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Infectious Diseases Society of America

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September 8, 2015

Submitted via: <http://www.regulations.gov>

Andy Slavitt, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201  
Attention: CMS-1631-P

Re: Comments on Medicare Program Revisions to Proposed Payment Policies under the Physician Fee Schedule for CY 2016 [CMS-1631-P]

Dear Mr. Slavitt,

The Infectious Diseases Society of America (IDSAs) appreciates the opportunity to provide comments on the CY 2016 Physician Fee Schedule (PFS) proposed rule. IDSAs represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, serious health care acquired infections, antibiotic resistant bacterial infections, as well as emerging infections such as Middle East Respiratory Syndrome coronavirus (MERS-CoV) and Ebola.

IDSAs members are committed to improving the quality and safety of patient care in a manner that aligns reimbursement with value-based principles. This PFS proposed rule outlines changes to the Physician Quality Reporting System (PQRS), the Quality and Resource Use Reports (QRURs) and the Value-Based Payment Modifier (VM), and the Physician Compare Website, among other Part B related issues. As well, this proposed rule is the first effort to engage the provider community on how best to implement the provisions called for in the Medicare Access and CHIP Reauthorizations Act (MACRA). Below, we submit our specific comments on these proposed changes. However, we begin with a description of our specialty and how our members in clinical practice operate within the health care system, as this will be useful background that explains our perspective. As well, this description of our specialty will help to provide rationale to our suggestions with respect to the implementation of MACRA provisions.

## The ID Specialist in Clinical Practice

The majority of ID specialists in clinical practice are employed physicians within large multispecialty groups affiliated with large hospital systems and/or academic medical centers. Of those that are in private practice, most are in small ID-focused practices with less than 5 physicians. ID specialists are not “proceduralists” but rather are cognitive specialists, providing most of their services using Evaluation & Management (E/M) codes. Across all ID specialists in clinical practice, the overwhelming majority of E/M codes billed are for services provided in the inpatient setting. In fact, from CMS data, we can report that 83% of the 6.6 million E/M services by ID specialists reimbursed by Medicare in 2012 were conducted in the inpatient setting.<sup>1</sup> Within the inpatient setting, ID specialist involvement in the care of patients with severe infections has been well-documented to produce decreased mortality, reduced length-of-stay, fewer readmissions, and/or lower costs.<sup>2,3,4</sup> The importance of highlighting the inpatient focus of ID specialty care, as well as the practice affiliation, is particularly significant when considering quality measurement and reporting under PQRS, EHR technology adoption, and resource use attribution related to the VM program. Those who are employed within large practices may have very little control over PQRS measure selection and reporting decisions made by practice management. Those who are in small practices have faced increased administrative burden in attempting to comply with PQRS, EHR Meaningful Use, and eRx. As CMS reports, “Compared with physicians in practices with 25 or more physicians, those in solo practice were less likely to participate in PQRS.”<sup>5</sup> We believe this applies to many ID specialists in solo or small practices.

In our discussions with CMS exploring quality reporting options for hospital-based physicians, we have highlighted the fact that there is currently only one PQRS measure (CMS Measure #130/NQF 0419: Documentation of Current Medications in the Medical Record – National Quality Strategy Domain: Patient Safety) that applies to inpatient E/M visits and is reasonably relevant for an ID specialist to perform. For those ID specialists practicing in the outpatient setting, very few PQRS measures are relevant. For example, the HIV/AIDS and hepatitis C virus (HCV) measure sets do not universally apply to our members as only a select portion of ID specialists focus on treating patients with these diseases. In addition, many of our patients with HIV and/or HCV are not Medicare beneficiaries. The majority of ID specialists who see patients in the outpatient setting are thereby forced to report on measures that are marginally relevant to their practice and more likely being performed by the patient’s primary care physician. From the recent “2013 PQRS & eRx Experience and Trends Report,” the top five most frequently reported individual measures by ID specialists are as follows:<sup>6</sup>

1. #130 - Documentation of Current Medications in the Medical Record
2. #226 - Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
3. #111 - Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years or Older
4. #110 - Preventive Care and Screening: Influenza Immunization
5. #128 - Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up

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<sup>1</sup> MEDICARE PART B PHYSICIAN/SUPPLIER NATIONAL DATA CALENDAR YEAR 2012 EVALUATION AND MANAGEMENT CODES BY SPECIALTY- available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareFeeForSvcPartsAB/downloads/EMSpecialty2012.pdf?agree=yes&next=Accept>

<sup>2</sup> Schmitt S, McQuillen DP, Nahass R, et al. Infectious diseases specialty intervention is associated with decreased mortality and lower healthcare costs. *Clin Infect Dis* 2014; 58:22–8.

<sup>3</sup> Hamandi B, Husain S, Humar A, Papadimitropoulis EA. Impact of Infectious Disease Consultation on the Clinical and Economic Outcomes of Solid Organ Transplant Recipients Admitted for Infectious Complications. *Clin Infect Dis* 2014; 59: 1074-1082

<sup>4</sup> Bai AD, Showler A, Burry L, et al. Impact of infectious disease consultation on quality of care, mortality, and length of stay in *Staphylococcus aureus* bacteremia: results from a large multicenter cohort study. *Clin Infect Dis* 2015; 60:1451–61

<sup>5</sup> 2015 National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Report – available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/National-Impact-Assessment-of-the-Centers-for-Medicare-and-Medicaid-Services-CMS-Quality-Measures-Reports.html>

<sup>6</sup> 2013 Physician Quality Reporting System and eRx Reporting Experience and Trends – available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/AnalysisAndPayment.html>

The second and fifth measures listed above are of questionable relevance to the ID physician's care of the majority of their patients. ID care is typically episodic and is focused on the acute problem for which the patient is referred to the ID physician for treatment.

In thinking about applicable measures under the VM program, (Acute and Chronic Ambulatory Care Sensitive Condition (ACSC) Composite, 30-day All-Cause Hospital Readmission, Per Capita Costs for All Attributed Beneficiaries, and Per Capita Costs for Beneficiaries with Specific Conditions measures), it is important to note that ID specialists are called on to provide services by the attending physician, and often the timing of when that consult is ordered has significant impact on the costs and outcome, (Schmitt et al).

### **Improving Payment Accuracy for Primary Care and Care Management Services**

In this rule, CMS has recognized that the "current E/M office/outpatient visit CPT codes were designed with an overall orientation toward episodic treatment,... these E/M codes may not reflect all the services and resources involved..." We appreciate this acknowledgement but we believe that this applies not just to office/outpatient visits but to all cognitive work captured by the E/M code set, including the inpatient and other sites of service.

As we have previously asserted, the current Medicare fee schedule is flawed in large part due to inherent biases in the valuation process that favor procedures, imaging, and laboratory services over cognitive services.<sup>7</sup> We reiterate the need for consideration of the complexity of medical decision-making on the part of many cognitive specialists and primary care physicians involved in the treatment of acute and chronic conditions. To this end, CMS proposes to use add-on codes that would capture "the different resources (particularly cognitive work) involved in delivering broad-based, ongoing treatment, beyond those resources already incorporated."

We applaud the agency for proposing to address the deficiencies in the existing evaluation and management (E/M) services. IDSA supports CMS' proposal to create add-on codes to reimburse currently uncompensated physicians' work associated with E/M services as a practical and expedient, though limited, solution to the undervaluation of E/M services. Again, we stress that these add-on codes should apply for the full set of E/M codes, across all sites-of-service. These add-on codes should follow the resource-based paradigm of RBRVS using work intensity as the unit of resource use. For primary care, the levels of intensity would recognize both the complexity of multiple interactions of medications and health problems and the post-visit work intensity for patients with multiple chronic conditions. For the specialist, the levels of intensity would correspond to disease state complexity and medical decision making.

While IDSA appreciates CMS' current proposal to more fairly recognize physician work in providing E/M services, it is limited in scope by its very nature and will at best be only partially successful. The existing E/M codes continue to be inadequately defined and valued – a gap that has grown substantially in the 30+ years since their initial Harvard valuation. In particular, the variability and intensity of the E/M work done by many specialties both within the face-to-face encounter as well as during the post-service period continues to evolve in complexity. Unfortunately, the existing E/M codes remain limited and fail to capture the diverse and growing efforts required within the current health care continuum. New research is needed to better identify and quantify the inputs that accurately capture the elements of complex medical decision-making. Such studies should take into account the evolving health care

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<sup>7</sup> Comments on Medicare Program Revisions to Proposed Payment Policies under the Physician Fee Schedule for CY 2014 [CMS-1600-P] - available at [http://www.idsociety.org/uploadedFiles/IDSA/Policy\\_and\\_Advocacy/Current\\_Topics\\_and\\_Issues/Access\\_and\\_Reimbursement/2013/IDSA%20Comment%20PFS%20CY2014\\_final.pdf#search=%22inherent biases in the valuation process%22](http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Access_and_Reimbursement/2013/IDSA%20Comment%20PFS%20CY2014_final.pdf#search=%22inherent%20biases%20in%20the%20valuation%20process%22)

delivery models with growing reliance on team-based care, and should consider patient risk-adjustment as a component to determining complexity. We urge CMS to commit to underwriting this research by hiring an expert contractor to work with stakeholders to develop a comprehensive understanding of E/M. IDSA supports exploration of alternative valuation models with the aim of improving the valuation of physician services that involve complex medical decision-making. Furthermore, we believe it is imperative that any research into an alternative valuation process include direct involvement of physicians and other healthcare providers who are the purveyors of the very medical services that are to be valued.

This research should:

- 1) describe in detail the full range of intensity for E/M services, placing a premium on the assessment of data and resulting medical decision making,
- 2) define discrete levels of service intensity based on observational and electronically stored data combined with expert opinion,
- 3) develop documentation expectations for each service level,
- 4) provide efficient and meaningful guidance for documentation and auditing, and
- 5) ensure accurate relative valuation as part of the PFS.

IDSA is hopeful that CMS will step forward to fund this needed research and we will be pleased to serve as a resource for the agency in its efforts to ensure accurate code definitions and valuations for Evaluation & Management services.

### **Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements**

CMS has proposed to revise the regulations specifying the requirements for which physicians or other practitioners can bill for incident to services. CMS believes that the physician or other practitioner who bills for the incident to service must also be the physician or other practitioner who directly supervises the service, in recognition of the personal role in, and responsibility for, furnishing services for which the physician or other practitioner is billing and receiving payment as an incident to his/her own professional services. Therefore, CMS proposes to amend the current regulations to state “that the physician or other practitioner who bills for incident to services must also be the physician or other practitioner who directly supervises the auxiliary personnel who provide the incident to services.” Furthermore, CMS proposes to remove the last sentence from the regulation that specifies that “the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.”

IDSA appreciates the clarity that CMS intends to provide with this proposed revision. For our members who provide Outpatient Parenteral Antimicrobial Therapy (OPAT) to patients receiving long term antibiotics outside the hospital for severe infections, this clarification will facilitate their compliance with payment regulations related to “incident to” services.

### **Physician Compare Website**

#### *Timeline and Selection of Publicly Reported Data*

CMS proposes to continue to adhere to its previously proposed plan to phase in public reporting, with the goal of reporting by late 2016 on performance data for all group practices and individual practitioners reporting via any PQRS mechanism in 2015. IDSA appreciates efforts to provide consumers with tools to make them better informed decision-makers. However, we reiterate our concerns about this ambitious timeline and warn CMS about the potential unintended consequences of releasing data too prematurely.

To minimize the inappropriate release of data and confusing or even misleading the public, IDSA does appreciate CMS' previously finalized decision to only make available to the public measures that prove to be valid, reliable, and accurate upon analysis; are deemed to be statistically comparable; that meet a minimum sample size of 20 patients; and that are not first year measures. We urge CMS to work closely with professional societies throughout this process and to be as transparent as possible regarding the outcomes of these analyses. For example, CMS notes that it is conducting consumer testing to determine which measures are most suitable for public reporting, yet we have yet to see any results nor hear anything about the progress of this work. We are curious to learn how consumers search for quality data on their available facilities and providers and what factors prove to be the most meaningful to consumers when making choices about their health care. Given the importance of patient satisfaction in assessing overall quality, the findings from this consumer testing would provide valuable insight to providers and specialty societies engaged in measure development. We also would like to reiterate our concerns about the 20 patient minimum threshold for reporting performance information on Physician Compare. A sample size this low will compromise the validity of the data, provide little information of value for patient decision-making, and may result in inaccurate conclusions about a physician's quality performance.

IDSA requests that CMS take the situation of ID and others into account when deciding what data to release to the public. For example, even if an ID physician's performance on the "Documentation of Current Medications in the Medical Record" measure proved to be valid and reliable and met minimum sample size requirements, these data still would not provide consumers with meaningful data regarding the quality of care related to infectious diseases. We also request that in instances where insufficient performance data exist that CMS provide clear disclaimers on the Physician Compare website. These should clearly explain why performance data for some physicians are not yet available and how the public should not view this as an indicator of poor performance, but rather the unavailability of relevant and meaningful measure data on which to evaluate such physicians.

CMS clarifies that it will make most of the data it deems suitable for public reporting available through a downloadable data file geared towards health care professionals, industry stakeholders, and researchers who are more able to accurately interpret complex data. Only select data will be deemed appropriate for consumers and actually posted on a physician's profile page. CMS' analysis of the data, along with consumer testing and stakeholder feedback, will determine specifically which measures are made available on physician profile pages versus being available within the larger database. While we appreciate CMS recognizing that only a limited set of data will be ready for public consumption, IDSA has strong concerns about this proposal. If measure data prove to be too complex for posting on physician profile pages, we do not believe they should be made readily available in raw form through a downloadable database which may lead to stakeholders misinterpreting the data. While we support transparency, the PQRS measure set is still largely irrelevant to ID physicians and the data collected are not refined enough to ensure meaningful and accurate determinations about physician quality. We ask CMS to consider restricting access to the PQRS raw data to specialty societies and health care research entities.

#### *Preview Period*

Another critical element of public reporting is ensuring that physicians are given an appropriate opportunity to review and correct their data before it is released to the public. CMS previously finalized a decision to give physicians a 30-day period to preview their results as they will appear prior to being published. IDSA recommends that CMS extend this preview period in order to give physicians more time to review the data, identify errors and to gather the evidence needed to refute any errors. Physicians currently face multiple reporting mandates and are consumed with feedback reports related to each of these programs (e.g., multiple Quality and Resource Use Reports, PQRS Feedback Reports, etc.).

Although feedback is very much appreciated, the time that physicians must take out of their daily practice to access and make sense of all of this information is not insignificant and should be better accounted for in the preview period. In the event that a physician discovers suspected inaccuracies in the data, the time it takes to analyze the metrics, develop and submit a response will likely be longer than 30 days. It must be kept in mind that since ID physicians provide >80% of their E/M services in the inpatient setting, we may require data from hospitals and obtaining data from these facilities often takes more than 30 days. We also request additional details on the recourse that would be available to a physician who identifies a problem or error during this preview period.

### *Benchmarking*

After considering multiple alternatives and taking into account the feedback of the public and a technical expert panel, CMS proposes to apply a measure-level benchmarking methodology known as the Achievable Benchmark of Care (ABC™) to set benchmarks for publicly reported PQRS measures, using a pared-mean process that takes the mean of the best performers on a given measure for at least 10% of the patient population. CMS claims this is a well-tested, data driven model that evaluates who the top performers are, and then uses that to set a point of comparison for all of those groups or individual EPs who report the same measure. CMS would use this benchmark to systematically assign stars to physicians under the Physician Compare five star rating system.

Whereas we cannot comment on the viability of the ABC™ methodology, IDSA strongly urges CMS to expand the pared-mean cohort to include the top performers that account for at least 25% of the patient population. As well, we request that CMS provide more details about how it would translate this benchmarking methodology into an assignment of a “star-rating.” While physicians who achieve the benchmark might get five stars, it is unclear how varying levels of performance below the benchmark will be indicated. As we have noted in the past, if the underlying data are not accurate, star ratings can result in arbitrary distinctions between physicians whose performance is neither clinically nor statistically different. We also question to what extent this benchmarking methodology ensures fair comparisons among similar physicians with similar patient populations and practice settings. While some PQRS measures are very specialty-specific and will only be reported by physicians with similar patient populations, others are more cross-cutting and might be reported on by a range of specialties who have very different patient populations and very different practice circumstances. Any benchmarking methodology adopted by CMS needs to parse out these distinctions to ensure they result in apples-to-apples comparisons. Physicians should not be lumped together for purposes of comparing performance. Even more broadly focused measures, such as “Documentation of Current Medications in the Medical Record,” should be adjusted to ensure performance comparisons among similar physicians.

We also question how this proposed methodology aligns with that used by CMS to benchmark quality measure data reported through the QRURs and used to determine payment adjustments under the VM. IDSA requests that CMS aim to minimize confusion by employing a standardized methodology to benchmarking across programs—especially the two programs (the PQRS and VM) that rely on the same quality measures.

Given the complexity of these issues, we urge CMS to proceed very carefully with the benchmarking and star-rating proposal. In order for such a system to achieve the goal of informing the public, as well as physicians being evaluated, both groups need to trust the methodology and believe that the ratings are more helpful than confusing.

### *Publicly Reporting Indicators of Value*

CMS also proposes, as early as late 2017 based on 2016 data, to include a “green check mark” on

individual and group practice profile pages who received an upward adjustment as a result of the Value Modifier (VM). In addition, CMS proposes to add to the Physician Compare downloadable database the 2018 VM quality tiers for cost and quality, based on the 2016 data, for group practices and individual EPs. The database would indicate if the group practice or EP is high, low, or average on cost and quality per the VM. CMS also proposes to include a notation of the payment adjustment received based on the cost and quality tiers, and an indication if the individual EP or group practice was eligible but did not report quality measures to CMS.

IDSA has repeatedly voiced its concerns about the manner in which CMS calculates the VM. As such, we strongly oppose CMS' proposals to provide the public with what we believe is misleading information regarding a physician's "value." As noted throughout this letter and in previous comment letters, the quality and cost measures used to calculate the VM are almost entirely irrelevant and beyond the control of ID physicians. Furthermore, the quality and cost measures have little, if anything, to do with each other, which results in a flawed value equation.

Even if CMS were to simply identify those who received an upward adjustment under the VM, we still feel this is problematic since it could lead the public to believe that physicians who do not have a green checkmark are low quality and/or inefficient providers when in fact they might have had higher risk or more acute patients or were automatically deemed as average cost or quality simply because no measures applied to them.

#### *Future Proposals Under Consideration*

CMS also seeks feedback on potential future proposals related to Physician Compare, including the posting of Open Payments data on individual EP profile pages, as well as stratifying publicly reported measure data by patient race, ethnicity, and gender or posting other types of measures (e.g. composites) that monitor trends in health equity. On the first issue, CMS is already required to make data detailing the financial relationships between drug and device manufacturers and health care providers available to the public. We believe it is inappropriate and misleading to post these data alongside data that are supposed to reflect the "quality" of physician care. In regards to the second issue, IDSA supports efforts to ensure more accurate data, including adjustments for patient risk factors and the stratification of performance data. However, given that we still do not have a strong foundation of quality data across all specialties, we caution against over-stratifying. If data are broken down by too many factors, it may become too difficult for the public to use in a meaningful manner.

### **Physician Quality Reporting System (PQRS)**

#### *New Measures for 2016*

CMS proposes to add the following measures to the PQRS measures for 2016:

- **Appropriate Treatment of MSSA - For MSSA Bacteremia, a  $\beta$ - lactam Antibiotic is the Drug of Choice in the Hospitalized Patient in the Absence of a Documented Allergy or Drug Intolerance:** Percentage of patients with MSSA bacteremia who received beta- lactam antibiotic (e.g., nafcillin, oxacillin, or cefazolin) as definitive therapy [claims, registry]
- **HIV Screening of STI patients:** Percentage of patients diagnosed with an acute STI who were tested for HIV [claims, registry]
- **HIV: Ever Screened for HIV:** Percentage of persons 15-65 ever screened for HIV. [claims, registry]
- **Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief

counseling if identified as an unhealthy alcohol user. [registry]

We are pleased that CMS has proposed the “Appropriate Treatment of MSSA” measure, as this is one of the measures that IDSA submitted via the CMS Call for Measures process. We provide more details on our efforts related to measure development below. This particular measure, should it be finalized, would be the first ID-relevant measure upon which our members might report to demonstrate quality care. Should CMS proceed to finalize this measure, IDSA requests that CMS proceed with a measure specification development in a transparent manner that invites broad collaboration. With respect to the two HIV-related measures, IDSA is supportive of their addition to PQRS.

#### *ID-Focused Measure Development*

As previously mentioned, PQRS participation rates remain low within many specialties, including ID medicine, due to a lack of meaningful and relevant measures. Understanding the importance of having pertinent measures for performance-based payment adjustments and public reporting, IDSA continues to dedicate efforts to developing clinical quality measures relevant to the treatment of infectious diseases. We have developed measure concepts for *Staphylococcus aureus* and have submitted these measure concepts to CMS in response to the ongoing CMS Call for Measures. They were not considered for inclusion in 2015, due to a need for validation and testing. We have also submitted the *Staphylococcus aureus* measure concepts to the National Quality Forum’s (NQF) Measure Inventory Pipeline in hopes that we may engage other stakeholders in an effort to further develop these and other measures. We are also working on a multi-pronged strategy to promote better antimicrobial stewardship. There is a substantial body of literature that links antimicrobial stewardship to reductions in *C. difficile* infections and health care costs, specifically, and, more broadly, to reductions in antimicrobial resistance overall, which is a huge concern at the national level.

The challenge that we face with these efforts is that to see measure development through the full process requires considerable financial investment. We are currently in the process of trying to engage other entities that may be willing to assist in further developing these measures, as well as patient outcome measures related to infectious diseases. We welcome the opportunity to provide CMS with a more in-depth update on the measures under development and other strategies we are pursuing to promote stewardship.

#### *The Consumer Assessment of Healthcare Providers Survey (CAHPS) for PQRS*

Currently, group practices of 100 or more providers participating in GPRO under *any* reporting mechanisms must also use *and bear the cost of* a CMS-certified survey vendor to report the CAHPS for PQRS survey to CMS. For the 2016 reporting year, groups with 25 or more that register *only for the GPRO Web Interface* would also have to report CAHPS for PQRS measures. IDSA appreciates that CMS’ proposal would exclude groups that report through other GPRO reporting mechanisms (e.g., registry, EHR) from this requirement, recognizing that these groups are likely more highly specialized and that the CAHPS for PQRS is not relevant to them.

While it is important to understand patient experience in the care setting, IDSA continues to believe that patient experience/satisfaction should not be a required element of reporting for providers since these are often subjective in nature and not directly under the control of the physician (e.g., physician wait times in a hospital setting). In many specialties, there is no direct correlation between higher patient experience scores and better clinical outcomes. Furthermore, holding physicians accountable for patient satisfaction measures may result in perverse incentives that actually lead to lower quality care (e.g. antibiotic overuse to satisfy patient requests). We urge CMS to instead focus on evidence-based, physician-driven clinical

quality measures for accountability purposes and to retain patient experience measures for internal quality improvement purposes only.

We also reiterate our concerns about requiring the use of certified survey vendors for CAHPS reporting, especially as this reporting option becomes a requirement that applies to an increasingly large number of physicians. The cost of working with a certified vendor may be prohibitive for many smaller practices. We encourage CMS either to assist with administration of the survey or to maintain this as an *optional* reporting mechanism.

### *Potential Future Proposals*

CMS also notes its intention to require the collection of quality data, stratified by race, ethnicity, sex, primary language and disability status, within each of the PQRS reporting mechanisms. It is not proposing to do so now, but seeks comments on facilitators and obstacles to collecting and reporting these attributes. As we noted earlier, we support adjustments to data that make them more meaningful and actionable for both consumers and physicians. However, we are concerned that the underlying foundation of PQRS data is not yet robust enough to stratify by all of these factors. Furthermore, we ask CMS to keep in mind the unique limitations of each PQRS reporting mechanism, which may make it difficult to collect this information. For example, claims data might not adequately capture the breadth of socio-demographic factors that need to be accounted for. While a clinical data registry has more flexibility to customize its data points, doing so could create an additional data collection burden on registry participants if the registry cannot easily extract this additional information from an EHR or other source due to lack of interoperability or uniformity of data definitions.

### **Value-Based Payment Modifier**

#### *Payment Adjustments*

For 2018, based on 2016 reporting, CMS will continue its two-category approach where groups and solo practitioners who do not satisfy PQRS fall into Category 2 and receive automatic cuts in addition to PQRS penalties. Those who do satisfy PQRS would fall into Category 1 and are subject to quality-tiering, which is the performance-based payment element of the VM. Unlike this year, where those with 2-9 EPs and solo practitioners are held harmless from downward adjustments, **all** groups and solo practitioners would be subject to upward, neutral, or **downward** adjustments derived under the quality-tiering methodology in 2018. CMS makes an exception for groups and solo practitioners consisting only of non-physician EPs. They will be held harmless from downward adjustments under the quality-tiering methodology in 2018 since this is the first year it applies to them.

Similar to this year, the maximum upward adjustment under quality-tiering in 2018 would be +4 times an upward adjustment factor (determined after performance period has ended) for groups with 10 or more EPs and +2.0 times an adjustment factor for groups with between 2 to 9 EPs and physician solo practitioners. The maximum payment at risk under quality-tiering in 2018 would be -4% for groups with 10 or more EPs and -2% for groups with between 2 to 9 EPs and physician solo practitioners. Category 2, applicable to those who fail to satisfy PQRS, would follow the same penalty structure, with larger groups at risk for higher penalties.

IDSAs appreciate that CMS is not proposing to raise the ceiling on potential penalties under this program for 2018 and that, consistent with other years, it is relying on a phased rollout where EPs in their first year of the program are held harmless from downward payment adjustments. However, due to our ongoing concerns about the program's reliance on questionable measures and methodologies to determine overall value, we request that CMS continue to hold smaller group practices and solo practitioners harmless from

downward performance-based payment adjustments in 2018. The current set of quality and cost measures, and the methods those measures rely on to attribute patients to physicians, are often of little relevance to smaller group practices and solo practitioners, who tend to be more specialized and/or focus on a single specialty. In many instances, CMS cannot even apply these measures to smaller groups and individuals because of an insufficient sample size of applicable patients. Until CMS has adopted a mechanism to incorporate quality data that is more relevant to specialists, as well as more accurate and clinically specific cost measures, we believe it should hold physicians harmless from downward performance-based payment adjustments under the VM.

### *Quality Measures*

CMS proposes to continue to base the VM largely on PQRS measures, as well as other acute and chronic care prevention measures that have very little to do with our specialty. IDSA reiterates its concerns about our specialty having a distinct lack of relevant measures in light of increasing penalties associated with the VM and the cumulative nature of total payment penalties facing physicians over the next few years.

### *Cost Measures*

IDSA has ongoing concerns about CMS' continued reliance on broad cost measures for this program, which assess the total amount billed per patient. While tracking costs (and quality) across the care continuum is important for developing policies to improve our care delivery system, these general assessments are not appropriate for individual physician accountability since they incorrectly assume that all physicians involved in the care of a patient have equal control over the care plan and treatment for a patient over the course of a year.

As we have stated previously, it is important for each physician caring for a patient to understand how he/she contributed to the patient's total cost of care, but it is not necessarily appropriate to hold each of these physicians *accountable* for the patient's *total* cost of care. In our specialty and others, accountability for cost could result in unintended consequences, such as physicians not ordering labs prior to prescribing antibiotics in order to minimize costs, which could lead to inappropriate antibiotic use, increased drug resistance, and harm to the patient, as well as the general public. In the worst case, it could lead to a disincentive to treat the sickest patients in a population. Furthermore, it is critical that cost measures have a more direct link to the quality measures used to assess value. The current set of cost measures has little relevance to the more condition/procedure-specific quality measures used to calculate the value modifier. If quality and cost measures focus on different elements of care, they cannot be used to draw accurate conclusions about overall value.

For all of these reasons, we would like to see CMS use the current set of cost measures for educational purposes only (i.e., via confidential feedback reports). Physicians should not be held accountable for cost performance until CMS has developed and carefully tested more focused episode-based cost measures that more accurately evaluate care over which a physician has control and allow for more equal comparisons of patient populations. We remain interested in CMS' ongoing work to develop specialty-specific episode-based cost measures and stand ready to assist with these efforts.

Recognizing that CMS will likely continue to rely on the current set of cost measures for accountability purposes, we request that it at least adopt policies that will minimize the inappropriate application of these measures. For example, CMS proposes to increase the minimum number of episodes required for the Medicare Spending Per Beneficiary (MSPB) measure to be included under the cost composite from 20 to 100 episodes. IDSA supports raising this threshold and requests that CMS consider increasing the case minimum even higher, to 200 cases, so that it is consistent with the methodology previously adopted by CMS for the All-Cause Hospital Readmissions quality measure included in the quality composite

beginning with the 2017 payment adjustment year.

CMS also seeks comment on potential future approaches to risk adjusting the Total Per Capita Cost Measures used under the VM. This request is in response to public concerns that the CMS-hierarchical condition categories (HCC) Risk Adjustment methodology currently applied to these measures does not accurately capture the additional costs associated with treating the sickest beneficiaries. CMS discusses potentially stratifying cost measure benchmarks by beneficiary risk score in the future so that groups and solo practitioners are compared to other groups and individual practitioners treating beneficiaries with similar risk profiles. In this way, within a given grouping (for example, a quartile or decile), beneficiary severity of illness and practice characteristics may be more fully recognized. IDSA is supportive of further exploration into this stratification methodology.

Finally, we continue to urge CMS to apply socioeconomic status adjustments to cost measures under the VM. A large body of evidence demonstrates that sociodemographic factors such as income and insurance status affect many patient outcomes, including readmissions and costs. Failing to adjust measures for these factors can lead to substantial unintended consequences, including harm to patients and heightened health care disparities by diverting resources away from providers treating large proportions of disadvantaged patients. It also can mislead patients, payers and policymakers by blinding them to important community factors that contribute to worse outcomes.

#### *Expansion of the Informal Inquiry Process to Allow Corrections for the VM*

IDSA appreciates that CMS finalized last year to give physicians a 60-day informal review period following the release of QRURs. However, in this rule, CMS notes that it will continue its approach of classifying a TIN as “average quality” in the event it determines CMS or a third-party vendor made an error in the calculation of the quality composite. CMS proposes to continue this policy for the CY 2017 payment adjustment and future adjustment periods or until such a time that the operational infrastructure is in place to allow the re-computation of data. IDSA opposes CMS’ long-term use of this automatic designation of “average quality” since it could penalize physicians who lack relevant measures to report on or who experienced a reporting error for reasons outside of their control (e.g., if a physician is designated as average or low cost, an average quality designation may result in a lower or no bonus payment versus a high quality designation, which would result in a bonus). Since these “average” designations could result in inaccurate assessments, which could be misinterpreted by the public, we recommend that CMS instead completely exclude physicians from the VM in these instances. In cases where this information is publicly reported, we also urge CMS to include an explanation as to why a performance score could not be calculated.

#### *Hospital-based Physicians*

In previous rule-making, CMS has discussed potential ways of providing hospital-based physicians (or solo practitioners who are hospital-based) with the option of electing the inclusion of Hospital Value-Based Purchasing (VBP) Program performance in their VM calculation in future years of the program. CMS does not offer any new proposals on this topic in this rule. However, we continue to encourage CMS to adopt a voluntary policy where groups and individuals could elect to use their hospital(s)’s VBP performance to calculate their VM payment adjustment. IDSA has long supported strategies to better assess the quality of hospital-based physicians and continues to believe that hospital-based physicians should have the option to self-attest to tying hospital VBP Program performance to the provider. There exists a subset of measures within the Inpatient Quality Reporting System (e.g. CLABSI, CAUTI, C. difficile, MRSA) that pertains to the clinical practice of infectious diseases as well as the work done within Infection Control and Prevention Programs and Antimicrobial Stewardship Programs. For some of our members, linking their quality performance to the performance of their facility on these measures

could prove reasonable and beneficial to the physician as well as the facilities by aligning quality objectives. We look forward to continued discussions with CMS on this matter.

### **Quality and Resource Use Reports (QRURs)**

As the information presented in the feedback reports takes on more significance due to the application of the VM and public reporting, it is absolutely critical that CMS continue to work to improve the QRURs reports. We appreciate work that CMS has done to date to refine these reports, to improve their timeliness by issuing them more frequently, and to provide more detailed drill down tables with data on which attribution and performance calculations are based. Still, our members continue to question the usefulness of these reports since the underlying data remain largely irrelevant and difficult to interpret and physicians continue to face difficulties accessing the reports.

We encourage CMS to continue to evaluate and refine the QRUR reports in consultation with medical specialty societies and other stakeholders. An important part of this process will be to further tailor the reports to each specialty by highlighting the measures/conditions of the report recipient, providing additional details on the physicians' patient population and other providers whose data may have influenced the report, and providing recommendations or action items. We also encourage CMS to continue to refine educational resources and other guidance to assist physicians with accessing and navigating the reports.

### **Provisions Related to the Medicare Access and CHIP Reauthorization Act (MACRA)**

In this rule, CMS seeks preliminary feedback on strategies for implementing both the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) provisions of MACRA. It is critical that CMS recognize a wide range of activities and payment models that are relevant to physicians in different specialties and practicing in a variety of settings. CMS must avoid the one-size-fits-all approach that currently limits meaningful participation by specialists in federal quality programs. CMS must recognize the limited control that physicians based in hospitals or who work in large academic or private systems now have over participating in these programs. For example, the hospital administration or a department within a hospital might decide, on behalf of physicians, to participate in the PQRS as a large group practice. In these cases, ID physicians often have no control over the selection of measures for which they are held accountable, often do not even see or have access to feedback reports, and are often unaware of PQRS participation decisions, in general. As well, large group practices may be better structured to enter into alternative payment models such as bundled payments while smaller groups or solo physicians will not have the economies of scale to participate in such arrangements, therefore having to resort to participation in MIPS. IDSA views the passage of MACRA as a new opportunity to create effective quality measurement programs tied to value-based payment that take into account the variety of practice patterns. We look forward to working with CMS and other stakeholders to achieve this objective.

### **Merit-based Incentive Payment System (MIPS)**

MIPS is applicable beginning with payments for items and services furnished on or after January 1, 2019. In this rule CMS seeks input on multiple provisions of the legislation to guide future policymaking. IDSA would like to take this opportunity to highlight one provision within MACRA that allows the Secretary certain flexibility for weighting performance categories and activities under MIPS in cases where "there are not sufficient measures and activities... applicable and available to each type of eligible professional involved." Recognizing that the definition of the term "eligible professional" is broad, we suggest that CMS first consider the subset of EPs that are employed as part of large practices or as

contractors to facilities. In considering this subset, CMS should recognize that these EPs have little control over the adoption of EHR technology within their practice settings and on the group's reporting of quality measures. For these types of EPs, CMS should consider exercising its discretion as granted within MACRA to adjust the weighting across the performance categories and allow this subset to focus their efforts on areas over which they have more control. Another subset to consider is that composed of EPs that bill an overwhelming volume of services in the inpatient setting where, for some specialties, there are not sufficient quality measures to fully assess the quality of specialty care delivered. As we have mentioned before, there are currently few PQRS measures that are relevant to the clinical practice of infectious diseases. For those ID specialists who bill an overwhelming percentage (80+%) of their services in the inpatient setting, the ability to perform in the MIPS program could prove challenging, and therefore shifting more weighting onto Clinical Practice Improvement Activities may be more meaningful. For this reason, we ask that CMS consider an adjustment of weighting across the MIPS performance categories for this subset of EPs.

#### *Low-Volume threshold*

CMS seeks comments on how to apply a low-volume threshold for purposes of excluding certain EPs from the definition of a MIPS eligible professional. IDSA supports the notion that a low-volume threshold should apply and believes it is most simply achieved as a minimum number of beneficiaries or cases treated by the provider or a minimum amount of allowed Part B charges billed by a provider during the period. We suggest that a minimum of 200 cases of Medicare FFS beneficiaries treated by a provider be the threshold as this is the case threshold that applies to the All-Cause Readmission measure within the VM program. We also suggest that CMS should allow EPs who fall beneath the threshold to have the option to participate in MIPS, so that they can avail themselves of possible payment benefits upon meeting program requirements.

#### *Clinical Practice Improvement Activities*

CMS seeks comments on what activities could be classified as clinical practice improvement activities (CPIAs) under MIPS. By statute, these activities must fall under at least the following subcategories:

- Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.
- Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry.
- Care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth.
- Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.
- Patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification.
- Participation in an alternative payment model.

IDSA appreciates the opportunity to present concepts for CMS to consider as CPIAs within the MIPS program and we are optimistic that these can be further developed in a manner that aligns quality efforts at the individual EP level with those at the facility level. Infectious Diseases specialists are all aware of the importance of Infection Control & Prevention and of Antimicrobial Stewardship and the effectiveness of these measures in minimizing healthcare acquired infections (HAIs) and antimicrobial resistance. IDSA has a long history of advocating for these programs, based on the medical literature that shows

benefits in terms of patient outcomes.<sup>8,9,10</sup> Many ID specialists lead these programs within their facilities/health care systems and the work done to implement and maintain these programs should be included as CPIAs, as they relate to patient safety and practice assessments as well as population health management. IDSA believes that CMS can account for this activity through simple attestation by the EP associated with these programs.

Another concept that IDSA would like CMS to consider as a CPIA is the implementation of an Outpatient Parenteral Antimicrobial Therapy program as a critical component of an efficient integrated health care delivery model. This requires expanded practice access for an infusion center (either office-based and/or HOPD) and/or integrated home care services in order to provide timely care coordination and patient follow-up for patients who are on IV-antimicrobials, possibly employing telehealth technology. IDSA publishes guidelines for OPAT and other forms of guidance exist to aid in implementing OPAT programs.<sup>11,12</sup> OPAT programs have been shown to effect early discharge of patients with infections amenable to OPAT as well as hospital admission avoidance (ED to outpatient transitions).<sup>13,14</sup> We believe that the activities related to implementing an OPAT program should qualify as CPIA under MIPS for infectious diseases specialists and we look forward to further discussion with CMS on these concepts. IDSA believes that CMS can account for this activity through simple attestation by the EP associated with these programs.

### **Alternative Payment Models (APMs)**

The statutory amendments related to APMs have payment implications beginning in 2019. In this rule, CMS is broadly seeking comment on: the criteria for assessing physician-focused payment models; the criteria and process for the submission of physician-focused payment models as eligible APMs, qualifying APM participants; the Medicare payment threshold option and the combination all-payer and Medicare payment threshold option for qualifying and partial qualifying APM participants; the time period to use to calculate eligibility for qualifying and partial-qualifying APM participants, eligible APM entities, quality measures and EHR use requirements; and the definition of nominal financial risk for eligible APM entities.

IDSA appreciates the willingness on the part of CMS to consider the aspects of APMs provided above. We understand that CMS will be issuing a Request for Information (RFI) in the coming months to explore in an in-depth manner how APMs should be structured and how they can best function to achieve their

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<sup>8</sup> IDSA Comments on Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies [CMS-3819-P] - available at [http://www.idsociety.org/uploadedFiles/IDSA/Policy\\_and\\_Advocacy/Current\\_Topics\\_and\\_Issues/Access\\_and\\_Reimbursement/2014/IDSA\\_HH\\_CoP\\_FINAL.pdf](http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Access_and_Reimbursement/2014/IDSA_HH_CoP_FINAL.pdf)

<sup>9</sup> IDSA Letter to CMS Re: Antimicrobial Stewardship (AS) as a Medicare Condition of Participation (CoP) – available at [http://www.idsociety.org/uploadedFiles/IDSA/Policy\\_and\\_Advocacy/Current\\_Topics\\_and\\_Issues/Advancing\\_Product\\_Research\\_and\\_Development/Antimicrobials/Letters/AS-IDSA-SHEA-CMS-CoP-Letter%20MAR\\_2014.pdf#search=%22stewardship%22](http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Advancing_Product_Research_and_Development/Antimicrobials/Letters/AS-IDSA-SHEA-CMS-CoP-Letter%20MAR_2014.pdf#search=%22stewardship%22)

<sup>10</sup> IDSA Letter RE: Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation, Proposed Rule, [CMS-3244-P] - available at [http://www.idsociety.org/uploadedFiles/IDSA/Policy\\_and\\_Advocacy/Current\\_Topics\\_and\\_Issues/Access\\_to\\_Quality\\_Healthcare/Comments/COP%20Proposed%20Rule\\_Final.pdf#search=%22Condition\\_of\\_participation%22](http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Access_to_Quality_Healthcare/Comments/COP%20Proposed%20Rule_Final.pdf#search=%22Condition_of_participation%22)

<sup>11</sup> Tice AD, Rehm SJ, Dalovisio JR et al. Practice guidelines for outpatient parenteral antimicrobial therapy. *Clin Infect Dis* 2004; 38:1651-72.

<sup>12</sup> Muldoon EG, Snyderman DR, Penland EC, Allison GM. Are We Ready for an Outpatient Parenteral Antimicrobial Therapy Bundle? A Critical Appraisal of the Evidence. *Clin Infect Dis.* (2013) 57 (3): 419-424.

<sup>13</sup> Reese L, Jacobus L, Lock J, Elizondo D, Bochan M. Utilization of an Outpatient Parenteral Antibiotic Treatment Center (OPATC) to Decrease Readmissions and Prevent Hospitalizations. . Poster Session presented at IDWeek 2013. 2013 Oct. 2-6; San Diego, CA.

<sup>14</sup> Bochan M, Sung A, Elizondo D, Lock J, Marcella S, Xie Y. Outpatient Parenteral Antimicrobial Therapy (OPAT) Treatment Center as Part of Integrated Care Delivery – Single-Center Experience from the First Three Years of Operation. Poster Session presented at IDWeek 2014. 2014 Oct. 8-12; Philadelphia, PA.

intended objective. At this time, we ask that CMS consider how concepts such as the Patient Centered Specialty Practice within a “Medical Neighborhood” can be used as the foundation on which to develop alternative payment models. Mindful of our members who are in small, single specialty groups or solo practitioners, IDSA requests that CMS offer viable options for EPs in these types of practices to enter into alternative payment models. We look forward to responding to the RFI and to collaborating with other stakeholders, along with CMS, towards creating APMs that have broad appeal.

### **Solicitation of Comments: Perceived Need for Regulatory Revisions of Policy Clarification Regarding Permissible Physician Compensation**

Recognizing that there have been significant changes in health care delivery and payment systems since the enactment of the physician self-referral law, CMS seeks comments on how to address issues where the prior legislation prohibits or inhibits the evolution towards value-based health care delivery. As CMS notes in the proposed rule:

Entities furnishing DHS [Designated Health Services] face the predicament of trying to achieve clinical and financial integration with other health care providers, including physicians, while simultaneously having to satisfy the requirements of an exception to the physician self-referral law’s prohibitions if they wish to compensate physicians to help them meet the triple aim and avoid financial penalties that may be imposed on low-value health care providers... According to stakeholders, structuring incentive compensation and other payments can be particularly challenging for hospitals, even where the payments are to hospital-employed physicians.

Under MACRA, the Secretary is to undertake two studies focused on the promotion of APMs and on the possible options to allow gainsharing arrangements through narrowly tailored provisions to allow activity that improves care while reducing waste and increasing efficiency. The findings from these reports, as well as the responses to CMS’ specific questions posed in this proposed rule, will inform future rulemaking.

IDSA appreciates CMS’ recognition that the physician self-referral law needs to be revisited in light of the changes in health care delivery and payment reform. As we have mentioned above, our members provide leadership in Infection Prevention and in Antimicrobial Stewardship across health care systems. The activities related to these programs are often accounted for in contractual agreements with health care facilities that attract scrutiny and concern over compliance of fair market value and physician self-referral law. Infection Prevention measures are widely recognized as being effective in reducing healthcare acquired infections. Furthermore, Antimicrobial Stewardship (AS) has been shown to achieve improved patient outcomes and reduced costs. Our members would like to propose gainsharing agreements between physicians and facilities for the provision of Infection Prevention and AS services, tied to quality and cost measures, yet have encountered reluctance to explore such arrangements on the part of facilities. Our understanding, based on anecdotal evidence, is that facilities have a general aversion to gainsharing agreements, in part because of obstacles presented by the self-referral law and regulations. IDSA has offered to support the submission of a gainsharing agreement for OIG review, on behalf of our membership, but no willing facility has stepped forward to explore such an agreement. It is our hope that CMS will see a need for new exceptions to the physician self-referral law to support shared savings or gainsharing agreements, as well as alternative payment models for programs like Infection Prevention and AS. Furthermore, in response to the question as to whether certain entities, such as those considered to provide high-value care, be permitted to compensate physicians in ways that other entities may not, IDSA is supportive of this concept. In the example given, CMS explains that a hospital that has performed well under the Hospital Value-based Purchasing Program would be allowed to pay bonus compensation from DHS revenue to physicians who helped the hospital meet the program metrics. We

believe that this should be allowed, especially for hospital-based physicians such as many ID specialists. IDSA looks forward to reviewing the studies that the Secretary will commission and to further engagement with CMS on these matters.

IDSA appreciates the efforts of CMS to promote improved patient safety and better quality of care as set forth in this PFS proposed rule. If you have any questions, please feel free to contact Andrés Rodríguez, Director for Practice & Payment Policy, at 703-299-5146 or [arodriguez@idsociety.org](mailto:arodriguez@idsociety.org).

Respectfully,

A handwritten signature in black ink that reads "Stephen B Calderwood". The signature is written in a cursive, slightly slanted style.

Stephen B. Calderwood, MD, FIDSA  
President

