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September 8, 2015

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

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services Proposed Rule [CMS-5516-P]

Dear Mr. Slavitt:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide comments on the Comprehensive Care for Joint Replacement (CCJR) Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services Proposed Rule. IDSA represents over 10,000 infectious diseases (ID) 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 infected joint prostheses, 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 virus disease.

IDSA members are committed to improving the quality and safety of patient care through the evolution of value-based health care delivery. This CCJR proposed rule represents an ambitious step forward toward achieving the "Better, Smart, Healthier" goal that aims to have 30% of traditional, or fee-for-service, Medicare payments tied to quality or value through alternative payment models, such as Accountable Care Organizations (ACOs) or bundled payment arrangements by the end of 2016, and tying 50 percent of payments to these models by the end of 2018. IDSA believes the proposals detailed in this rule generally represent an opportunity for ID specialists to demonstrate how the specialty care they provide to patients who develop severe infections, particularly those associated with a lower extremity joint replacement (LEJR) procedure, play a critical part in achieving positive outcomes with efficient use of resources. Below, we submit our specific comments on the proposed rule.

Financial Arrangements – Gainsharing Payments

In this rule, CMS proposes that hospitals will be the entities financially responsible for the episodes under the CCJR model and anticipates that hospitals will want to enter into contractual arrangements with providers/suppliers caring for beneficiaries in CCJR episodes, in order to align financial incentives with the goals of improving quality and efficiency of LEJR episodes. Such providers/suppliers will be referred to as "CCJR Collaborators." CMS specifies that these collaborators would

...directly furnish related items or services to a CCJR beneficiary during the episode and/or specifically participate in CCJR model LEJR episode care redesign activities, such as attending CCJR meetings and learning activities; drafting LEJR episode care pathways; reviewing CCJR beneficiaries' clinical courses; developing episode analytics; or preparing reports of episode performance, under the direction of the participant hospital or another CCJR collaborator that directly furnishes related items and services to CCJR beneficiaries.

Furthermore, CMS specifies in this rule that a cap on gainsharing payments to a CCJR collaborator will be set at 50 percent of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services furnished to the participant hospital's CCJR beneficiaries during a CCJR episode by that physician or nonphysician practitioner. CMS indicates that this cap of 50 percent on Gainsharing Payments to an individual physician or nonphysician practitioner is consistent with the same policy for the BPCI initiative.

IDSA understands the need for CMS to set forth specific parameters to determine the scope and function of participation agreements between CCJR collaborators and participating hospitals. The success of the CCJR model depends on the accurate accounting of efficient clinical care and cost savings related to each LEJR episode. However, we are particularly concerned about the gainsharing cap with the basis being services provided under the Medicare Physician Fee Schedule. We anticipate that many of our members may play an active role in CCJR model LEJR episode care redesign activities, providing input in the drafting of care pathways with respect to infection prevention and antimicrobial stewardship. As well, ID specialists may play a role in reviewing CCJR beneficiaries' clinical courses, offering treatment options in cases when an infection results and facilitating care transitions by designing and managing outpatient antibiotic courses. The work involved, on the part of the ID specialists, is not accounted for in services billed under the Medicare PFS. As explained in the proposed rule, it is not apparent how these episode care redesign activities should be accounted for within the gainsharing payment calculation. Therefore, we ask that CMS clarify how activities such as infection prevention and antimicrobial stewardship that support successful LEJR episodes should be accounted for in order to apply to the gainsharing payments. In fact, we believe that CMS could potentially do away with the arbitrary cap given that the proposed policy that payments must be "actually and proportionally related to the care" of beneficiaries in CCJR episodes and that the CCJR Collaborator must be contributing to the care redesign strategies of the participant hospital is a better program safeguard against abuse while simultaneously allowing for rewards based on activities that are not separately billable under the Medicare Physician Fee Schedule.

Furthermore, in the event that ID specialists are able to participate as CCJR collaborators and receive gainsharing payments, we express our concern that such remuneration may draw scrutiny and concern over compliance with fair market value assessments. We ask that CMS give consideration to this and provide guidance in the CCJR final rule, and in any other guidance related to the Anti-kickback statute, as to how hospitals and CCJR collaborators should engage in negotiations, in light of these concerns.

Post-discharge Home Visits

CMS proposes to waive the "incident to" rule set forth in § 410.26(b)(5), to allow a CCJR beneficiary who does not qualify for home health services to receive post-discharge visits in his or her home or place of

residence any time during the episode. Specifically, CMS proposes to allow licensed clinicians, such as nurses, either employed by a hospital or not, to furnish "incident to" services under the general supervision of a physician, who may be either an employee or a contractor of the hospital. Under this proposal, the services furnished under such a waiver would be billed under the PFS by the physician or nonphysician practitioner or by the hospital to which the supervising physician has reassigned his or her benefits. In the latter scenario, the post-discharge home visit services would not be "hospital services," even when furnished by clinical staff of the hospital. Up to 9 post-discharge home visits could be billed and paid during each 90-day post-anchor hospitalization CCJR episode. According to CMS, the waiver would not apply for beneficiaries who would qualify for home health services under the Medicare program, therefore these visits could not be billed for such beneficiaries.

IDSA commends CMS on proposing this waiver for purposes of effecting efficient care and cost-savings within a LEJR episode. ID specialists work with their surgical colleagues to ensure every precautionary measure is taken to prevent infection; however, there are cases where patients still become infected. Many times, these infections can be treated with intravenous antibiotics in the home setting (Outpatient Parenteral Antimicrobial Therapy – OPAT) but, due to Medicare PFS restrictions, home infusion therapy is not available to Medicare beneficiaries. The waiver that, as proposed, would apply to "incident to" services such as OPAT would enable patients with severe infections to receive their treatment at home as they recover from their procedure and could provide for significant cost savings. However, within the CCJR model, OPAT administered in the home may likely need to exceed 9 home visits, especially when one considers that there may be other clinical reasons that may require nurse home visits (e.g., physical therapy). IDSA requests that CMS consider allowing an exception to the 9 post-discharge home visit limitation in cases where the patient is receiving OPAT, in order to allow for instances where the full course of therapy exceeds 9 home visits. As well, we request that CMS allow for "incident to" services such as OPAT to be billed using existing codes that accurately capture the work involved in providing this service. The proposed G-code that CMS intends to use for billing of the "incident to" services as "coordinated quality of care" does not cover the services related to OPAT

We believe that the allowance for OPAT to be provided under the proposed waiver to Medicare beneficiaries could enable significant efficiency in the care provided without compromising outcomes. In the same theme of efficiency, IDSA supports the proposed waiver for geographic site requirements for billing telehealth services. ID specialists are currently using telehealth services to provide effective care to patients in areas that have limited access to infectious diseases expertise and for a variety of infectious diseases. Telehealth services used to support and enhance OPAT services have the potential to greatly improve patient outcomes while reducing the cost of care for a LEJR episode.

IDSA appreciates the efforts of CMS to advance alternative payment models and promote safe, efficient, value-based care delivery through the proposals set forth in the CCJR 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.

Respectfully,

Stephen B. Calderwood, MD, FIDSA

Stephen B Calabarusal

President

¹ Parmar P, Mackie D, Varghese S, Cooper C. "Use of Telemedicine Technologies in the Management of Infectious Diseases: A Review." Clin Infect Dis 2015: 60(7): 1084-94.

² Eron L. Telemedicine: the future of outpatient therapy? Clin Infect Dis 2010;51 Suppl 2:S224-30.