September 4, 2012

Marilyn Tavenner, RN
Acting Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1590-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Comments on Medicare Program Revisions to Proposed Payment Policies under the Physician Fee Schedule for CY 2013 [CMS-1590-P]

Submitted electronically through www.regulations.gov; CMS-1590-P

Dear Acting Administrator Tavenner,

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide comments on the FY 2013 Physician Fee Schedule (PFS) proposed rule. IDSA represents more than 9,800 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research in the area of infectious diseases (ID). The Society's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the United States and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, surgical infections, those with cancer or transplants who have life-threatening infections caused by unusual or drug-resistant microorganisms, people living with HIV and AIDS, and new and emerging infections, such as severe acute respiratory syndrome (SARS) and H1N1 influenza.

IDSA 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 code valuation process, the Physician Quality Reporting System (PQRS), the Electronic Prescribing (eRx) Incentive Program, the Physician Resource-Use Feedback Program and the Value-Based Payment Modifier (VBPM), the Medicare Shared Savings Program (MSSP), and the Physician Compare Website, among other Part B related issues. Below, we submit our specific comments on these proposed changes.
Potentially Mis-valued Services under the PFS

As noted in the proposed rule, CMS intends to enter into a contract to explore the development of a new model that will better validate physician work for new and existing codes. We look forward to learning more about this new model through future rulemaking and 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. 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. \(^1\) **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 any alternative valuation process should include direct involvement from physicians and other healthcare providers, who are the purveyors of the very medical services that are to be valued.

Electronic Prescribing (eRx) Incentive Program

CMS proposes improvements to the eRx program with the addition of two hardship exemption categories. These exemptions would apply to the 2013 and 2014 payment adjustment periods. The two new exemption categories are as follows:

- Eligible professionals or group practices who achieve meaningful use during certain eRx payment adjustment reporting periods.
- Eligible professionals or group practices who demonstrate intent to participate in the EHR Incentive Program and adoption of Certified EHR Technology

IDSA supports the expansion of the exemption criteria to spare those eligible professionals who are making efforts to comply with the program.

Primary Care and Care Coordination

We welcome the proposal to refine PFS payment for post-discharge care management services, recognizing that current E/M codes do not appropriately account for the work involved in non-face-to-face, comprehensive, coordinated care management for beneficiaries that are discharged from a hospital or skilled nursing facility (SNF). As part of a multi-year strategy exploring the best means to encourage care coordination services, CMS has proposed a HCPCS G-code to describe care management involving the transition of a beneficiary from care furnished by an admitting physician during a hospital stay to care furnished by the beneficiary’s outpatient physician. **IDSA views this as an important first step towards promoting care coordination for patients but believes there is much work to be done with respect to adequately capturing the work performed and promoting care coordination between physicians.**

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The post-discharge transitional care HCPCS code (GXXX1), as described in the proposed rule, accounts for some of the important work required by the outpatient physician who “receives” the discharged patient to ensure continuity of care for the beneficiary. We agree that the G-code should be used for patients whose medical and/or psychosocial problems require moderate or high complexity medical decision-making. We do not believe that the G-code should require a face-to-face encounter, as this may create undue burden on the patient, patient’s family, and the receiving physician during the time that the patient has been recently discharged from the facility. A requirement for a face-to-face encounter with an exception process could prove confusing and administratively challenging as it would require communication of exceptions criteria and audit/appeals processes. As well, it is proposed for consideration that the G-code only be used by physicians and non-physician practitioners who are “qualified to assist beneficiaries in managing post-transition changes in conditions and treatments.” We suspect that defining and confirming this qualification would prove burdensome and may detract from efforts to encourage and ensure that all activities of care coordination take place with the aim of avoiding readmissions. However, we ask that CMS define further the qualification process and their expectation as to the most appropriate providers who should seek this qualification, (i.e. physicians and advanced care practitioners who actively manage the beneficiaries’ medical conditions longitudinally in the post-hospital discharge outpatient period).

CMS states in the rule that they believe the current hospital discharge management codes (99238 & 99239) adequately capture the care coordination services required to discharge a beneficiary from hospital or skilled nursing facility care. However, we disagree that these current discharge management codes adequately recognize the work involved in transitioning a patient from an inpatient status. As infectious disease specialists, we often treat patients with complex, severe infections that require strict adherence to antimicrobial treatment protocols post-discharge. This treatment may be delivered in a primary care or consultative role. Ensuring these instructions are effectively conveyed to patients and caregivers, in addition to ordering/arranging for post-discharge follow-up professional services and testing, can require additional work and medical decision-making that is not currently recognized in the existing codes. As consultants, ID physicians cannot bill the discharge management codes, and thus this work is unaccounted for under our current coding system. We believe that the aim should be to avoid hospital readmissions through team-based collaborations and we seek to ensure “interconnectivity” within teams of physicians that span both sides of the discharge. IDSA looks forward to working with CMS and other stakeholders to promote comprehensive care coordination through the evolution of accurate coding.

Payment for Molecular Pathology Services

IDSA recognizes that the field of molecular pathology and the development of rapid diagnostic tests is ever-evolving and holds much promise through innovation. Indeed, within the area of infectious diseases, there is research underway to develop point-of-care diagnostic tests that will lead to advances in infection control and rapid identification of pathogenic organisms. We understand that the current Clinical Laboratory Fee Schedule may be limited in its application to new diagnostic tests and that some of these tests may be described as physicians’ services, therefore falling under the Physician Fee Schedule. Our concern over the expansion of the
PFS to include novel diagnostic tests is focused on the potential negative impact it may have with respect to budget neutrality adjustments applied to the overall fee schedule. While the proposed rule limits discussion to the 101 new molecular pathway codes, we, along with CMS, anticipate additional molecular pathology codes to be developed in an on-going manner and this heightens our concern, should future codes also be brought in under the PFS. IDSA encourages CMS and other stakeholders in the molecular pathway community to establish an appropriate system to reimburse new diagnostic tests, leaving the technical component of a service under the CLFS and the professional component of a service in the PFS, similar to how diagnostic Radiology services are handled.

Physician Compare and Physician Quality Reporting System

IDSA commends CMS on its commitment to making the Physician Compare website a constructive tool for Medicare beneficiaries that provides consumers with information to make healthcare decisions. CMS has started to implement a phased approach to adding quality data to the Physician Compare website, allowing for appropriate infrastructure development needed to support to the collection of additional types of measures. CMS will only post data on Physician Compare if it is technically feasible, the system is set up/adjusted to post information and the data is useful, sufficiently reliable, and accurate. The ACA requires that Medicare include a process to ensure the data published on the Physician Compare Website provide a robust and accurate portrayal of a physician's performance and a process to ensure appropriate attribution of care when multiple providers are involved in the care of the patient. For all measures reported on the Physician Compare website, CMS proposes to post a standard of care, such as those endorsed by the National Quality Forum (NQF), which will serve as a standard for consumers to measure individual provider and group level data. IDSA encourages CMS to share further details, in a collaborative manner, on how it plans to ensure reliable and accurate information and, more importantly, how it plans to educate consumers as to the appropriate interpretation of quality measure performance data provided via Physician Compare. It is our hope that consumers will be appropriately oriented to the data provided, with explanations that include possible reasons for why there may be lack of reportable data, (i.e. lack of applicable measures to the specific specialty). This will help to ensure consumers do not come away with a negative impression of providers who have no quality data displayed.

The proposed rule states the intention to utilize the Physician Compare website to publicly report physician performance results, beginning in 2013 for performance information related to group practices. For individual physicians, PQRS performance measures will be reported beginning in 2015. From the 2010 PQRS Experience Report, we note that only 16.1% of eligible Infectious Diseases specialists have participated in the PQRS program, (the overall program participation rate for all eligible professionals is 26%). Many factors contribute to this low participation rate. Many of the over two hundred PQRS measures currently available do not apply to conditions that ID physicians commonly treat or services that ID physicians typically provide, (the most commonly reported measures by ID physicians in 2010 were related to “adoption/use of EHR,”

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“Influenza Immunization for Patients ≥ 50 Years Old,” and “Pneumonia Vaccination for Patients 65 Years and Older.”). As well, many ID physicians are hospital based, either in academic medical centers or community hospitals. The lack of available accountability measures presents a significant challenge to including meaningful performance information for predominantly hospital-based physicians, including those who primarily serve in consultative roles, on the Physician Compare Website. The dearth of physician-level inpatient measures must be addressed before CMS can accurately report hospital-based physicians’ performance results on the Physician Compare Web Site.

CMS has invited comments on the proposal to allow measures that have been developed and collected by approved and vetted specialty societies for inclusion on Physician Compare. IDSA is willing to explore this further as it would serve the interests of our members and may align with the long-term quality improvement initiatives of the Medicare Program, and more broadly with value-based health care delivery. IDSA urges CMS to provide more details as to how this concept may be realistically implemented and as to the full scope that CMS envisions of medical specialty societies reporting on behalf of their memberships.

The proposed rule details plans for inclusion of the patient experience of care measures, largely collected through the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS). CMS is considering two options: (1) to publicly report the 2013 data collected for all group practices and ACOs, or (2) collect 2013 data as a baseline to be shared with group practices and ACOs only, with public reporting to begin with 2014 data. IDSA recognizes the benefits of allowing group practices and ACOs to establish a baseline and then determine what changes should be implemented to guide improvement in patient experience of care, therefore we are in support of the alternative option proposed by CMS.

In order to further facilitate reporting for PQRS and to avoid penalties in 2015 and 2016, CMS proposes two additional reporting options. These options include:

(i) satisfactorily reporting 1 PQRS measure or measures group using the claims, registry, or EHR-based reporting mechanisms during the 12 month reporting period (2013 and 2014, respectively); or
(ii) electing the newly proposed administrative claims-based reporting option for a proposed set of administrative claims-based measures.

This proposed mechanism does not require an eligible provider (EP) to submit quality data codes (QDCs) on Medicare Part B claims. Rather, the proposed administrative claims-based reporting mechanism will use claims EPs already submit for purposes of Medicare billing. IDSA supports these options which, we believe, facilitate reporting by EPs and encourage broader participation in the PQRS program.

In proposing this option, CMS has limited the number of applicable measures, (indicated in Table 64 of the proposed rule). In table 65, CMS indicates those measures that are not proposed for inclusion in the administrative claims option. Of these, there are two that are particularly relevant to Infectious Diseases specialists, #0568 – Appropriate Follow-Up for Patients with HIV, and #0584 – Hepatitis C: Viral Load Test. IDSA requests that, at a minimum, these two
ID-related measures be added to the list for inclusion in the newly proposed administrative claims option and suggests that CMS enhance the flexibility of this proposed option by allowing a broader collection of quality measures to apply.

**Value-based Payment Modifier**

The proposed rule sets forth specific long-term goals aimed at establishing the value-based payment modifier to rely on measuring physician performance (both quality of care and cost) at four levels (to the extent practicable) – the individual physician level, the group practice level, the facility level (for example, hospital), and the community level. In the near-term, CMS proposes to rely on the quality measure data collected through the PQRS Group Practice Reporting Option (GPRO) and Medicare EHR Incentive Program to obtain most of the performance data for the value-based payment modifier. This will apply in 2015 to physician groups of 25 or more eligible providers. In 2017, CMS will apply the value-based payment modifier to individual physicians and groups with fewer than 24 eligible professionals. For hospital-based physicians, CMS proposes that an option be provided that will allow these physicians to be assessed based on the performance of the hospital at which they are based. Furthermore, CMS also seeks to start a discussion on how best to incorporate individual, hospital-based, and community-based quality and cost measures as a component of the value-based payment modifier so that quality measurement strategies can be aligned across providers and settings of care.

As we have stated in previous comment letters, there is broad consensus that the Value-Based Payment Modifier must include robust outcomes and composite measures that accurately describe each provider’s role, including inpatient consultants, during an episode of care that may span multiple facilities. However, even the best measures will be of limited value without the ability to interconnect the disparate pieces into an episode that not only captures the physician services but also captures (and accurately attributes) every relevant test, treatment, and procedure from the admission to 30 days post discharge. We recognize that additional quality measures and attribution methodologies are in development to capture physician performance. Until these have been fully developed and endorsed, tying hospital-based physicians’ performance to the performance metrics of their hospitals may be a viable option for the short-term. However, several issues must be addressed at the onset to establish the parameters for such an option to materialize. For example, a verifiable linkage must exist between a physician and a facility/facilities to accurately attribute the inpatient/outpatient measures for each facility to the individual EPs. Furthermore, for physicians who see patients at more than one facility, there should be a way to assign performance measures from across the facilities, weighted proportionately by the volume of services provided by the individual physician at each facility. As well, the program would have to entice sufficient participation of a large segment of a facility’s medical staff. It will be essential for a facility to establish a critical mass to ensure “buy-in” and shared responsibility to achieve high quality care across the Inpatient and Outpatient Quality Reporting measures. An individual physician may have exemplary

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performance, however if the hospital does not have the same level of performance, an individual physician would be unfairly and negatively impacted. Typically, an individual physician has a limited impact on the overall performance of a facility. IDSA welcomes the opportunity to discuss the feasibility and further development of this concept with CMS and other stakeholders.

CMS proposes to include four outcome measures in the Value-based Payment Modifier that assess the rate of potentially preventable hospital admissions. Two of these proposed measures are composites of existing measures being used in the Physician Feedback Reports:

- Composite of Acute Prevention Quality Indicators
  - Bacterial Pneumonia - the number of admissions for bacterial pneumonia per 100,000 population
  - UTI - the number of discharges for urinary tract infection per 100,000 population
  - Age 18 Years and Older in a one year time period
  - Dehydration - the number of admissions for dehydration per 100,000 population

- Composite of Chronic Prevention Quality Indicators
  - Diabetes Composite (Uncontrolled diabetes, Short-term/Long-term diabetes complications, lower extremity amputation for diabetes)
  - COPD
  - Heart Failure

The other two outcome measures proposed for inclusion in the Value-based Payment Modifier are the all-cause hospital readmission measure (as used in Medicare Shared Savings Program) and the 30-day post-discharge visit measure, (employed in the Physician Group Practice Transition Demonstration).

IDSA commends CMS for its efforts to include outcomes measures in the Value-based Payment Modifier but we question whether these measures, as specified in the proposed rule, are the most appropriate. Our concern with these measures lies in how well the attribution methodology accurately links a physician’s involvement to the outcome being measured and whether appropriate risk-adjustment is achieved. As we noted in our comment letter in response to the Proposed Rule for the Hospital Inpatient Prospective Payment System, we urge CMS to exercise caution and prudence in the use of measures whose risk adjustment has not been fully vetted, as this may lead to a system that exaggerates measures for physicians that treat more complicated patients, as infectious diseases specialists often do.4

For the attribution of cost measures, CMS is proposing to apply the “plurality of care” method, (which attributes a beneficiary to the group practice that billed a larger share of office and other outpatient E/M services than any other group of physician practice) for physician groups of 25 or more. Given that this will thereby align attribution of costs of the same beneficiary population as considered in the assessment of quality measures for the reporting physician groups, IDSA supports this proposal. Furthermore, for individual physicians, IDSA supports the application of the “degree of involvement” attribution method, as was used in the Physician Feedback Reports. We would, however, like to express our concern over the proposal to attribute the Medicare paid

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amounts for the items and services billed under the PFS at the TIN level for physician groups. Our primary concern relates to how costs will be compared across multi-specialty physician groups and how the specialty-mix within these physician groups leads to cost variances. As we noted earlier, not all hospitals have infectious diseases specialists on staff. As well, not all multi-specialty physician groups include ID specialists. When comparing groups based on the costs of the services provided to similar (risk-adjusted) patients with the same condition (i.e. pneumonia), costs may vary as a result of the mix of specialties in the group practice. We ask that CMS provide clarity on how they will account for specialty-mix in their application of the value-based payment modifier to physician groups.

In order to establish a method to score or calculate Value-based Payment Modifier, CMS developed two models that compare the quality of care furnished to costs:

1) a quality tier model and
2) a total performance score model.

IDSA commends CMS for proposing alternative models to consider. Based on what has been described in the proposed rule, we support the application of the quality-tiering methodology to score the Value-based Payment Modifier. The quality-tiering model compares the quality of care composite by classifying the quality of care composite scores across physicians into high, average, and low quality of care categories based on whether they are statistically above, not different from, or below the mean quality composite score. Likewise, CMS proposes to classify groups of physicians into high, average, and low cost categories based on whether they are significantly above, not different from, or below the mean cost composite score. In order to ensure that the value-based payment modifier does not cause unintended consequences in which groups of physicians decline to treat the most difficult cases, CMS proposes that the scoring methodology provide a greater upward payment adjustment (+1.0%) for groups of physicians that care for high-risk patients (as evidenced by the average HCC risk score of the attributed beneficiary population) and submit data on PQRS quality measures through PQRS via the GPRO using the web-interface, claims, registries, or EHRs. Our support is based on the fact that the quality-tiering methodology provides some incentive to ensure care for difficult-to-treat beneficiaries. As we have stated above, infectious diseases specialists routinely treat critically ill patients with severe infections, therefore we understand the challenges and the extensive resources associated with treating these patients. We feel however, that the low reimbursement differential to provide care for the sickest and most complex Medicare beneficiaries is not adequate to prevent “cherry picking” and the avoidance of this vulnerable population.

Stepping back to look at the framework that CMS is working within, as provided by the National Quality Strategy, we recognize that our collective efforts should be focused on the development of patient-centered and outcome-oriented measures that are common across all sites-of-service wherever possible. CMS has indicated their intent to develop measures that apply at the community level, in addition to those that apply at the practice and individual EP level. IDSA has met with CMS representatives from the Center for Clinical Standards and Quality to discuss measure development for infectious diseases and antimicrobial stewardship with the aim of
“horizontal integration” across all sites-of-service. We thank CMS for its willingness to discuss these matters and look forward to continued collaboration in pursuit of common goals.

Medicare Coverage of Hepatitis B Vaccine

IDSA supports the proposal from CMS to expand coverage of the Hepatitis B vaccine to all beneficiaries diagnosed with diabetes mellitus, thereby promoting further alignment with recommendations of the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP). Specifically, CMS proposes to modify the definition of high-risk groups by adding persons diagnosed with diabetes mellitus, and cover the Hepatitis B vaccine and its administration for these beneficiaries.

IDSA has continued to call attention to the lack of coverage of all ACIP recommended vaccines under Part B. Currently, Medicare beneficiaries have access to the influenza and pneumococcal vaccinations under Part B. As well, subsets of beneficiaries can receive their hepatitis B vaccination under their Part B benefit. The remaining ACIP-recommended immunizations may be accessed under Part D, if the beneficiary has purchased a Part D plan. This split in coverage for different vaccines creates inequities across the Medicare patient population and imposes administrative challenges for patients, physicians, and pharmacists. The United States Government Accountability Office (GAO) released a report evaluating the vaccination status of Medicare beneficiaries which highlights the significant challenges that exist for Medicare beneficiaries seeking access to recommended vaccinations.5

As you know, the ACA requires Medicare to waive the Part B deductible and coinsurance for preventive services that have a Grade of A or B from the United States Preventive Services Task Force (USPSTF). Prior to the ACA, the USPSTF had, in 1996, cited ACIP as having cognizance over immunization recommendations. On the website of the USPSTF, it states that,

> “Some recommendations for clinical preventive services fall within the scope of not only the USPSTF but also other federal agencies. For example, adult and childhood immunizations are addressed by the CDC Advisory Committee on Immunization Practices (ACIP)… Although the USPSTF considers these recommendations part of its portfolio of recommended clinical preventive services, it refers clinicians to the ACIP active evidence review process and recommendations for 2 reasons: The USPSTF does not have adequate resources to keep such recommendations current, and it does not wish to duplicate the efforts of the ACIP.”6

IDSA asks CMS to consider, given that the ACIP recommendations are part of the USPSTF “portfolio of recommended clinical preventive services,” that the USPSTF should endorse these recommendations with a Grade of A or B. We contend that this action, which

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would resolve the inequities that have been discussed above, is within the scope of the USPSTF mission. We note that this simple administrative formality will close a longstanding gap and enhance access to valuable preventive services for Medicare beneficiaries. We ask CMS to engage the USPSTF and other relevant stakeholders in order to pursue this solution.

Conclusion

IDSA appreciates the Agency’s consideration of our comments on the 2013 Physician Fee Schedule Proposed Rule. If you have any questions or comments, please feel free to contact Andres Rodriguez, IDSA’s Senior Program Officer for Practice & Payment Policy, at (703) 299-5146 or via email at arodriguez@idsociety.org. We look forward to working with CMS as it finalizes this regulation.

Respectfully,

Thomas G. Slama, M.D.
President