposure prophylaxis (PrEP) of HIV to the Medicare Telehealth Services List with a permanent status. IDSA agrees with and strongly supports the addition of individual counseling with a permanent status. PrEP is a critical part of the strategy to dramatically reduce new HIV cases and end HIV as an epidemic. **Because only one-third of people who could benefit from PrEP have access to it, with significant disparities among the people most heavily impacted by HIV, it is imperative that access is expanded through the Medicare program. Accounting for the physician work rendered in this process will encourage its use throughout primary care and help tremendously in the goal to prevent new HIV cases in the United States.**

Frequency Limitations

CMS proposes to remove the frequency limitations for the provision of subsequent care services in inpatient and skilled nursing facility settings and critical care consultations via telehealth for CY 2025. IDSA supports the removal of these frequency limitations to remove arbitrary barriers to care.

Audio-Only Communication

CMS proposes to allow audio-only communication technology to meet the definition of "telecommunications system" for the purposes of furnishing telehealth to beneficiaries in their homes, when certain conditions are met. However, CMS notes that, with the expiration of PHE-related telehealth flexibilities Dec. 31, 2024, a patient's home would not be a permissible originating site except in limited cases.

We have previously shared the value of audio-only technology in management of ID conditions, as it is often the only means by which some Medicare beneficiaries will be able to access ID care, even absent the pandemic. Broadband internet remains limited or nonexistent in many areas of the country, making access to audio-visual technology nearly impossible. Moreover, in our experience, some Medicare beneficiaries find audio-visual technologies difficult to use, while others feel uncomfortable using it altogether. This is particularly true for those with certain health conditions, including those managed by ID clinicians, who prefer the increased privacy afforded via audio-only care. **We encourage CMS to improve reimbursement for telephone E/M services so that reimbursement reflects the care provided, not the device used. We urge CMS to work with Congress to extend flexibility on originating site requirements and geographic restrictions, as well as allow the use of audio-only telehealth.**

Direct Supervision via Virtual Presence

CMS proposes to allow for direct supervision via virtual presence using audio/video real-time communications technology on a permanent basis, but only for a subset of incident to services when: (1) the service is provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision, and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; or (2) the service is an office or other outpatient E/M visit for an established patient that may not require the presence of a physician or other qualified health care practitioner. (Note that, in previous comment solicitations, CMS suggested that Level I ED visits might be subject to such a policy but has since concluded that ED services would not wholly be furnished by auxiliary personnel, so has excluded them from this proposal.) For all other services, CMS proposes to continue to allow for direct supervision via virtual presence using real-time audio and visual interactive telecommunications technology through 2025. **IDSA supports allowing direct supervision via virtual presence on a permanent basis.** IDSA proposes that direct supervision should be included, at least for the "uncomplicated" antimicrobial infusions given, as many ID practices also provide biologic infusions that have a higher chance of infusion reactions and would be considered "complicated."

Teaching Physician Supervision via Virtual Presence

CMS proposes to continue its current policy to allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings, but only when the service is furnished virtually. IDSA supports this continuation and also recommends supervision of ID fellows as they are still considered physicians in training.

Additional Payment Provisions

Hepatitis B Vaccines

CMS reviewed that hepatitis B vaccines are covered at no cost to the beneficiary as a Medicare Part B benefit for "beneficiaries who are at high or intermediate risk of contracting hepatitis B" but stated that "the regulations are outdated as these risk categories have been shown ineffective and are no longer the focus of how the medical community discusses hepatitis B infection and prevention." To address this, CMS proposes to establish that "[i]ndividuals who remain unvaccinated against hepatitis B are at intermediate risk, at minimum, of contracting hepatitis B virus." CMS also proposes to define individuals as at "intermediate risk" if their hepatitis B vaccine status is unknown. IDSA supports this language change, as it better aligns with public health strategies to expand hepatitis B vaccination to individuals who are unvaccinated against hepatitis B or whose hepatitis B vaccine status is unknown.

Revisions to Payment Policies for Hepatitis B Vaccine

CMS proposes to expand the list of individuals who are at high or intermediate risk of contracting hepatitis B as, currently, hepatitis B vaccination claims require a physician's order and cannot be roster billed by mass immunizers. If this proposal is finalized, CMS will remove its policy that the administration of a Medicare Part B hepatitis B vaccine has to be preceded by a physician's order. Therefore, CMS will also change its procedures to allow mass immunizers to use the roster billing process to submit Medicare Part B claims for hepatitis B vaccines and their administration. **IDSA supports the proposal to remove the limitations for the hepatitis B vaccine administration.**

Medicare Part B Payment for Preventive Services

COVID-19 Monoclonal Antibodies and Their Administration

On March 22, 2024, FDA issued an emergency use authorization (EUA) for Pemgarda (pemivibart) injection, for intravenous use. Pemgarda is a monoclonal antibody product indicated for use for preexposure prophylaxis to help prevent COVID-19 in adults and children 12 years of age and older who meet certain criteria. CMS established specific coding and payment rates for the administration of Pemgarda through technical direction to MACs and information posted publicly on the CMS website. Since Pemgarda is used for preexposure prophylaxis of COVID-19, which CMS is covering under the Part B preventive vaccine benefit even after the EUA declaration for drugs and biological products is terminated (so long as such products still have market authorization), CMS plans to propose long-term coding and payment rates for the administration of this product in future rulemaking. IDSA supports this proposal with the hope that a code for therapeutic care can be implemented in the future.

Revisions to Payment Policies for Hepatitis B Vaccinations in Rural Health Clinics and Federally Qualified Health Centers

Additionally, CMS proposes to use statutory authority it identifies at 1833(k) to align payment for hepatitis B vaccinations in rural health clinics (RHCs) and Federally Qualified Health Clinics (FQHCs) with the payment for pneumococcal, influenza and COVID-19 vaccinations in those settings. This proposal means that CMS will pay for hepatitis B vaccines and their administration in RHCs and FQHCs at 100% of reasonable cost for all populations identified for coverage at §410.63(a). If this policy is finalized, then effective Jan. 1, 2025, RHCs and FQHCs would bill for Part B hepatitis B vaccines in the same manner as they currently bill for pneumococcal, influenza and COVID-19 vaccines, that is, on their cost report. To implement this proposal, CMS proposes to amend the regulations at §405.2466(b)(1)(iv), to add hepatitis B vaccines to the list of vaccines covered in RHCs and FQHCs at 100% of reasonable cost. If revisions to §405.2466(b)(1)(iv) are finalized as proposed, CMS would make corresponding changes to guidance in the Medicare Benefit Policy Manual, Chapter 13, and Medicare Claims Processing Manual, Chapter 9, as well as necessary operational changes. **IDSA strongly supports CMS covering the payment of hepatitis B vaccinations at RHCs and FQHCs.**

Payment for Drugs Covered as Additional Preventive Services (§410.152)

CMS notes that it has not yet utilized the authority under 1833(a)(1)(W)(ii) as it has not covered any additional preventive service that would require use of the authority, specifically for any drugs or biologicals (hereinafter, referred to as drugs). CMS notes, however, that it released a Proposed National Coverage Determination (NCD) for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention on July 12, 2023. The proposed NCD announced CMS' intent to cover and pay for PrEP under Section 1861(ddd) authority, and a decision on the NCD is forthcoming. For the reasons stated above, access to PrEP is imperative for individuals at risk of contracting HIV. **IDSA supports CMS' intent to pay for PrEP and awaits a decision on the NCD.**

Proposed Fee Schedule for Drugs Covered as Additional Preventive Services

While drugs covered as additional preventive services (DCAPS drugs) are not subject to payment rules under Section 1847A, which generally requires payments made according to an average sales price (ASP) methodology, CMS expresses an interest in setting drug payment limits under Part B as consistently as possible. CMS therefore proposes that the payment limit for a DCAPS drug be determined using the methodology described in Section 1847A of the Act (also referred to as ASP methodology) or, if ASP data is not available for a particular drug, to use an alternative pricing mechanism, as described below. CMS proposes to update the fee schedule quarterly, on the same schedule as the ASP pricing file, which is updated each calendar quarter. **IDSA supports the alignment of drugs paid under Medicare Part B and no cost sharing for beneficiaries.**

Quality and Value-Based Care Provisions

Merit-Based Incentive Payment System

CMS is proposing to maintain the threshold to avoid a Merit-Based Incentive Payment System (MIPS) penalty of up to 9% at 75 points for the CY 2025 performance year/2027 MIPS payment year. Research continues to show that MIPS is unduly burdensome; is disproportionately harmful to small, rural and independent practices; exacerbates health inequities; and is divorced from meaningful clinical outcomes.

IDSA is urging Congress to make statutory changes to improve MIPS and address fundamental problems with the program by replacing steep penalties that disproportionately hurt small and rural practices, prioritizing access to timely and actionable data, reducing burden, aligning MIPS with facility quality programs and incentivizing the development and reporting of new clinically relevant quality and cost measures.

MIPS Value Pathways

The Role of MIPS Value Pathways in Transforming MIPS

CMS continues to incrementally develop and maintain MIPS Value Pathways (MVPs) that are relevant and meaningful for all clinicians who participate in MIPS to support a full transition to MVPs. CMS has not proposed a target year to sunset traditional MIPS; however, it believes it is critical to develop a plan to sunset traditional MIPS for the awareness of all interested parties so they may plan their work accordingly to coincide with this timeline. According to CMS, continuing to maintain the traditional MIPS submission option may impair MVP adoption by clinicians who have an available MVP. Slow adoption may delay the benefits of MVPs, which will simplify MIPS and improve comparable clinician performance data that helps to drive value and inform clinician selection by patients.

To develop a timeline for the full transition to MVPs, CMS is seeking feedback through an RFI on clinician readiness for MVP reporting and MIPS policies needed to sunset traditional MIPS and fully transition to MVPs in the CY 2029 performance period/2031 MIPS payment year. This timeline would ensure MVPs may be voluntarily reported during a period of 6 to 7 years while traditional MIPS is available, allowing clinicians time to prepare for MVP reporting and to engage in the development of the MVP inventory. CMS appreciates that it must ensure that any MIPS policies that require rulemaking to sunset traditional MIPS are proposed and finalized, and that adequate prior notice is provided to clinicians who may need to update their systems and work processes to report MVPs. CMS also continues to assess remaining MVP gaps that must be filled and to confirm participation options for MIPS eligible clinicians, as discussed below. CMS anticipates that it may be ready to fully transition to MVPs by the CY 2029 performance period/2031 MIPS payment year.

IDSA continues to have reservations about the way MVPs are being implemented, and we 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. For example, 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 the HIV and hepatitis C virus 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 nonproceduralists/cognitive physicians who provide most of their services using E/M codes, many of which are billed in the inpatient setting. 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 developing 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 is limited to the current inventory of MIPS quality measures and does little to incentivize the development or use of more innovative and meaningful measures. IDSA encourages CMS to adopt policies to address these shortcomings and to work with professional societies to increase the number and use of relevant clinical quality measures. **IDSA would greatly appreciate an opportunity to partner with CMS to explore the development of new measures to populate future MVPs for infectious diseases conditions that are reportable by multiple specialties within the hospital setting.**

We also encourage CMS to expand opportunities for facility-based clinicians to get MIPS credit for outcomes they contribute to within their institutions, which might be measured under a separate CMS quality program. The number of clinicians who have qualified for facility-based scoring under MIPS to date has been lower than expected, which might signal a need to reevaluate and update this policy. Doing so would not only provide ID physicians with a more meaningful participation pathway but would also promote team-based approaches to care and minimize duplicative reporting.

Given these ongoing challenges, IDSA strongly urges CMS not to mandate MVPs starting in 2029, but to instead preserve choice in the program and to work with stakeholders, including IDSA, to address some of the underlying limitations of the program that make it challenging for ID physicians to participate meaningfully and successfully.

Regarding subgroup reporting, while we recognize that this policy is aimed at encouraging more focused and specialized reporting of measures, if the measures simply do not exist in the program, then this mandate will put specialties that are already struggling under this program at a greater disadvantage. **We ask CMS to reconsider its previously finalized policy of requiring multispecialty groups participating through an MVP to form subgroups for purposes of reporting data. If CMS continues to move forward with this mandate, we urge it to not impose restrictions on the formation or makeup of subgroups. Subgroup reporting is expected to add a new layer of burden to MIPS, and practices should maintain the ability to choose how best to organize its clinicians for purposes of quality reporting.**

Modification to Infectious Disease MVP

CMS is not proposing to modify the previously finalized Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP within the quality performance category of this MVP by proposing to add or remove quality measures from the MVP. However, CMS is proposing to modify the Q340: HIV Medical Visit Frequency quality measure, which includes a proposed measure title update.

IDSA was pleased that last year, CMS expanded the set of quality measures offered under the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP to include broadly applicable quality measures that are relevant to infectious disorders and that encourage antimicrobial stewardship, medication reconciliation and receipt of appropriate immunizations and preventive screenings. This expansion makes the MVP more accessible to members of our specialty who might not only see HIV patients. **However, we continue to strongly oppose the inclusion of the Total Per Capita Cost (TPCC) measure in this MVP**. As we have expressed in the past, this measure captures aspects of care that ID physicians do not have direct control over, and it provides little meaningful or actionable data to help clinicians understand what they can do to lower costs and improve the value of care. Importantly, for our specialty in particular, is the failure of the measure to account for short-term investments that might actually result in savings and higher-quality care over the long term. We should be aiming to promote good stewardship of resources, not simply cost containment. The goal should be to do the right thing the first time, even if that is more expensive upfront, which is extremely important in the context of managing a chronic condition like HIV. Otherwise, broad, total cost measures like this could result in harm to the patient. **We urge CMS and Acumen to work with IDSA to develop cost measures that more accurately reflect the care provided by ID physicians and the unique needs of their patients.**

In the interim, we strongly recommend that CMS remove the TPCC measure from the program. CMS' decision to revisit and revise this measure numerous times over the years demonstrates its weaknesses and the fact that it is not working as intended. CMS should not use this measure simply as a placeholder in the absence of more focused and clinically accurate measures, particularly given the risk of unintended consequences that negatively impact patient care.

Traditional MIPS

Data Completeness Criteria

For the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, CMS previously finalized an increase in the data completeness criteria threshold from at least 70% to at least 75%, following concerns expressed about CMS' proposal to increase it to at least 80%. In this rule, CMS proposes to maintain this higher threshold for two additional years. Specifically, for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years:

- A MIPS eligible clinician, group, virtual group, subgroup and APM Entity submitting quality measures data on Qualified Clinical Data Registry measures, MIPS CQMs or eCQMs must submit data on at least 75% of the MIPS eligible clinician, group, virtual group, subgroup or APM Entity's patients that meet the measure's denominator criteria, regardless of payer.
- A MIPS eligible clinician, group, virtual group, subgroup and APM Entity submitting quality measures data on Medicare Part B claims measures must submit data on at least 75% of the MIPS eligible clinician, group, virtual group, subgroup or APM Entity's patients seen during the corresponding performance period to which the measure applies.
- An APM Entity, specifically a Shared Savings Program (SSP) Program Accountable Care Organization (ACO) that meets the reporting requirements under the APP, submitting quality

measure data on Medicare CQMs must submit data on at least 75% of the APM Entity's applicable beneficiaries eligible for the Medicare CQM who meet the measure's denominator criteria.

CMS continues to believe that it is important to incrementally increase the data completeness criteria and believes that maintaining the 75% threshold for a total of 5 years would provide sufficient time for MIPS participants to adjust to this higher threshold. **IDSA agrees with CMS' decision to extend the 75% threshold until 2028 and thanks CMS for this extension.**

Modifications to the Infectious Disease Specialty Set

The Infectious Disease specialty set takes additional criteria into consideration, which include, but are not limited to, whether a measure reflects current clinical guidelines, and whether the coding of the measure includes relevant clinician types. CMS requests comment on the measures available in the proposed Infectious Disease specialty set.

- Gains in Patient Activation: Many other specialty sets utilize this tool in their measures, and IDSA supports the implementation of this measure to be applied to ID-specific care.
- COVID-19 Immunization: This measure is proposed for multiple specialties that have longitudinal engagement with patients, such as cardiology and OB/GYN care. Given the unique political concerns surrounding COVID-19 immunization in particular, this measure could be difficult to achieve high-quality benchmarks. Many patients will accept other vaccines but will not accept the COVID-19 vaccine. If providers are benchmarked against a national average for this measure, the regional variation in political views toward COVID-19 immunizations will cause a disadvantage for ID providers in certain geographic regions of the country.

RFI: Guiding Principles for Patient-Reported Outcome Measures in Federal Models, and Quality Reporting and Payment Programs

CMS is committed to elevating the patient voice in health care by incorporating more patient-reported outcome measures (PROMs) and patient-reported outcome performance measures (PRO-PMs) in CMS quality reporting and payment programs and CMS Innovation Center models. A potential path forward is the development of an accessible and unified database of PROMs/PRO-PMs used in programs and payment systems in health care by federal, state-based and commercial payers, and health care systems. The PROMs in this database could serve as a resource for the subsequent development of PRO-PMs.

At the same time, considerations for a data infrastructure that allows PROMs and PRO-PMs to be integrated into clinical workflow with minimal cost and administrative burden, with data seamlessly shared across different health care settings and systems, is important. While there may be important reasons for not restricting PROMs/PRO-PMs to a strictly defined data infrastructure, CMS seeks to avoid the evolution of multiple PROM/PRO-PM repositories that may inhibit the development of these measures and potentially impose additional costs on clinicians and health care systems.

IDSA supports the development of unified databases of PROMs in programs and payment systems to be integrated into clinical workflow with minimal cost and administrative burden, and this development would allow for data to be shared across different health care settings and systems.

Improvement Activities Performance Category

CMS proposes to modify IA-ERP_6, titled "Vaccine Achievement for Practice Staff – COVID-19," to revise its target goals and to expand its focus and promote the vaccination of staff for COVID-19, as well as influenza and hepatitis B. **IDSA supports the expansion of IA-ERP_6 to promote increased vaccination of health care system staff.** This will help protect the workforce from serious illness, helping them to continue to provide essential long-term patient care.[3] This modification will also help limit potential spread of diseases to vulnerable patients.

Promoting Interoperability (PI)

RFI: Public Health Reporting and Data Exchange

CMS is working in partnership with CDC and the Office of the National Coordinator to explore how the Promoting Interoperability performance category could advance public health infrastructure through more advanced use of health IT and data exchange standards.

CMS sets forth the following four goals that inform the questions in this RFI:

1. The meaningful use of CEHRT enables continuous improvement in the quality, timeliness and completeness of public health data being reported;

2. The meaningful use of CEHRT allows for flexibility to respond to new public health threats and meet new data needs without requiring new and substantial regulatory and technical development;

3. The meaningful use of CEHRT supports mutual data sharing between public health and health care providers; and 4. Reporting burden on MIPS eligible clinicians is significantly reduced.

Within this RFI, CMS wants to explore how PI could advance public health infrastructure through more advanced use of health IT and data exchange standards. CMS noted how the COVID-19 PHE highlighted the interdependencies of public health and health care, and the importance of timely, integrated and interoperable data exchange across the health ecosystem to protect the health and safety of patients, populations and the broader public. **IDSA supports efforts to expand health IT and data exchange, especially during a pandemic, but recommends an integrated dashboard containing data on COVID-19, flu and RSV.**

Alternative Payment Model Performance Pathway

[3] Lee JT, Althomsons SP, Wu H, et al. Disparities in COVID-19 Vaccination Coverage Among Health Care Personnel Working in Long-Term Care Facilities, by Job Category, National Healthcare Safety Network — United States, March 2021. MMWR Morb Mortal Wkly Rep 2021;70:1036–1039. DOI: http://dx.doi.org/10.15585/mmwr.mm7030a2.

CMS proposes to create within the APM Performance Pathway (APP) the APP Plus quality measure set beginning with the CY 2025 performance period/2027 MIPS payment year to align with the Universal Foundation measures under the CMS National Quality Strategy. CMS is not proposing to modify the existing APP quality measure set, which already includes five of the 10 Universal Foundation measures. Instead, it proposes to establish the APP Plus quality measure set as a second, optional measure set that would be comprised of all of the measures in the existing APP quality measure set and would additionally incrementally adopt the remaining five Universal Foundation measures from the CY 2025 performance period/2027 MIPS payment year through the CY 2028 performance period/2030 MIPS payment year. Under this proposal, a MIPS eligible clinician, group or APM Entity that reports the APP may choose to report either the APP quality measure set or the APP Plus quality measure set.

CMS proposes the following measure, which will be added incrementally:

Beginning with the CY 2028 performance period/2030 MIPS payment year and continuing for subsequent performance periods: quality measure #487: The Screening for Social Drivers of Health and quality measure #493: Adult Immunization Status. These measures are currently available as MIPS CQMs but are not currently available as eCQMs or Medicare CQMs. If this proposal is finalized, CMS would make these measures available prior to the start of CY 2028 performance period/2030 MIPS payment year to report as eCQMs and, for Shared Savings Program ACOs only, Medicare CQMs. **IDSA supports the inclusion of this new immunization status given the impact of social determinants of health on ID and the disproportionate impact of infectious diseases on marginalized populations.**

Qualifying Participant (QP) Thresholds and Partial QP Thresholds

The Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118-42, March 9, 2024), amended Section 1833(z)(2) of the act by extending for payment years 2025 and 2026 (performance periods 2023 and 2024) the applicable payment amount and patient count thresholds for an eligible clinician to achieve QP status. Specifically, for the 2024 performance period/2026 payment year:

- Medicare Option:
    - QP threshold will remain at 50% for the payment amount method (rather than increase to 75%) and 35% for the patient count method (rather than increase to 50%);
    - Partial QP thresholds will remain at 40% for the payment amount method (versus 50%) and 25% for the patient count method (versus 35%).
- All-Payer Combination Option:
    - QP thresholds for payment year 2026 (performance period 2025) will remain at 50% for the payment amount method (versus 75%) and 35% for the patient count method (versus 50%).
    - Partial QP thresholds for payment year 2026 (performance period 2024) will continue at 40% for the payment amount method (versus 50%) and 25% for the patient count method (versus 35%).

In this rule, CMS proposes to amend §414.1430 to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count methods under the Medicare Option and the

All-Payer Option with respect to payment year 2026 (performance year 2024) in accordance with amendments made by the CAA, 2024.

In payment year 2025, QPs in Advanced APMs will receive a lump-sum APM Incentive Payment equal to 3.5% payment of their estimated aggregate paid amounts for covered professional services furnished during CY 2024 (down from 5%). In payment year 2026, this incentive payment drops to 1.88%. Also beginning in payment year 2026, there are two separate PFS conversion factors – one for QPs (0.75) and one for all non-QP eligible clinicians (0.25). The thresholds to achieve QP status beginning in the 2025 QP performance period will increase to 75% (from 50%) for the payment amount method, and 50% (from 35%) for the patient count method.

IDSA strongly opposes physician APM incentive payments dropping per consecutive year and an increase to the QP threshold. An increase in the QP threshold fails to account for the number of clinicians who have relied on the COVID-19 hardship exception since 2019. These ID clinicians that have been struggling to keep up with the administrative cost of compliance will be hardest hit if CMS finalizes a higher performance threshold for next year. IDSA urges CMS to encourage Congress to resolve these issues.

Request for Information: Building Upon the MVP Framework to Improve Ambulatory Specialty Care

CMS is considering a model design that would increase the engagement of specialists in value-based payment and encourage specialty care provider engagement with primary care providers and beneficiaries. Specifically, CMS is exploring developing a model for specialists in ambulatory settings that would leverage the MVP framework. As currently envisioned, participants under this model would not receive a MIPS payment adjustment. Instead, a model participant would receive a payment adjustment based on (1) a set of clinically relevant MVP measures that they are required to report and (2) comparing the participant's final score against a limited pool of clinicians (other model participants of their same specialty type and clinical profile, who are also required to report on those same clinically relevant MVP measures). Currently, under MIPS, performance and the subsequent payment adjustment are based on a range of measures voluntarily reported by clinicians, who receive a final score based on the submitted measures. A clinician's performance is assessed against a pool of all clinicians, regardless of specialty type or the services they provide. CMS expects that a more targeted approach, where clinicians are evaluated (1) on a set of relevant performance measures they are required to report and (2) among clinicians furnishing similar sets of services, would produce scores and subsequent payment adjustments that are more reflective of clinician performance. A more targeted approach to measurement would also offer more insight into how clinical decisions and processes, such as care coordination, affect patient outcomes. CMS expects this ambulatory specialty model would be implemented no earlier than 2026, ensuring participants have sufficient time to prepare for the model.

We refer CMS to our earlier comments in response to its RFI on Transforming the QPP and potentially transitioning to mandatory MVPs. **IDSA does not view MVPs as an adequate solution to accurately capture and drive improvements in value**. In addition to the limitations associated with existing quality and cost measures described earlier in our letter, the quality and cost measures in MVPs lack alignment. As a result, it is not possible to measure changes in quality relative to changes in cost, which

also means that MVPs will not produce an accurate picture of overall value. The ongoing lack of specialty-focused APMs is a problem that must be addressed through comprehensive, focused solutions – not simple fixes such as MVPs, which do nothing to promote coordination of care, to improve the accuracy of value assessments or to recognize innovative investments in value-based care that fall outside of the four siloed and rigid categories of MIPS.

Conclusion

IDSA thanks you for your attention to these important issues impacting prevention and treatment of infectious diseases. We hope that our comments are useful as you work to finalize the CY 2025 Medicare PFS rule. If you have any questions or if we may be of further assistance to you, please do not hesitate to contact Amanda Jezek, IDSA senior vice president for public policy and government relations, at ajezek@idosciety.org.

Sincerely,

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IDSA President