December 31, 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 Payment Policies under the Physician Fee Schedule for CY 2013 [CMS-1590-FC]

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

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) final 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.

The final rule sets forth guidance for physician payment and indicates CMS’s direction for future exploration of payment reform that achieves quality improvement and patient safety through value-based principles. IDSA members are committed to achieving these same objectives and we intend to engage CMS in payment reform that appropriately values physician services that involve complex medical decision-making. Herein, we respond to specific details provided in the final rule and look forward to collaborating with CMS in the near future.
Bundled or Episode-of-care Payments

We look forward to studying the report from CMS on bundled or episode-based payment, due to Congress in early 2013. This report will provide recommendations and implementation options to cover physicians’ services related to one or more prevalent chronic conditions. As mentioned in the final rule, CMS has met with medical specialty societies, private payers, healthcare system administrators and others to better understand what opportunities may exist. In particular, we look forward to engaging CMS in a discussion of bundled payment options for the treatment of hepatitis C virus (HCV). CMS will recognize this as a prevalent chronic condition within the Medicare population, as the Centers for Disease Control and Prevention (CDC) has recently issued guidelines, calling for the screening of the 1945 – 1965 (“baby boomer”) birth cohort.\(^1\) The CDC’s analysis projects that birth cohort testing would identify approximately 800,000 new infections and save 121,000 lives.\(^2,3\) ID specialists are prepared to treat HCV with new and advanced therapies, appropriately tailored to promote patient safety and high quality health care, to achieve the ultimate patient outcome for this disease – cure and prevention of cirrhosis, hepatocellular carcinoma, and death. HCV is an important prevalent chronic condition that warrants attention and may prove to be an opportunity to bundle payment for physician services related to its treatment.

Primary Care and Care Coordination

We commend CMS for adopting, with some modifications, the transitional care management (TCM) codes that were developed through the AMA CPT/RUC process. As we stated in our comment letter to the proposed rule, IDSA views adoption of these codes 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. With these TCM codes, CMS has demonstrated an interest in exploring how best to optimize care coordination as well as recognized the value of non-face-to-face work performed by a physician or other qualified health care professional. IDSA is hopeful that this will allow for recognition of the non-face-to-face work performed by all physicians involved in a patient’s successful transition from the inpatient setting to the community. As well, IDSA and other cognitive specialty societies seek to broaden discussion with CMS on the valuation of E/M services in a manner that appropriately accounts for the breadth of face-to-face and non-face-to-face services provided in complex medical decision-making.

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Physician Quality Reporting and Value-based Payment Modifier

IDSA commends CMS’s efforts to align reporting requirements and establish consistency of definitions across the many quality related programs (PQRS, EHR, eRx, etc). We also appreciate the expansion of exemption options for the eRx program and of reporting options for the PQRS program. With respect to the value-based payment modifier, we remain concerned with the implementation, even at the revised group practice size (100 or more eligible providers) to which the VBM modifier will apply. We reiterate our call for appropriate vetting of attribution methodologies and quality measures. Furthermore, we are particularly interested in the development of a value-based payment modifier option for ID specialists and other hospital-based physicians, and would welcome the opportunity to share our perspective with representatives from CMS.

Code-specific Issues – Fecal Microbiota Therapy

CPT code 44705 - Preparation of fecal microbiota for instillation, including assessment of donor specimen, is a new code developed through the AMA CPT/RUC process to describe and value microbiota treatment of patients suffering from refractory, relapsing Clostridium difficile diarrhea. The code has received a recommended work RVU of 1.42, (direct crosswalk to 99203 – Level 3 office or other outpatient visit, new patient). In lieu of using this newly developed code with the respective work value, CMS has indicated in the final rule its intent to use HCPCS code G0455 with a work value of 0.97, (cross walking to 99213 – Level 3 office or other outpatient visit, established patient). It is proposed that this G-code report both the work of preparation and instillation of the microbiota. CMS contends that Medicare would only pay for the specimen that is ultimately used for the treatment of the beneficiary, citing authorization to only pay for costs directly related to the diagnosis and treatment of a beneficiary.

IDSA disagrees with CMS’s plan to de-value the work performed across both procedures (preparation and instillation). Referring to the preparation of the microbiota, there is extensive physician work involved in determining whether a patient is a suitable candidate for fecal donation. This work is often performed by Infectious Diseases specialists, and must take into account recent antibiotic use, travel, transmissible pathogens, and immunodeficiency disease that relate to the potential donor. There may be occasions where the work related to instillation of the microbiota may need to be performed by a second health professional, such as a gastroenterologist or surgeon. By bundling the payment for the preparation and installation, this results in a situation where one physician will receive payment for his/her services as well as for those services provided by the other physician.

Furthermore, CMS has listed G0455 as having a non-facility PE RVU value of 2.48 without an explanation of how this value was derived. IDSA seeks to address this matter with CMS in order to provide further details and clarify how these procedures can be used in this often life-threatening clinical scenario. For instance, if CMS will only pay for the successful donor specimen, in conjunction with the instillation, then beneficiaries will have to be advised of the cost of screening which they may be at risk of paying out-of-pocket, in the event the specimen is deemed unsuitable. This may require the physician to provide an Advanced Beneficiary Notice of Non-coverage (ABN) Form CMS-R-131 to the beneficiary. We believe that CMS has failed
to recognize the clinical circumstances for those beneficiaries who require this treatment for recurrent *C. difficile* infections, and should consider coverage of more than one donor specimen screening when clinically appropriate. At a minimum, CMS should communicate further guidance to clarify how this G-code should be reported when multiple donor screens have been performed. We hope to engage CMS in a discussion of the valuation of this procedure in a way that maximizes its appropriate use and avoids erroneous reporting.

**Medicare Coverage of Hepatitis B Vaccine**

We are pleased with the CMS decision to expand coverage for hepatitis B vaccine and its administration to all individuals diagnosed with diabetes mellitus, not just those individuals with diabetes that are receiving glucose monitoring in facilities, such as nursing homes. In doing so, CMS cited the strong evidence provided by the Advisory Committee on Immunization Practices (ACIP) in their recommendation to provide the hepatitis B vaccination to these patients. As mentioned in our comment letter to the proposed rule, we encourage CMS to explore expansion of coverage for all ACIP recommended vaccines as a means of promoting wellness, with associated cost savings, across the spectrum of Medicare beneficiaries.

**Conclusion**

IDSA appreciates the Agency’s consideration of our comments on the 2013 Physician Fee Schedule Final 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.

Sincerely,

David Relman, M.D. FIDSA
President, IDSA